element

# TESTING TIPS

**Cardiovascular Implant Pulsatile Fatigue Testing: Inner Diameter, Radial Strain, and Compliance Calculations**

Stent/graft testers are typically equipped with pressure transducers and a laser micrometer to obtain pressure and mock vessel outer diameter data during pulsatile fatigue testing of intravascular medical devices.

When cardiovascular devices are deployed inside mock vessels, the inner diameter (ID) of the vessel is the same as the device's outer diameter (OD). As a result, devices experience the vessel ID strain which is the true strain target. However, the laser micrometer measures mock vessel OD, which is converted to OD strain. Therefore, the target ID strain needs to be converted into a corresponding OD strain for direct monitoring and control purposes.

The equations below outline how to make these conversions and how vessel inner diameter, radial strain and compliance are calculated from measurements taken during testing. An example is also included for reference purposes.

## RADIAL STRAIN DEFINITIONS AND CALCULATIONS

**ID radial strain calculation:**

$$ID\ Strain\ (\%) = \frac{(ID_{max} - ID_{min}) \times 100\%}{ID_{min}}$$

**OD radial strain calculation:**

$$OD\ Strain\ (\%) = \frac{(OD_{max} - OD_{min}) \times 100\%}{OD_{min}}$$

ID radial strain to OD radial strain ratio for thick walled artery in constant length:

$$* \frac{\%ID}{\%OD}\ Strain\ ratio = \frac{ID\ Strain\ (\%)}{OD\ Strain\ (\%)} = \frac{\frac{(ID - 2b)}{2b}}{\frac{(OD - 2a)}{2a}} = \left[\frac{1 + \frac{a^2}{b^2} - \mu\left(1 - \frac{a^2}{b^2} + 2\mu\right)}{2(1 - \mu^2)}\right]$$

Where:

| | |
|---|---|
| a = | nominal OD radius of artery |
| b = | nominal ID radius of artery |
| μ = | Poisson's Ratio (.47) |
| OD = | pressurized OD diameter of artery |
| ID = | pressurized ID diameter of artery |

*The $\frac{\%ID}{\%OD}$ *strain ratio* Formula is established using constant length constraint(s). Refer to E.2 of Annex E in ISO 25539-1 AMENDMENT 1 2005-07-15.

**Pressurized artery OD calculation:**

$$OD\%\ Meas = \frac{(OD_{max} - OD_{min}) \times 100\%}{OD_{avg}}$$

$$OD_{max} = OD_{avg}\ (1 + 0.5 * OD\%Meas)$$

$$OD_{min} = OD_{avg}\ (1 - 0.5 * OD\%Meas)$$

**Pressurized artery ID calculation:**

$$ID_{max} = ID_{nom} + \frac{ID_{nom}(OD_{max} - OD_{nom})}{OD_{nom}} * \frac{\%ID}{\%OD}\ strain\ ratio$$

$$ID_{min} = ID_{nom} + \frac{ID_{nom}(OD_{min} - OD_{nom})}{OD_{nom}} * \frac{\%ID}{\%OD}\ strain\ ratio$$

$$ID_{mean} = ID_{nom} + \frac{ID_{nom}(OD_{avg} - OD_{nom})}{OD_{nom}} * \frac{\%ID}{\%OD}\ strain\ ratio$$

max = maximum  min = minimum  nom = nominal

## MOCK VESSEL COMPLIANCE

Compliance is the ability of a mock vessel to distend with increasing transmural pressure or recoil with compressing force. Mock vessel compliance calculations are critical when device testing needs to simulate physiologic vessels.

**ID compliance (ID radial strain per 100mmHg) calculation:**

$$ID\ Compliance\ (\%) = \frac{(ID_{max} - ID_{min}) \times 10^4\%}{ID_{min} \Delta P}$$

## EXAMPLE CALCULATION

Let's look at an example (for reference purposes only) to illustrate how to calculate strain and compliance using the equations above.

In this example, we will assume the following:

- Artery nominal ID = 20.75mm
- Artery nominal wall thickness = 2.0mm
- a = 12.375 mm
- b = 10.375 mm
- μ = 0.47
- f = 1.2Hz
- ΔP = 64 mmHg
- Mean P = 120 mmHg
- Temperature = 37±2°C

$$\frac{\%ID}{\%OD}\ Strain\ ratio = \frac{ID\ Strain\ (\%)}{OD\ Strain\ (\%)} = \frac{\frac{(ID - 2b)}{2b}}{\frac{(OD - 2a)}{2a}} = \left[\frac{1 + \frac{a^2}{b^2} - \mu\left(1 - \frac{a^2}{b^2} + 2\mu\right)}{2(1 - \mu^2)}\right] = 1.399$$

$OD\%\ Meas = 2.45\%$

$ODavg = 25.86$

$OD_{max} = OD_{avg}\ (1 + 0.5 * OD\%Meas) = 26.18$

$OD_{min} = OD_{avg}\ (1 - 0.5 * OD\%Meas) = 25.54$

$$ID_{max} = ID_{nom} + \frac{ID_{nom}\ (OD_{max} - OD_{nom})}{OD_{nom}} * \frac{\%ID}{\%OD}\ strain\ ratio = 22.42$$

$$ID_{min} = ID_{nom} + \frac{ID_{nom}\ (OD_{min} - OD_{nom})}{OD_{nom}} * \frac{\%ID}{\%OD}\ strain\ ratio = 21.68$$

$$ID_{mean} = ID_{nom} + \frac{ID_{nom}\ (OD_{avg} - OD_{nom})}{OD_{nom}} * \frac{\%ID}{\%OD}\ strain\ ratio = 22.05$$

$$ID\ Strain\ (\%) = \frac{(ID_{max} - ID_{min})\ x\ 100\%}{ID_{min}} = 3.43\%$$

$$ID\ Compliance\ (\%) = \frac{(ID_{max} - ID_{min})\ x\ 10^4\%}{ID_{min} \Delta P} = 5.36\%$$

If you have questions about these calculations or would like assistance with your cardiovascular device's fatigue testing, please contact us to discuss how we can help.