Endovascular Technology: The Palmaz intravascular stent and the Auth Rotablator

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Introduction

The Palmaz Intravascular Stent and the Auth Rotablator are two promising developments in the treatment of Peripheral Vascular Disease (PVD), which is defined by limited blood flow to the body outside of coronary circulation due to vascular obstruction. These obstructions are caused by the fatty lesions that characterize atherosclerosis. So, to better understand this technology, this paper will first examine the biological mechanisms contributing to the formation of the atherosclerotic lesions that cause PVD.

Atherosclerosis, a form of arteriosclerosis (hardening of the arteries), is a condition evidenced by the formation of arterial plaque due to a combination of changes in the tunica intima of a vessel. Accumulations of plaque, or lesions, increase in size over time and begin to decrease the diameter of the vessel’s lumen, impeding blood flow. The mechanism of development for these plaques is theorized to be triggered by some form of damage to the endothelium of the vessel (R. Ross p488). After this initial damage, further
events contribute to lesion formation, such as the accumulation and infiltration of Low-density Lipoproteins (LDL's), the accumulation of platelets and clotting factors, and the proliferation and migration of smooth muscle cells into the lumen. It is, however, that initial endothelial damage that allows these secondary contributions to take place.

The endothelium is a simple squamous epithelial sheet, one cell thick, lining the lumen of a healthy artery. These elongated squamous cells are positioned with their long axis parallel to the direction of arterial flow and are joined by junctional complexes, making them extremely adherent to each other. These qualities make the endothelium, coupled with the basement membrane a strong, frictionless barrier against the passage of material across the artery wall (M. Ross p285-6). Damage to this barrier, which may occur due to a number of factors, is the first step toward the development of an atherosclerotic lesion.

Endothelial damage may occur simply due to mechanical stress, like that caused by the constant pressure of hypertension, or chemical stress, such as that caused by the toxins of cigarette smoke (Porth p358). Damage can also occur, in a less direct way, due to a limitation of blood supply to the vessel itself. Every artery has its own vascular network called the vasa vasorum, located in the tunica adventitia of the vessel (M. Ross p287).
Psychological stress can result in vaso-constriction, and the resulting ischemia can damage the vessel from the outside inward.

As blood cholesterol levels increase so do interactions between macrophages and the endothelium. The macrophages move through the junctional complexes into subendothelial space (Porth p358). This is the earliest event in the formation of fatty streaks (R. Ross p493). Fatty streaks are a premature form of atherosclerotic lesions. Observed in children as young as ten, they develop in anatomical sites that correlate directly with the more mature “fibro-muscular” atherosclerotic lesions, strongly suggesting a “precursor - product” relationship between the two (R. Ross p488). The macrophages that migrate below the endothelium have receptors for LDL's. “It is probable that the capacity of the macrophage to take up these lipo-proteins and to de-esterify and re-esterify cholesterol may be important to their ability to accumulate lipid” (R. Ross p 493). As this macrophage-mediated lipid steak grows, it becomes large enough to break apart the intercellular junctions of the endothelium - much like weeds growing beneath a paved walk - exposing the subendothelial space (Porth p 358). Regardless of the circumstances of the assault, once the slick, frictionless lining of the lumen is damaged, platelets accumulate at the sight and atherogenesis is under way.

The endothelium usually prevents the accumulation of platelets due
to its slickness and its ability to form anti-thrombic substances, but any form of endothelial injury will promote platelet adherence and the release of clotting factors (R. Ross p492). When activated, platelets release Thromboplastin (M. Ross p186). This acts to start a chain reaction which ultimately results in the production of Fibrin. Subsequently, a fibrous mesh network entangles platelets and red blood cells over the exposed subendothelial tissue, forming a clot (Curtis p752).

Platelets not only provide part of this fibrous component but also trigger the production of the muscular component of the lesion. Platelets secrete at least two growth factors, one of which in particular, platelet-derived growth factor (PDGF), is significant to atherogenesis. Smooth muscle cells, located just beneath the basement membrane, have receptors for PDGF. PDGF is “both chemotactic and mitogenic, and thus can induce both migration and proliferation” (R. Ross p492). Therefore, the smooth muscle cells exposed to platelet accumulation not only reproduce mitotically but also transverse the basement membrane into the clot and undergo further mitosis. This adds significantly to the mass of the lesion occupying luminal space. Furthermore, growth factors almost identical to PDGF are released by both macrophages and endothelial cells, “thus, endothelial injury could result in the release of growth factors from any or all of the three sources” (R. Ross
p496). LDL's play a role here as well. They may further accumulate due to LDL receptors present on smooth muscle cells, adding mass to the lesion (R. Ross p492). LDL's may also be a co-factor in the proliferation of the smooth muscle (Porth p358).

Interestingly, to compensate for the growth of these lesions, the artery has developed a natural adaptation. Very large plaques have been found to exist without impeding on lumen caliber because of the artery's ability to enlarge itself to limit the stenosing effect of the lesion. “In the human left main coronary artery, such enlargement keeps pace with increases in intimal plaque and is effective in preventing lumen stenosis until the area of the plaque occupies approximately 40% of the cross-sectional area” (Ahn VI p541). The mechanism for such an adaptation is not completely defined but may involve atrophy and dilation of the uninvolved portion of the wall. This adaptation, however, is not fail-safe, as these lesions do eventually cause stenosis. Basically, an artery can enlarge itself to keep pace with the stenosis, but only to a certain point. After it reaches pathologic proportions, medical science has developed ways of correcting the stenosis mechanically. The placement of a vascular stent, a prosthetic cage which physically holds open the lumen, and the removal of the lesion through rotational atherectomy are two such mechanical enhancements of the artery's natural adaptive process.
In conclusion, atherosclerotic lesions develop due to some injury to the endothelial layer of a vessel. Fatty streaks, the earliest form of these lesions, are macrophage mediated accumulations of LDL's below the endothelium and can grow to break apart endothelial junctions. Mature lesions consist of fatty accumulations, clotting elements, and massive proliferation and migration of subendothelial smooth muscle. To compensate for reduced lumen caliber, arteries have a natural adaptive enlargement process that is effective but limited, and these natural limits can be expanded though surgical intervention.
Chapter 1

Attempting to expand the limits of the balloon
The most developed, successful and established minimally invasive endovascular treatment of atherosclerosis is the well publicized Percutaneous Transluminal Balloon Angioplasty (PTA). PTA utilizes a catheter consisting of a balloon at the distal end. The balloon, when inflated, dilates vessel stenosis, opening the lumen by redistributing plaque along the intima, and hydrostatic pressure of the blood flow is relied on to maintain the new diameter. PTA has been employed to treat stenosis in the coronary, aortic, iliac, femoral, popliteal, tibial, mesenteric and renal circulations (Ahn IV p425).

The benefits of this procedure are impressive. As an adjunct to surgery it limits the severity of the procedure, saving hundreds of lives and millions of dollars annually. It holds up to 93% success rates at one year and 92% after two years in common sites of usage, such as the iliac arteries (Ahn III p292). However, the success rates are much less impressive when certain variables are introduced into the equation. Most of these variables have to
do with rebound stenosis, the location and tortuosity of the vessel, as well as the eccentricity and rigidity of the lesion (Topol p858). “The major problem of restenosis, which occurs in up to 40% of cases [coronary data] after an initially successful procedure, and continuing technical difficulties in dealing with certain types of lesions (particularly those that are calcified or in distal locations) have stimulated research into alternative methods” (Bertrand p470). So, it is not the lack of success of PTA but the limitations of that success that has fueled the need for further development.

Many roads have been taken in the past two decades with the common goal of furthering PTA and therapeutic endovascular technology in general. Laser angioplasty, introduced in 1982, drew much popular attention. The public’s fascination with the “21st century” technology of laser light and its anticipated applications, in both the lay and scientific worlds, is understandable, but before these applications can become reality further development is still required. Laser angioplasty, as of yet, is really Laser-assisted Balloon Angioplasty (LABA). The laser is only utilized to create a passage for the guide wire of the balloon catheter if the occlusion is of a severity that does not already allow passage. Final dilation is still the result of PTA (Ahn IV p426). Though LABA does allow the treatment of many lesions otherwise untreated by PTA, guide wires can usually cross occlusions without assis-
stance, so “the number of patients who require LABA is . . . quite small” (Ahn, IV p426-7). Two drawbacks limit laser angioplasty from wider application: it’s difficulty in safely vaporizing lesions that are calcified and its inability to discriminate between healthy intima and lesion. Vessel wall perforations plague the development of laser angioplasty (Ahn III p292). Perhaps this “21st century” technology will actually have to wait until the 21st century before it realizes its full potential. For now, advancements of a more mechanical nature, have led to the more effective treatments of atherectomy and stenting.
Chapter 2
The Auth Rotablator
The term atherectomy is used to refer to any procedure which excises the lesion from the vessel, performed with the placement of a catheter percutaneously or through an arteriotomy far from the diseased site. Its technological development has taken many forms. The Simpson Peripheral Atherocath utilizes an advancing cutter in a metal housing. A balloon inflates, forcing plaque into the housing where it is excised (Ahn IV p427). The Trac-Wright catheter works with a rotating cam tip and high-pressure irrigation. It follows the path of least resistance, using no guide wire. So, like laser angioplasty it is an ideal pre-PTA procedure, burrowing a hole for the balloon catheter’s guide wire (Ahn IV p428).

The Transluminal Extraction Catheter removes plaque entering its cone shaped housing with internal rotating blades. Plaque is aspirated through a hollow catheter into vacuum bottles (Ahn IV p429).

However, the most recently approved atherectomy device is the focus of this paper. Designed by David Auth, PhD., The Auth Rotablator, in theo-
ry, addresses the problems associated with calcified lesions, intimal flaps, arterial dissections, eccentric lesions and embolism down stream from the lesion. The Rotablator is an oval-shaped burr that rotates on an axial guide-wire, while also tracking back and forth along that guide-wire, with the purpose of removing a calcified lesion transluminally (Ahn III p293).

The foremost hemisphere of the brass burr is embedded with numerous diamond chips each of which acts as a microknife. The chips range from 22 to 45 um (Ahn I p873). These microknives are the key to the rotablator’s design. Because they remove hard material rather than trying to displace it (like PTA), they are ideal for calcified lesions. Furthermore, because they are removing the lesion no intimal flaps remain to cause turbulence in blood flow; the intraluminal surface is left polished and smooth (Ahn III p295). These microknives also address the problem of vessel dissection and perforation because, unlike the laser, they are selective cutters. “The differential cutting of the burr allows it to grind the hard plaque selectively, instead of the elastic wall of the artery, thus minimizing potential for perforations” (C.R.A.G. p509-10). The selectivity relies on the fact that the elastic tissue of the artery can deflect around the diamond edge while the calcified lesion is rigid and therefore chopped under the force (Ahn III p293). These cutters also address the problem of embolism because they pulverize the plaque into
a colloidal suspension of particles, generally smaller than red blood cells, which have little potential to embolize (Ahn IV p428). Even in the earliest studies, particles produced were "generally small enough to go through the canine capillary circulation to be removed easily by the reticuloendothelial system" (C.R.A.G. p510).

All of these characteristics add up to a device that is best suited for the rigid, calcified lesions common in diabetic patients, as well as the stenotic, sometimes eccentric lesions of the popliteal, and superficial femoral arteries (Ahn I p874).

Rotational Atherectomy can be done percutaneously or through an open arteriotomy, however the later is preferred because it does not limit the burr size to 3mm. Burrs can range from 1.25mm to 6.0mm and are chosen in relation to the diameter of the vessel (Ahn I p874).

Before the procedure, lesions are documented, sometimes endoscopically and always angiographically. Ankle/brachial indices, a comparison of blood pressure in the arm (unaffected by the lesion), and the ankle (affected by the lesion), are also taken. All data is taken with the purpose of post-treatment comparison in the determination of success (C.R.A.G. p510). Drug treatment consists of 24 to 48 hours of an intravenous Dextran/Papaverine combination for the purpose of expanding plasma volume (Ahn II p273).
The procedure begins with the insertion of an introducer sheath: 7, 9, 12 or 14 French. A small atraumatic guide wire is passed through the lesion. This small guide wire is replaced by a more rigid .009 inch guide wire with the aid of an exchange guide catheter. With the original guide wire and the exchange guide catheter removed, the burr is passed over the remaining rigid guide wire to the site of the lesion. Rotation is now activated (Ahn I p874-5).

The drive shaft, encased in a protective, flexible plastic sheath, is connected to a turbine driven by compressed air. Air pressure which controls the rpm's is in turn controlled by the surgeon through a pedal or a dial. A sliding knob, controlling the advance and retreat of the burr, is controlled by the surgeon on the top of the turbine casing. A pin-vise, controlling the guide wire orientation is located on the proximal end of the turbine casing (Ahn III p923). Maintaining speeds of 100,000 to 200,000 rpm's the burr is advanced slowly into the lesion in a “vibrato-like to-and-fro manner”. A small diameter burr is initially used and replaced sequentially by larger burrs over the same guide wire (Ahn I p875). This process is continued until recanalization, defined as the residual stenosis being less than 25% smaller than the lumenal diameter of the normal native vessel, is achieved (C.R.A.G. p510). The rotary time ranges from 30 sec. to 35 min., and the entire procedure may
last between 15 minutes and 2 hours (C.R.A.G. p510).

After the procedure, the patient is placed on anti-coagulation drugs for 24 hours and aspirin long term (Ahn I p875). Post-operative physical exams include ankle/brachial indices at various follow-up intervals and possibly continued angiography (C.R.A.G. p510).

Success in each of two series of studies (one at Stanford, one at UCLA) was defined in three categories. "Intraoperative arteriographic success" is defined as the "reduction of the lesion to a residual stenosis of less than 25% with no significant intimal flaps, dissections or perforations visualized by intraoperative radiography" (Ahn II p274). "In-hospital success" is defined as "Intraoperative success" combined with postoperative improvement of ankle/brachial indices by greater than .15, the presence of a palpable pulse distal to the atherectomy, and improved capillary refill, skin color and warmth. "Late success" is defined as persistence of all above criteria (Ahn II p274).

The UCLA study reported a 93% success rate of the "Intraoperative" nature (Ahn II p274). Although the Stanford study showed only a 77% "Intraoperative" success rate, it increased to 84% when confined to the superficial femoral artery, the site most suited for rotational atherectomy (C.R.A.G. p511). The "In-hospital" rate was lower, with the UCLA figure
dropping to 72%. This is slightly disappointing but not tragic as the numbers were equal to or better than those of the other atherectomy devices (Ahn II p276) (C.R.A.G. p513). Furthermore, many failures were seen as preventable in the future through more careful procedures (C.R.A.G. p 513).

Long-term patency, however, is currently the largest obstacle facing the Rotablator. It certainly lives up to its billing as a specialized cutter; “the lack of perforation and late aneurysmal changes in the current study were predicted . . . and suggest that the elastin fibers of the arterial wall remain intact” (Ahn II p279). However, its ability to create an lumen that remains open for a significant length of time is currently very suspect, as “Late success” data was very disappointing. Primary patency rates were as low as 9.5% after two years in the UCLA study (Ahn I p875). In the Stanford study most of the restenosis or reocclusion occurred within a year (C.R.A.G. p515). Both studies lean toward the belief that this failed long-term patency lies mostly in hyperplasia of the intima, rather than rethrombosis, because, though the intima is never lacerated, it can become denuded during the procedure. Timing of the failed patency as well as direct visual documentation of hyperplasia supports this conclusion (Ahn II p 279).

Though it does fulfill some of its design’s promises (eliminating most calcified lesions without dissecting or perforating the vessel) the feeling
remains that the Rotablator, at this stage in its development, may not significantly improve long-term patency. Both the UCLA and Stanford studies see the overall results as disappointing, saying, the Rotablator is not yet clinically effective. Recent writings by Samuel S. Ahn, M.D. (Associate Clinical Professor of Surgery, UCLA Center for Health Sciences) and his colleague Darwin Eton, M.D., F.A.C.S. (Associate Professor of Surgery, Division of Vascular Surgery at the University of Southern California) acknowledge long-term patency limitations caused by recurrent stenosis secondary to neointimal hyperplasia as “the major obstacle major obstacle to more widespread use of atherectomy technology” (Ahn V p502). However, they also stress that it is too soon to know for sure, implying that not enough data has been collected for a truly accurate picture of the technology’s effectiveness. They write, “As this technology evolves and patient accrual increases, the restenosis rate will be better defined” (Ahn V p502). With support for the technology, M.R. Balaji, M.D., F.A.C.S. (Clinical Associate Professor of Surgery University of Rochester) explains that his personal experience with the Rotablator has been more promising. He states that shorter lesions are better suited for Rotational Atherectomy, and selecting lesions more suitable to the procedure yields better results. At any rate, no authority is ready to bury the technology, agreeing that its potential benefits warrant further
development and clinical testing.
Chapter 2
The Palmaz Intravascular Stent
When the vascular question is long-term patency, the technological answer may very well be intravascular stents.

Reclosure rates, either very abrupt or after a short time, still damage PTA statistics, and, as discussed in the previous chapter, atherectomy is not yet the answer to that problem. Stents are intravascular prosthetics, usually coils or cages, introduced to the vessel percutaneously, which expand the lumen and then remain as long-term physical supports of optimal patency.

Two major causes of reclosure are intimal dissection and elastic recoil (Katzen p942). It is the long-term physical presence of a stent that is the key to addressing these problems (Ahn IV p429). “Intravascular stents provide a mechanical means to overcome elastic recoil and to compress the plaque and intimal dissections against the wall creating a more rounded vascular channel” (Katzen p942). The opposition of recoil also eliminates the need for the surgeon to overdilate the vessel (Palmaz p730). Over a period of four to six weeks, the stent actually becomes integrated into the intima of
the vessel, covered with a true endothelium that in studies thus far seems to be free from the atherosclerotic process (Katzen p492). “The smooth and regular lumen obtained should decrease or prevent the development of luminal irregularities after angioplasty (Palmaz p 730). Furthermore, the stents long-term hold on lesion works in the prevention of intimal flaps and emboli (Ahn VI p542).

The idea of percutaneously placing a spiral stent was introduced in 1969 by Charles Dotter, the man who introduced PTA to the scientific community five years prior (Zollikofer p272). Interestingly, he actually touched on the concept of stenting in that earlier paper on PTA (Katzen p941). The lack of technology and interest, however, delayed further development of the idea until circa 1980. It was then that Dr. Maass and group of scientists began experimenting with a self-expanding spring coil at the University of Zurich (Zollikofer p723). It is from this point that the development of stenting, like that of atherectomy, begins to take many paths. By 1988 a number of variations on the concept were being reported ranging from permanent to temporary, from self-expanding to balloon-expanding, from metallic to non-metallic to even bio-degradable (Katzen p941-42).

The **Double-helix Spiral Prosthesis**, developed out of the Mass group's early spring coil design, was the first expandable stent used clinically.
It was a steel double-helix spring that was mounted on a flexible delivery instrument (Zollikofer p273). When released, it expanded under its own force, opening the lumen. The Wallstent, which has been used clinically since 1986 in both coronary and peripheral arteries is made of stainless-steel filaments woven into a tubular criss-cross pattern. Because none of the filaments are soldered were they cross, it is fully flexible. When mounted on the introducer, it is stretched longitudinally, subsequently decreasing its diameter. When released at the site of the occlusion, it rebounds to its natural shorter, wider shape forcing the lumen open (Zollikofer p 276). Another interesting development in stent technology is shape memory alloy stents, although their development has many obstacles to overcome before clinical use is practical. The basic premise relies on the characteristics if Nitinol, a nickel titanium alloy. Nitinol wire is shaped in the form of a spiral and heated to 500° C. When cooled it can be stretched into a straight flexible wire. After delivery, when the Nitinol is warmed by the patients body temperature, it “remembers” the shape at which it was heated and coils, expanding the lumen (Zollikofer p274).

This paper will focus on the branch of stenting’s developmental tree leads to the extensively tested Palmaz Intravascular Stent, used clinically since 1987 (Zollikofer p274). Though, it has had limited application in the
femoral-popliteal region, it is best suited, and most often used on iliac lesions (Katzen p941). The design of the Palmaz stent consists of a seamless cylinder of medical-grade stainless steel. The cylinder wall has parallel, staggered rows of slots, which allows it to expand under pressure (Palmaz p728). Mounted on an angioplasty balloon catheter the stent is advanced percutaneously to the site of the lesion. The balloon is inflated, and the stent expands, opening the lumen and remaining as long term physical support (Palmaz p728).

Before the procedure, heparin is introduced into the bloodstream (Palmaz p728). The patient is also taking aspirin regularly for two days prior and is asked not to eat or drink anything after midnight the night before (Johnson&Johnson). Ankle/brachial indices and angiography are diagnostic tools of the procedure.

The stent, unexpanded, measuring 3.1 x 30 mm is mounted on an angioplasty balloon catheter that can be inflated to an 8mm diameter. To hold its position on the balloon the ends of the stent are crimped with a specially designed tool (Zollikofer p274). The stent/balloon assembly now complete, it is introduced into the vessel in a teflon sheath through a hemostatic valve. When treating iliac lesions, which is most commonly the case, the stent is introduced into the femoral artery. The lesion may have been previously
dilated through conventional PTA in order to allow the passage of the teflon sheath across it. Once the teflon sheath is in place, the stent is advanced to the site of the lesion (Palmaz p728). Fluoroscopic imaging allows the surgeon to make proper placement of the stent (Johnson & Johnson). “Positioning of the stent before expansion is accomplished with at least two of three reference points as follows: bone landmarks, external metallic markers, and contrast injection images either freeze frame or depicting the map of the vessels” (Palmaz p728).

Once in place, the balloon is inflated, expanding the stent and the lesion, leaving the prosthetic steel mesh flush with the lumen of the vessel. Inflation pressure ranges from 8 to 12 atm (Palmaz p 728). The stent can potentially expand to a diameter of 7 to 15 mm. Therefore, if it is necessary, the original 8mm balloon may be removed and replaced with a larger balloon to further expand the same stent (Zollikofer p274). In the event that the stent is not long enough to open the whole stenosis, a second stent may be placed next to the first, overlapping it by 5-8 mm (Palmaz p728). After the implanted stent is sufficiently expanded, as evidenced by ankle/brachial pressure gradient measurements and angiography, the balloon is deflated and the catheter removed. The puncture wound is controlled by manual compression (Palmaz p728).
The patient is confined to bed for eight hours and may usually leave the hospital after the next day. Follow-up exams and angiography are scheduled. Aspirin is continued long-term (Palmaz p728).

A study, first published in 1988 and updated in 1990, headed by the developer, Dr. Julio Palmaz, was the basis for FDA approval (Katzen p946). The results were quite positive. Ankle/brachial indices improved directly after stent placement. Post-procedural angiograms showed complete dilation of most vessels, with "smooth, parallel edges" of the stent and the natural lumen of the vessel (Palmaz p729-30).

However, although immediate post-procedural success is imperative, the true value of stenting, and the Palmaz stent in particular, is supposed to be long-term patency. "The promising hemodynamic and clinical results obtained in our series of iliac stent placements may reflect the fact that most of our patients had isolated iliac artery stenosis and good blood outflow. Similar results may have been obtained with conventional balloon angioplasty in the same patients. However, on the basis of our laboratory experience, we expect the long-term benefits to be superior in patients treated with stents" (Palmaz p730). Needless to say much interest exists in studying the long-term results.

Dr. Palmaz and associates conducted a randomized trial comparing
Patients who underwent PTA only to Patients who had stents placed with no previous PTA. The data at 24 months shows a clear divergence of the two groups. The stent group were observed to have patency rates 10% to 15% higher (Katzen p947).

Expectations are supported with early success more so in reference to the Palmaz Intravascular Stent than the Auth Rotablator, but the future of both technologies is still to be determined. At any rate, both are truly promising developments in the quest to overcome the limitations of PTA.
Artwork
This illustration is unique in the collection primarily because of its origin. It was requested by Dr. Balaji as an illustration that would be particularly useful to him, therefore it has a more distant connection to the other pieces. The purpose of the illustration is to show a progression of procedures, which are invasive, commonly performed prior to the advent of intraluminal stenting, which is minimally invasive. The other procedures include Thrombo-endarterectomy, Aorto-biiliac bypass, Aorto-bifemoral bypass, Femoral-femoral bypass and axillary-femoral bypass.

In the beginning, many layouts were created and compared to each other. Two concepts had to be demonstrated in the illustration: first, a chronological progression of the procedures and second, a separation between the invasive procedures and minimally invasive stenting. Two semifinal layouts were chosen. One which showed stenting larger, to the right of a horizontal orientation, while the invasive procedures were grouped to the left and pictured at a lesser scale. The second design featured stenting in the
center of a vertically oriented illustration, while the non-invasive procedures orbited in a clockwise chronological progression. This design was ultimately chosen. The clockwise orbit best expressed the chronological progression and the separation of invasive and non-invasive procedures.

With a layout in mind, sketches were begun. Each procedure was sketched separately, nearly 200% of the size that they would finally appear. Pencil drawings were created using sketches provided by Dr. Balaji, along with conceptual understanding of the procedure and medical reference books. Preliminary sketches were presented for review of accuracy, until an approved drawing was completed for each of the six procedures.

Each drawing was then ready to be inked. The sketches were taped to a board, and piece of piece translucent of double-sided kid finish drafting film was taped over the top. A size .000 Rapidograph drafting pen was used to ink the general shapes. Templates and flexible curves were used for inorganic shapes, and organic shapes were inked freehand. A larger diameter pen was used to add line-weight variations on inorganic shapes, and a size .00 sable brush was used to add weight to lines defining organic shapes. Line-weight creates a feeling of dimension to an otherwise flat medium. A razor was used to scratch off highlights and the end of lines crossing behind other lines. Once completed the inks were photo-statted 50% of the original
size. They were then cropped and layed out on drafting film in the previously discussed “clock-wise orbit” design. Lines connecting the invasive procedures were illustrated with a pen and T-square. Finally, the whole page was photo-stated at 100%.
This painting was done as a cover illustration for a hypothetical informational brochure on the Palmaz Intravascular Stent. Being cover art, it had to say many things about the procedure as a whole, a wide commentary that could be both editorial and dramatic. This multifaceted requirement was best served by a montage approach.

The focus had to be the stent itself, along with the iliac arteries, for this is the region where it is best suited and most commonly used. X-ray technology always a major part of the procedure, an angiogram was chosen as a secondary image. Crediting the men and women who perform the procedure and also tying in to the angiographic theme, an operating room scene was chosen as a third image. Pictured are two physicians viewing an angiographic monitor while inserting the catheter. Many montage sketches were completed combining these three elements. An early idea, included an iliac artery coming off of an angiogram into three-dimensional reality. The final design, however, includes an angiogram sitting below a three-dimensional
aorto-iliac region, mirroring its condition. For example, the right common iliac is undergoing the procedure, so the corresponding artery in the angiogram is unoccluded. Likewise, the occlusion present left side is also reflected in the angiogram.

Once a final design and pencil drawing was completed, the drawing was transferred to Strathmore Double weight illustration board, to begin the final illustration which was to be a combination of watercolor and air brush. A watercolor under-painting was the first step. Cool and dark prussian blue was washed into the general areas of shadow and warm, glowing lemon yellow was washed into areas of highlight. Little care is taken to stay between pencil lines at this stage; letting under washes slip into other areas helps unify a piece. No blues or yellows were washed into the operating room scene. It was completed with a limited palette of yellow ochre and burnt sienna in order to give it a rich amber glow while still allowing it to fall back in the composition, so as not to compete with the stent, the primary focus of the piece.

After the first washes dried, local colors were applied. Due to the variance of materials and textures different approaches were taken with each element of the piece. The arteries were treated with washes of Windsor Newton light red, a color which translates the organic pinks and reds of
human tissue remarkably well. Washes of color were left fairly loose to keep the organic feeling in contrast with the slick manufactured texture of the instruments. The fatty lesion in the left common iliac was treated with the same looseness. Ochres and yellows were used to give it a yellow, fatty appearance, and again light red was used as a unification device. Objects pick-up colors from surrounding objects so using an arterial color helps create the illusion that the fat is sitting inside the artery.

The inorganic components, the catheter, the balloon and the stent were treated with much more controlled, sharper washes, and, in fact, much of their look was created with later applications of airbrushed acrylic paint. Masking tape masks were carefully placed and cut before washes were applied to the catheter to achieve the high-contrast, hard edged reflective surface. The balloon was created with washes of ceurelian blue. Surrounding colors were also washed in, and detail was faded just inside the edges of the balloon with a rough eraser, in order to create an illusion of transparency. Sharp highlights were applied with white gouache to represent the taut shiny surface of an inflated balloon. The angiogram was completed with flat washes Payne’s grey in a manner that would suggest the photo-negative appearance of an X-ray.

With the watercolor washes completed and dry, the airbrush could be
applied. The artery and the angiogram were masked-off and the background was airbrushed with a broad covering of Burnt sienna and prussian blue to darken some of the washes and to unify it into one complete space, bringing the high-contrast, high-detail elements to the forefront. More masks were applied to the piece and cast shadows were airbrushed onto the internal artery wall to create the illusion that the catheter, balloon, and stent are existing in the space within the artery and to strengthen the concavity of the artery. Next, everything was masked, and the small meshwork of the stent was carefully cut out with a razor blade, exposing the board in only the shape of the stent. Over this exposed mesh work, a metal cylinder was airbrushed with a hard highlight; dark, sharp core shadow and reflected light using colors from the surrounding environment. The mask was then removed and the cylindrical features were only left in the shape of the diamond-slotted stent. Lastly, lens flares were air-brushed onto the stent to complete the illusion of reflective metal.
Like its counter-part on the cover of the stenting brochure, this illustration (for the cover of a hypothetical Rotablator brochure) had to say many things about the procedure as a whole, being both editorial and dramatic. Again, this was best served by a montage.

The focus had to be the technology at work in the vessel it is best suited and most commonly used, in this case the femoral artery. To identify the vessel as the femoral artery it is shown in its landmark surroundings in the adductor canal. The artery in the illustration is running along the canal created by the vastus medialis and the adductor longus, accompanied, as in life, by the femoral vein, the saphenous nerve, and the nerve to vastus medialis. A human figure, grasping his thigh, with femoral arteries visible through his transparent flesh is present in the background. The computer blips of an ankle/brachial gradient run along the bottom in the foreground.

With a final pencil drawing complete, it was transferred to strathmore double-weight illustration board, and the water color under painting was
begun. Before applying any paint, thin line tape was put down as a mask in the shape of gradient lines in the area that the ankle/brachial blips were to be. This allowed me to paint over this area and remove the tape after painting leaving an absence of color in the shape of a graph. The first wash begins with applications of prussian blue to the shadow areas and yellows to the highlights. Letting the washes flow freely, not being so concerned with boundaries of color, at this stage makes for a more unified piece in the end.

As in the cover art for the Palmaz Stent, no blues or yellows were used in the human figures. Only ochres and siennas were used because they create a rich but monochromatic tone as not to compete with the main focus of the piece.

After the under washes dried, local colors were applied, and, as always an element’s surface characteristics dictated its treatment. The muscle is fibrous and organic, so it was treated with loose washes that followed the directions of its fibers. The right side of the vastus medialis was treated with light red and crimson to show the reflected light present when sitting next to a red object such as the femoral artery. Most of the muscle color is achieved with burnt and raw sienna. Those colors give a natural muscle hue as well as allowing the adductor longus to fade easily into the ochres and siennas of the background and the human figure.
Nerves were to be portrayed as whitish yellow so they had to pick up colors from their environment. The nerve on the left was created with washes of siennas and light red (especially in the reflected light) to create the illusion that it was in the same space as the artery and muscle. The nerve on the right has washes of blue in reflected light to give the illusion that it is floating over the blue femoral vein. Yellows were applied to both nerves as they do have a subtle hue of their own. The lesion is treated with free-flowing yellow washes to represent its fatty make up. Siennas and reds are used as core shadow colors. The artery and vein were treated similarly but with different color schemes. Light red and Alizarin crimson washes make up most of the artery while prussian blue was used mostly in the vein.

The back of the burr was painted with sharply contrasted, tight washes to show that it is an inorganic, metal object as opposed to the many organic elements surrounding it. The highlights on the burr pick up yellows, siennas and reds from the surrounding environment while the reflected light glows blue because the vein is positioned behind it. Shadows were hard, sharp and dark applications of Payne's grey. This treatment served to create the illusion of a shiny reflective metallic sur-

face. The front of the burr, with its diamond studs, was treated with the same color scheme but softer and more broken to represent its non-uniform surface, and light and dark specks of color were placed to represent the diamond chips. Lastly, after
all washes were dry a rough eraser was used to remove the hard edges of some of the washes and to strengthen some of the highlights.

Everything dry, airbrush could now be applied for the finishing touches. Various masks were cut so that the color could be applied selectively. The dissected edges of muscles were darkened and solidified, and the shadows cast onto the muscles by the artery, vein and nerve were painted in. The femoral arteries were airbrushed into the legs of the figure in the background. It is important to get the lumens of the vessels very dark, because the contrast that is created helps give the illusion of being hollow. That contrast is difficult to achieve with watercolor so the lumens were airbrushed. Lens flare highlights were airbrushed onto some of the diamond chips on the burr to give the illusion that they are catching light. Motion implying “swooshes” were airbrushed on the back of the burr and catheter to create the illusion of spinning. A glow was airbrushed in the shape of the ankle/brachial index computer blips on top of the graph, and lastly, acrylic paint was applied with a brush over these glowing shapes to give them an internal hard edge.
Designed to give simple succinct information, the orientation drawings had to show the viewer the point of entry of the catheter, and the anatomical destination of the catheter. It was important to demonstrate that the stent catheter, destined for the iliacs, is introduced in the femoral artery and is advanced cranially to the stenosis. Conversely, in the second drawing, it was also important to stress that the Rotablator, destined for the superficial femoral artery, was introduced in the femoral artery.
and proceeds caudally to the stenosis.

A male figure is depicted in each from head to knees. The pertinent arteries are visible. The catheter is shown entering the femoral artery, and the area of stenosis is highlighted with a thick circle. That circle is projected to a larger scale over the figure’s left shoulder. Inside the projection more details can be seen: the lesion and the tip of the guide wire with an arrow illustrating the direction of catheterization for each.

Content and layout were decided with preliminary sketches, and each orientation piece was drawn about 200% of the size they would finally appear. When the final drawings were approved they were inked.

The sketches were taped to a board and a translucent piece of double-sided kid-finish drafting film was taped over the top. A .000 rapidiograph was used to ink the general outline of all the elements, as well as for stippling. Circle templates and a french curve was used to ink the more precise shapes. A .00 sable was used to add line weight where appropriate. An X-acto knife was used to scrape off ink to depict highlights and lines passing behind other lines.

When the originals were complete they were photo-statted at 50% to tighten the line work and match intended print size.
Rotational Atherectomy
The purpose of this collection of illustrations is to explain, in a step by step manner, the basic concept behind Rotational Atherectomy. The process is broken down into four main steps. First, the vessel is shown with the lesion in place. The next frame shows an early pass of a small diameter burr. The third portrays a latter pass with a burr of larger diameter, and the final illustration shows the smooth inner lumen of the vessel when the lesion is completely removed.

Because these illustrations had a very specific purpose - namely to instruct - they were more direct than the cover illustrations. The information concisely meets the objectives of the lesson at a level the learner is prepared to understand.

Pencil sketches were completed of the four steps and presented for approval on their accuracy. After approval, they were placed on a light table and a piece of white Color-aid paper was placed over them. The final illustrations were to be completed with “carbon-dust”. The drawings could be
seen through the Color-aid, and they were traced lightly with a charcoal pencil. A “pool” of charcoal dust was created by scratching the charcoal pencil on a sandpaper pad. Tone was applied to the paper by picking up dust with a sable brush and placing it on the page, or was applied directly with the carbon pencil itself. The brush was then used to blend the tone in the drawing. A kneaded eraser was used to remove tone in the areas of light. With the brush, highlights were blended on the vessel and the lesion but were left sharp on the burr to represent the shiny metallic surface.
Intravascular Stenting
Aalogous to the teaching illustrations completed for Rotational atherectomy, the purpose of this collection of illustrations was to explain the basic concept behind the Palmaz vascular stent. This procedure was also translated into four major steps. First, the stent, unexpanded and mounted on a deflated angioplasty balloon, is positioned at the site of the stenosis. Second, as the balloon inflates it begins to expand at each end where it encounters no resistance from the stent, and, as the pressure increases, the stent expands from the ends inward. Third, fully expanded under the pressure of the inflated balloon, the stent compresses and pushes the lesion out from the center of the lumen. Fourth, with the balloon removed, the stent remains as a prosthetic support, insuring patency.

Preliminary drawings were completed and approved. The final illustrations were to be completed in pen and ink, but to a more complex and developed level than the simple orientation illustrations. Double-sided kid-finish drafting film was placed over the drawings. A .000 Rapidigraph pen
to start some outlining and stippling. Because of the range of elements in the illustrations and the surface qualities of each, specific pen techniques were used to represent specific textures. The fatty lesions were stippled to represent their soft organic mass. The vessels were completed in contour line to reflect the concavity of the surface, and cross contour lines were added to bring tone to the shadows. The deflated balloon was drawn with stylized, simple line, and it was created freehand to reflect its limpness. The inflated balloon and the stent were completed with stylized, simple line drawn with the aid of squares, rulers, french curves, and templates to illustrate their taut plastic or hard metallic surface qualities. Variations in line weight were achieved with thicker pens and a .00 sable brush. An X-acto knife was used to scratch lines crossing behind each other and also to add highlights.

Completed, the original inks were photo-statted to 75% of their original size.
Since neither series of teaching illustrations were completed in color, these two pieces were done as color references. One step from each series was chosen to be completed as a color reference for the set.

The first step of the stenting series and the third step of the atherectomy series were chosen. The drawings used to create the non-color illustrations were transferred to strathmore double-sided illustration board. The art was then completed in watercolor, using the watercolor techniques described previously.
References


