This discussion centers on the serious need to understand the implications of stents as permanent implants. Stents differ from the traditional products used in standard interventional techniques which are simply used once and discarded.

With stents, we are talking about an implant which is left in a patient for a lifetime. I think we all agree there is some version of stent mania alive and well throughout the world today. What does this mean? It means all kinds of new stents, with more configurations, wider indications, more materials, more shapes and more sizes. I think it is important that we ask a lot of questions about what’s going on in stent mania. This is not a normal situation for interventional cardiology. Because interventional cardiologists have never dealt with permanent implants in the past, there should be caution.

One serious warning with another major cardiac implant, heart valves, occurred in the field of cardiovascular medicine. Certainly what occurred with the Bjork–Shiley valve is not something we want to see repeated in interventional cardiology. Because interventional cardiologists have never dealt with permanent implants in the past, there should be caution.

One serious warning with another major cardiac implant, heart valves, occurred in the field of cardiovascular medicine. Certainly what occurred with the Bjork–Shiley valve is not something we want to see repeated in interventional cardiology. Over 80,000 of these valves were implanted before they were taken off the market in 1986. Failure of a tiny strut in the valve has been blamed for the deaths of more than 360 people. A fund of $200-$500 million has been established to cover the liability claims. This implantable device was vulnerable to metal fatigue.

Today we are talking about metal stents that contain tiny struts which are also vulnerable to metal fatigue. It is important that we work together to avoid a repeat of such a disaster with stents.

How can we do that? We need to form a partnership of the industrial community and the interventional cardiology community and together demand high manufacturing testing standards and proof of safety before a stent is implanted. We need to review current stent designs and, of course, look very closely at future or new stent designs. Can we prevent all device failures or other as–yet–undiscovered difficulties? Probably not all. But a focused partnership is a good approach. Many stents appear to look alike or there is the inference that they are equivalent. Some scanning electron micrographs suggest that this is not true.

Often, you might see these magnificent slick photographs in marketing literature, where two stents look identical (Figure 1). Both of these stents have been implanted into human coronary arteries. But, when you look closely, these seemingly identical stents are quite different (Figure 2).
The stent on the left does not appear to have edges as smooth as the stent on the right, thus it may not be as biocompatible. At higher magnification (Figure 3), it is even more clear which stent might be the most biocompatible when implanted permanently.

At even higher magnification, (Figure 4) we get a good look at the stent surface differences and understand them. Since the greatest risk with stenting is subacute thrombosis, it is important to...
compare these two stents in equal magnification to better anticipate the risk of subacute thrombosis (SAT) due to surface roughness or defects.

These other stent configurations reveal wire crossover points and nonuniform coil expansion (Figure 5). It is important to understand what these configurations mean in relation to surface stability, neointima laydown, flexion and laminar flow. Here, at closer magnification, are endpoints of these stent configurations (Figure 6). Is it safe to have sharp ends on a device inside an artery permanently? Consider also the effect of turbulence potentially caused by a non–stable protruding design. Another example (Figure 7), allows us to focus on stent construction and the different materials that are used. These two struts are welded together introducing a different material. The exterior weld appears more complete than the interior. The question of the weld fracturing over time should be asked about his device that is being implanted in humans today. This next stent device has components held together by knotted sutures (Figure 8). Although this is a magnified view, would the question of turbulence attracting thrombus be raised with this configuration as well as stability for a smooth healing process? Isn’t a smooth biocompatible surface important for complete cell coverage and thus healing? Stent design does affect the healing process as seen in these close–up images of neointima formation (Figure 9). Smooth uniform coverage of endothelial cells on the stent surface is clinically important as opposed to incomplete or excessive cell adhesion.

Metal fatigue of a device requires very careful testing. There are tests that are designed to duplicate what might be occurring during a 10–year period of time that a stent is implanted in humans (Figure 10). This is determined through a heavy stress–and–fatigue test. Figure 11 illustrates a magnified view of a stent which appears to be in pretty good shape. But as you start to stress these

Figure 4. SEM 250x magnification of two “seemingly identical” stents indicates surface texture differences and makes issue of thrombus aggregation that is decreased on smooth stent surface.

Figure 5. Two different stent configurations are detailed in these SEM images. Wire cross–over points and non–uniform stent expansion impact device stability, flexion and laminar flow.
materials under a simulation test they start to weaken and show more evidence of damage as is apparent in comparative SEM images (Figure 12). Ultimately stress and fatigue can cause the device to fracture or break. A clean break in the stent is shown in Figure 13. So it is possible for stents to break and to have failures. It is very possible.

The question is, how much do interventional cardiologists really know about stents that are being implanted? Is there enough information? Certainly device failure information is not what
we want to see in newspaper headlines. We have seen this happen with other permanent implants.

So what kind of information do we really need to make a sound clinical decision about an implantable stent device? Certainly we need material testing information, preclinical results and clinical test outcomes at a bare minimum.

Can we do testing for metal fatigue and stress? Is it possible to predict failure? The answer is, yes, very definitely yes.

The simulation tests described previously exist today. The performance of these tests can and should be performed. Other materials testing should be done including: radial strength, recoil

Figure 9. Neointimal laydown or healing process in these SEM images demonstrates differences caused by stent designs/configurations.

Figure 10. Schematic of a Stress/Strain Testing System for intravascular stents that simulates 10 years (400 million cycles of systolic/diastolic endurance.)
Animal data needs to be well distributed and well understood. This is also true for randomized clinical trials information and results. There is always a controversy over randomized clinical trials and whether or not they are always appropriate. But they are the new standard. They are the gold standard and emphasis should be placed on them. Can we all look at scanning electron microscopy as shown earlier? Can we get confirmation of metal stress and fatigue study results? Can we get published randomized trial outcomes? This information needs to be available. Cardiology certainly has been accustomed to classification systems. We currently use several systems of disease classifications. My suggestion is to consider a Stent Classification System.

Without a standard Stent Classification System the confusion caused by so many new stents may be overwhelming. At the last count, there were about 52 different stent configurations currently...
offered and available. Here are some suggestions that could classify stents by some of these key points.

**CLASS ONE** for stents would require:
2. Over 100,000 stents implanted.
3. Five–year follow–up on patients/published.
4. No major recalls or problems.
5. Certification and compliance of the performance standards following the FDA recommended guidelines. There is a published document available today recommending test standards for FDA approval.

**CLASS TWO**
1. Initiation of randomized control studies.
2. Approximately 50,000 stents implanted.
3. Published 3–year follow–up.
4. Some performance standards published but less than FDA.

**CLASS THREE**
1. Human trials have begun, no randomized studies.
3. *In vitro* tests available.
4. Minimal test results available.

**CLASS FOUR**
2. Manufacturing requirements — no results available.

This is not the only way, but some form of classification is required including the format of information that needs to be available for review. A partnership between industry and the interventional cardiology community is needed for this to succeed. I suggest and recommend that we establish a worldwide team of physicians and manufacturers to set guidelines for stent classifications.

We should move forward with some kind of system, perhaps supported by the European Society of Cardiology and the American College of Cardiology by the end of this year. I have been contacted by a number of manufacturers in the business and we are planning to move forward on this. I welcome your comments and participation.