Balloon Angioplasty Finite Element Analysis:

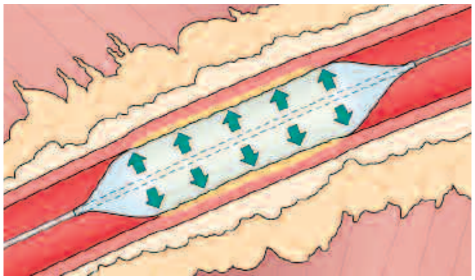
Comparing undamaged vessel stresses for semi-compliant vs. non-compliant balloon expansion into a plaque-coated vessel

To better understand the effects of different angioplasty balloon compliances, a Finite Element Analysis (FEA) computer simulation was performed by Computer Aided Engineering Associates, Inc. using commercially available nylon (semi-compliant) and PET composite (non-compliant) balloons.[1] The simulations demonstrate the effect of balloon compliance on vessel stress during angioplasty.

Not All Angioplasty Balloons Are Created Equal

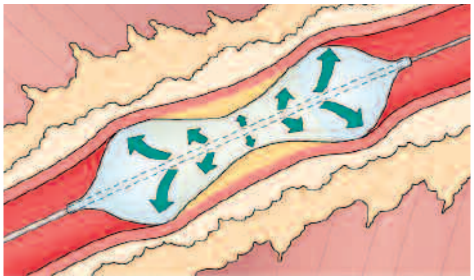
Different angioplasty balloon materials provide differing degrees of compliance, which is typically characterized as the amount of diameter growth in the balloon between nominal and rated burst pressure. Non-compliant balloons inflate to pre-set diameters even at higher pressures while semi-compliant balloons are prone to overstretching in areas of less plaque and do not exert equal forces without balloon distortion.[2] Nylon is more compliant than PET, and different types of nylon may exhibit differing magnitudes of compliance.[3]

Non-Compliant Angioplasty



Shape retention
Greater dilating force at lesion

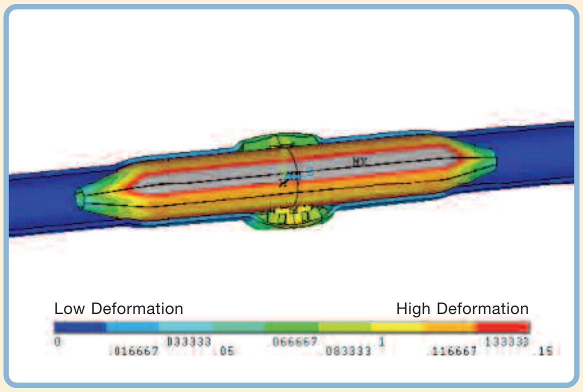
Semi-Compliant Angioplasty



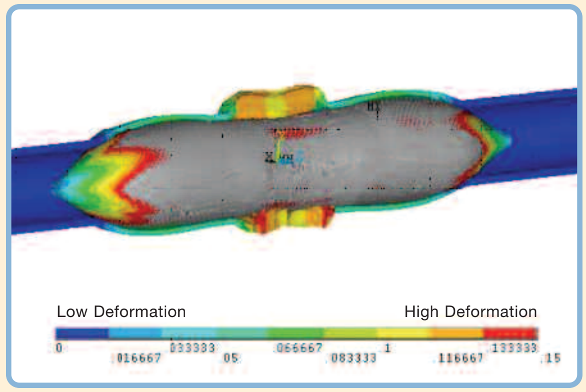
Hourglasses around lesion
Less dilating force at lesion

Vessel Deformation

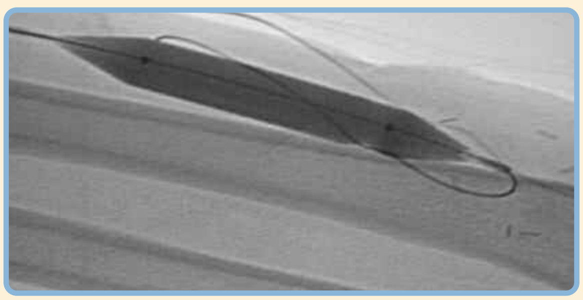
The illustrations[1] demonstrate the vessel deformation induced by inflation of the non-compliant balloon as compared to the semi-compliant. The diameter of the non-compliant balloon is fairly consistent, even at high pressures, while the semi-compliant balloon expands in diameter as atmospheres are increased and "hourglasses" or "dog-bones" around the lesion. The nominal diameters of these balloons match the internal diameter of the vessel. The non-compliant balloon was modeled at 27 atm while the semi-compliant balloon was modeled at 20 atm as these are the highest rated burst pressures for commercially based 8 mm diameter PET and nylon balloons respectively.



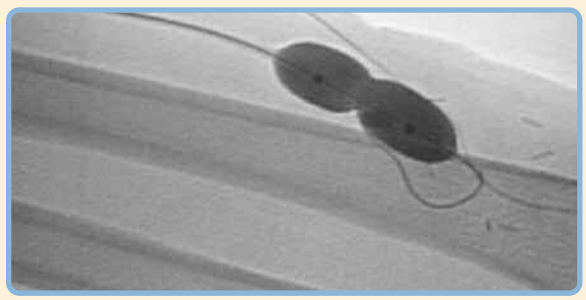
Non-Compliant Balloon Expanded to 27 ATM — Total Displacement (in.)[1]



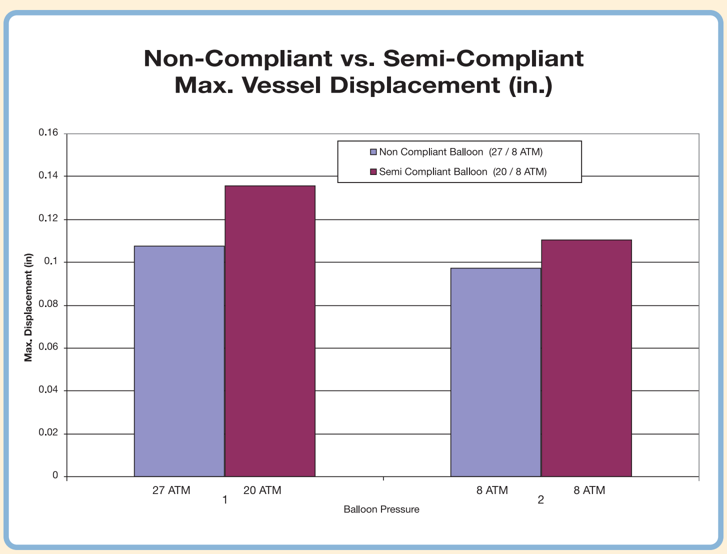
Semi-Compliant Balloon Expanded to 20 ATM — Total Displacement (in.)[1]



Non-Compliant Balloon Expanded Beyond Nominal Pressure[4]



Semi-Compliant Balloon Expanded Beyond Nominal Pressure[4]

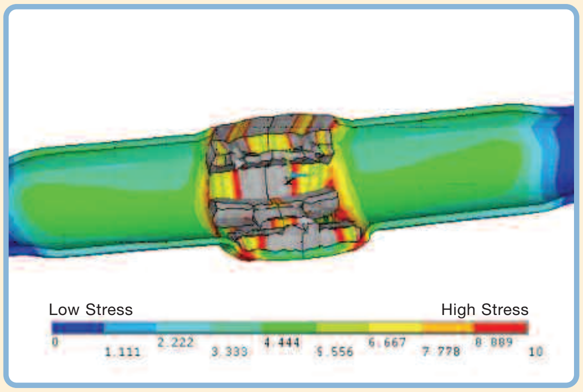


Comparison of Vessel Deformation under Full Balloon Inflation[1]

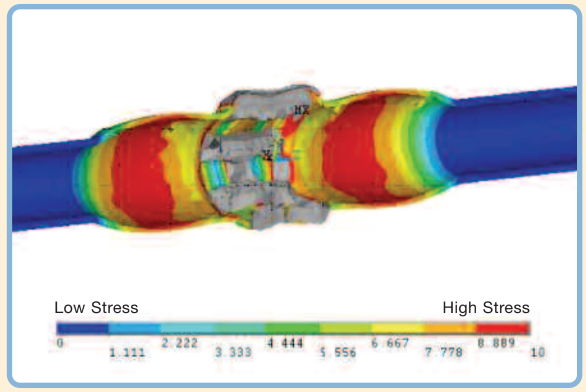
Vessel Stress

This simulation shows the amount of vessel stress delivered by the non-compliant and semi-compliant balloons in both the stenotic and normal (non-stenotic) sections of the inflation area; the stress scale ranges from no stress (dark blue) to the most stress (red).

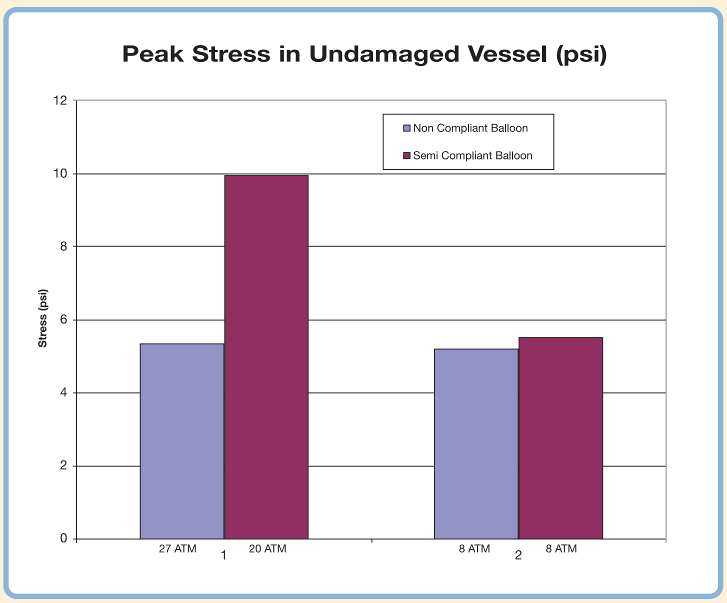
In a typical 8 mm vessel, the representative semi-compliant balloon produces a large variation in peak stresses in the undamaged vessel, while the stresses remain relatively constant in the non-compliant balloon under variable inflation. Note that the nominal diameter of these balloons is 8 mm.



Non-Compliant Balloon Expanded to 27 ATM — Stress (psi)[1]



Semi-Compliant Balloon Expanded to 20 ATM — Stress (psi)[1]



Comparison of Peak Stress (psi) in Undamaged Vessel[1]

Conclusions:

Based on the Finite Element Analysis described in this report, it appears that:

- Semi-compliant balloon angioplasty causes higher stresses in the normal (non-stenotic) vessel than non-compliant angioplasty.
- Non-compliant balloons can be inflated to higher pressures without overexpansion of the normal vessel.

Finite Element Model

The balloon expansion analyses calculate the deflections and stress distribution in the vessel, plaque, and balloon with results in the undamaged vessel highlighted. Fracturing of the plaque is explicitly simulated in the calculations. The time history simulation of the balloon, vessel, and plaque replicates the angioplasty procedure. All simulations were performed with the explicit dynamics ANSYS-LS/DYNA nonlinear finite element analysis program. Material properties used to simulate the balloons were derived from testing, while the material properties of the catheter and vessel came from literature.

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