



# Luminal Area Stenosis Calculation in the Presence of Continuing Stent Expansion of Peripheral Self-Expanding Stents

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# Purpose

The purpose of the study was to evaluate a new method of calculation of “% Luminal Area Stenosis” for peripheral self-expanding stents in the presence of continuing stent expansion, in comparison with a current histomorphometric calculation of “% Luminal Area Stenosis” used for balloon expandable (coronary) stents, and to understand how the stent expansion influences patency in self-expanding stents.

# Background

- Currently, “% Luminal Area Stenosis” for peripheral self-expanding stents is calculated by the same histomorphometric method used for balloon expandable (coronary) stents in pre-clinical studies.
- Balloon expandable stent provides a good reference point for histomorphometric measurements and calculations of in-stent stenosis because stent diameter/area does not change. On the other hand, nitinol self-expanding stents are implanted oversized, and continue to expand in diameter post-implantation.
- It has been observed that luminal patency of self-expanding stent does not correlate well with histomorphometric “% Luminal Area Stenosis” in long term animal studies, and could cause confusion in correct interpretation of the reported % stenosis data, such as a high % area stenosis in a patent artery.

# Materials and Methods

1. Twenty-four pairs of overlapped Nitinol self-expanding stents, 8 mm diameter x 28 mm length, were implanted in the right or left iliofemoral arteries of Yucatan Mini-Swine for 90 (n=8), 180 (n=8) and 360 (n=8) days.
2. Stent-to-artery oversizing ratio was 1.2:1 to 1.4:1 at stent implantation.
3. Stent and lumen diameters during implantation and follow-up were measured by quantitative vessel angiography (QVA).
4. Explanted stented arteries were processed for histomorphometric measurement of lumen area and neointimal area.
5. Two calculation methods on “% area stenosis” were applied for comparison.

*The stents used in the study have not been approved for human peripheral vascular use in the US.*

# Calculations of In-Stent Luminal Area Stenosis

1. A current method adopted from balloon expandable stents (BES) based on neointimal area from histomorphometric data (explants only)

$$\% \text{ AreaStenosis}_{BES} = \frac{(IELA_{exp} - LA_{exp})}{IELA_{exp}} \times 100\%$$

*IELA* – internal elastic lamina area

*IELA*  $\approx$  Stent Area

*NIA* (neointimal area) = *IELA* – *LA*

*exp* – explant time

2. A proposed method applicable for self-expanding stents (SES) based on luminal area loss from lumen areas at implantation and explantation times.

$$\% \text{ AreaStenosis}_{SES} = \frac{(LA_{imp} - LA_{exp})}{LA_{imp}} \times 100\%$$

*LA<sub>imp</sub>* – lumen area at the time of stent implantation

*LA<sub>exp</sub>* – lumen area at the time of stent explantation

$\Delta LA$  (luminal area loss) = *LA<sub>imp</sub>* – *LA<sub>exp</sub>*

*imp* – implant time

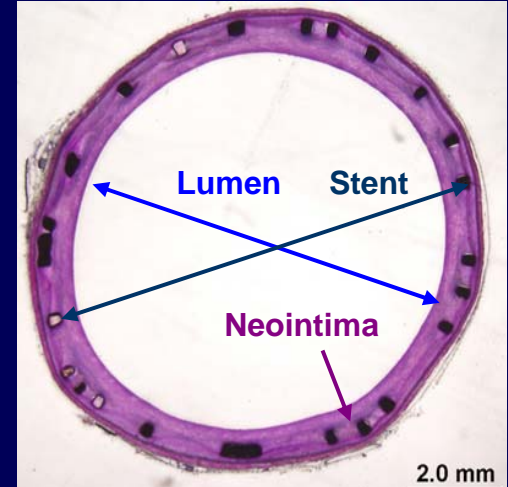
# Relationship of Luminal Area Loss with Neointimal Area ( $NIA$ ) and Stent Area ( $SA$ )

Lumen Area (at given time  $t$ )

$$LA_t = SA_t - NIA_t$$

Luminal Area Loss (from implant to explant)

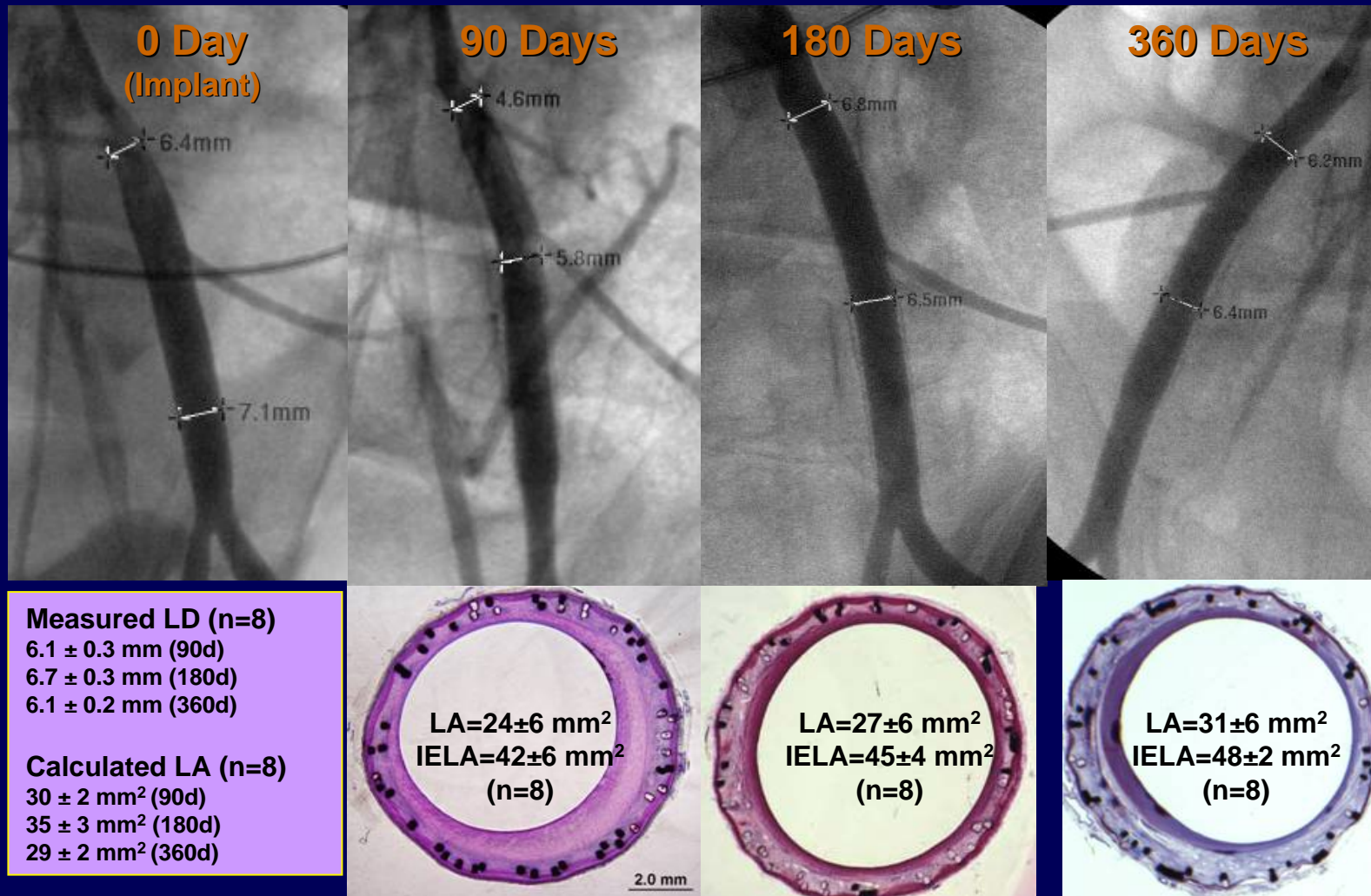
$$\Delta LA = NIA - \Delta SA$$



**Based on above equation, the following is observed:**

- For balloon expandable stent, there is no stent area change, i.e.  $\Delta SA = 0$ , so luminal area loss is equal to neointimal area as measured by histomorphometry.
- For self-expanding stent, stent area increases with time, i.e.  $\Delta SA > 0$ , so luminal area loss is less than neointimal area, off-set by stent expansion.

# Angiographic and Histomorphometric Analyses of SES Implanted in Porcine Iliofemoral Arteries

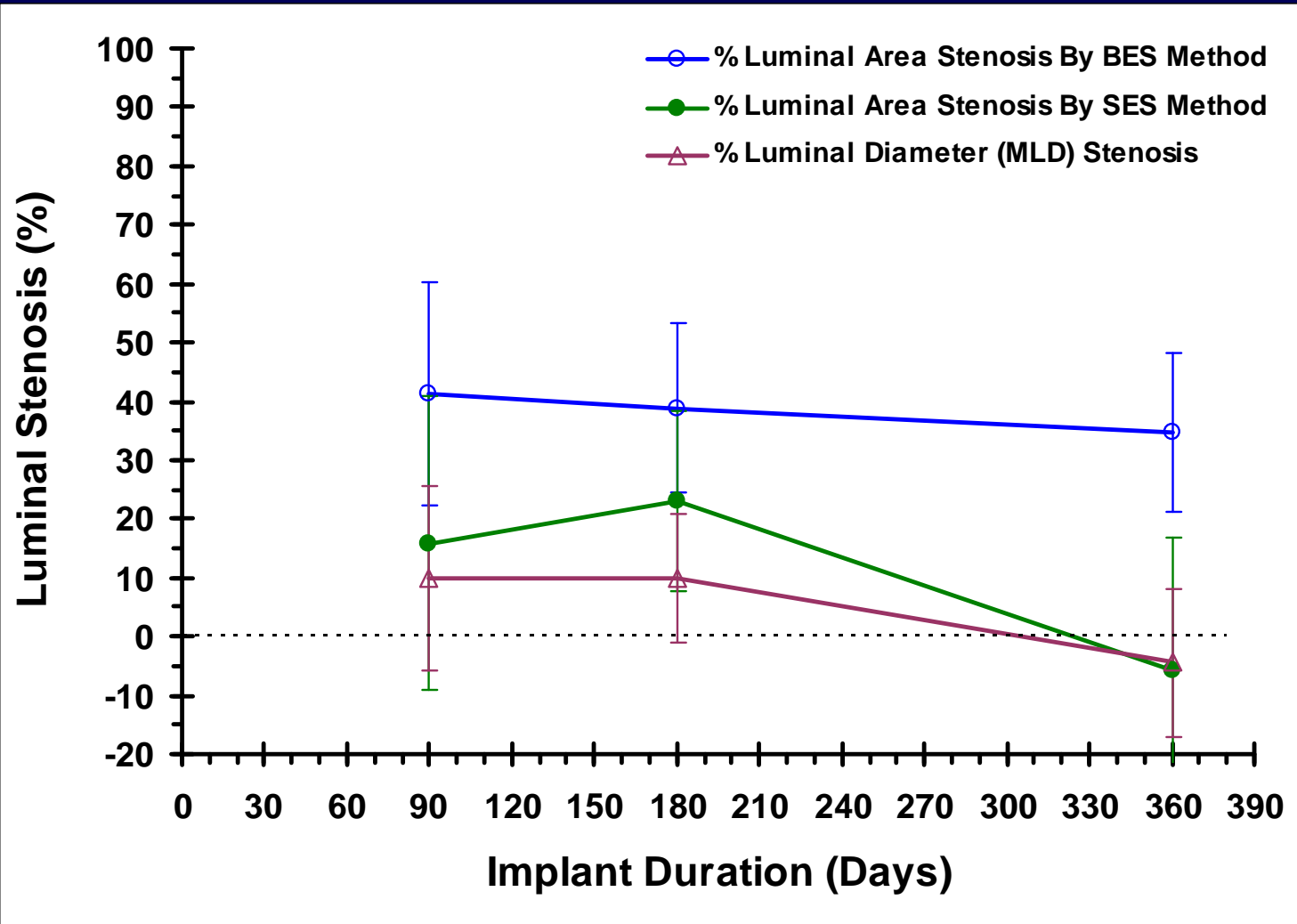


\* Angiograms at implantation were used for lumen area calculation at day 0 assuming round cross section in the healthy vessel of the model. Alternatively, IVUS or OCT may be used for lumen area visualization and measurement.

# Calculated Stenosis For SES Implanted in Porcine Iliofemoral Arteries

<b>Calculated Stenosis (%, n=8)</b>	<b>Explantation Time (Days)</b>		
	<b>90</b>	<b>180</b>	<b>360</b>
<b>% Area Stenosis by BES method</b>	<b>41% ± 19</b>	<b>39% ± 14</b>	<b>35% ± 14</b>
<b>% Area Stenosis by SES method*</b>	<b>16% ± 25</b>	<b>23% ± 15</b>	<b>-5% ± 23</b>
<b>“Clinical” Stenosis using Proximal Diameter as Reference</b>	<b>-0.8% ± 21</b>	<b>8.5% ± 8.5</b>	<b>-2.4% ± 11</b>

# Changes of Luminal Area and Diameter Stenosis With SES Implantation Time



data represent mean  $\pm$  SD; data on file at Abbott Laboratories.

# Conclusions

1. Due to continuing stent expansion post-implantation, the proposed method of % area stenosis calculation for self-expanding stent represents intraluminal changes more accurately in long term pre-clinical studies with peripheral arterial stents
2. Theoretical and experimental results showed that the luminal area loss due to neointimal hyperplasia could be off-set in part by continuing stent expansion in normally oversized self-expanding stent.
3. Two sets of lumen area data are required for % area stenosis calculation for self-expanding stents:
  - 1) lumen area at implantation, may be obtained by IVUS, OCT, or angiography;
  - 2) lumen area at explantation, may be obtained by histomorphometry, IVUS, OCT or angiography.