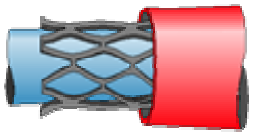
ABSTRACT



We sought to determine whether intimal hyperplasia provoked by stents stem from injury imposed by stent expansion characteristics.

Rabbit femoral arteries were exposed and their external wall marked in a gridded fashion. An arteriotomy was performed, and stents were inserted and expanded within the marked region while being videotaped. Computer analysis of mark displacements yielded axial, circumferential, and torsional arterial strain componenets as a function of time and distance along the stented region. These data were compared with *en face* and cross-sectional histologic sections of the center and end regions to correlate specific mechanisms of stent expansion with resulting arterial injury.

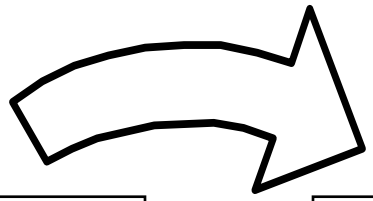
The ends of the stent inflated first at 2-4 atm of pressure and opened nonuniformly into a fishmouth (single-ended) or dumbbell (double-ended) shape. The center of the stent opened with increasing pressure while contracting along its axis, causing the already-inflated proximal and distal regions to scrape the intima longitudinally inwards. The magnitude of stent dogbone correlates well with both scraping deendothelization and arterial injury (R^2 values of 0.87 and 0.82 respectively).

***Conclusions*: 1) Stent expansion *in-vivo* is nonuniform, which 2) produces vascular injury that varies with location. 3) This mechanism of injury is an important determinant of stent restenosis.**

	proximal end	mid-stent	distal end
angle at maximum dogbone	.56 ± .12	.16 ± .03	.33 ± .13
injury score	.18 ± .06	.11 ± .02	.25 ± .04
14 day intimal area (mm^2)	.83 ± .11	.52 ± .05	.70 ± .11

HYPOTHESIS

Acute mechanical arterial injury produced by stents during expansion is an important determinant of restenosis



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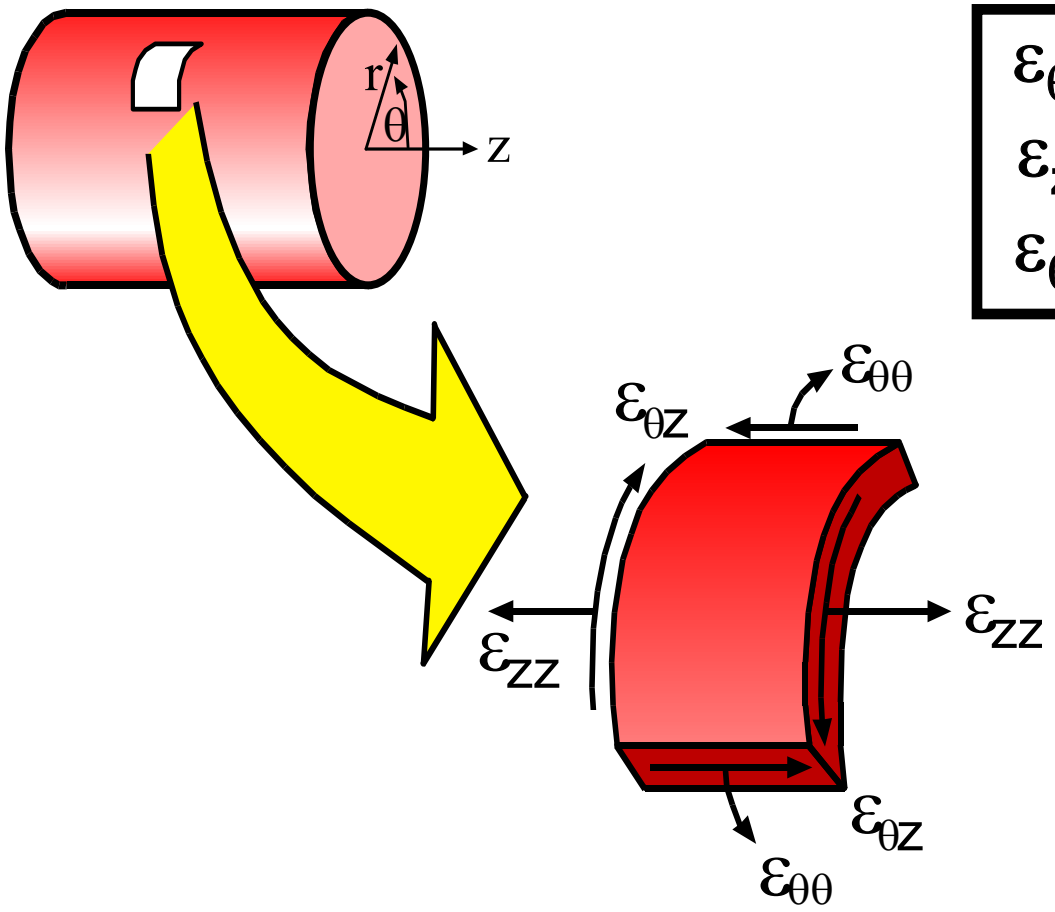
paste histology photos here

Acute mechanical injury here **is a key determinant of the chronic response**

DEFINITION OF STRAIN



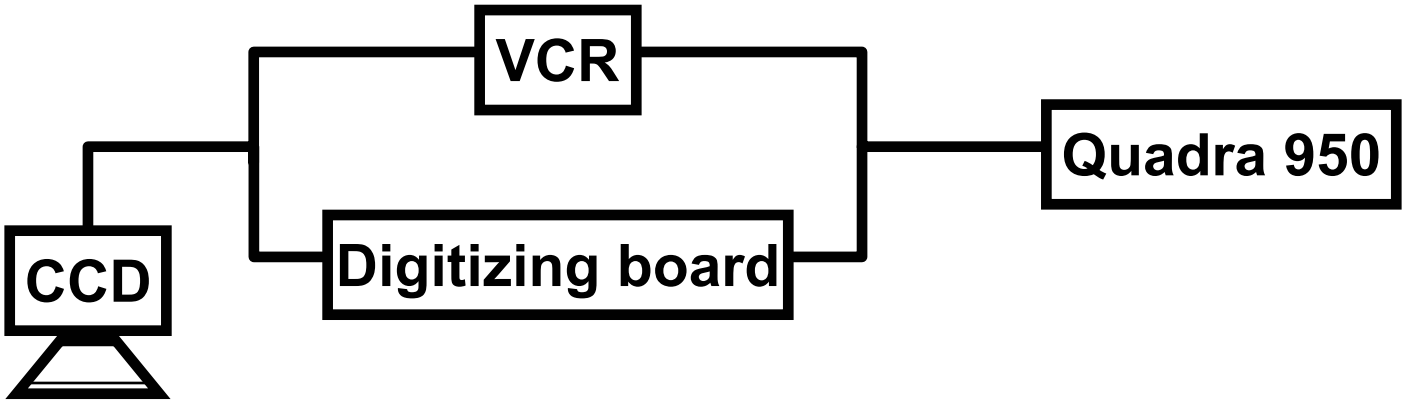
$\varepsilon_{\theta\theta} \Rightarrow$ increase in diameter

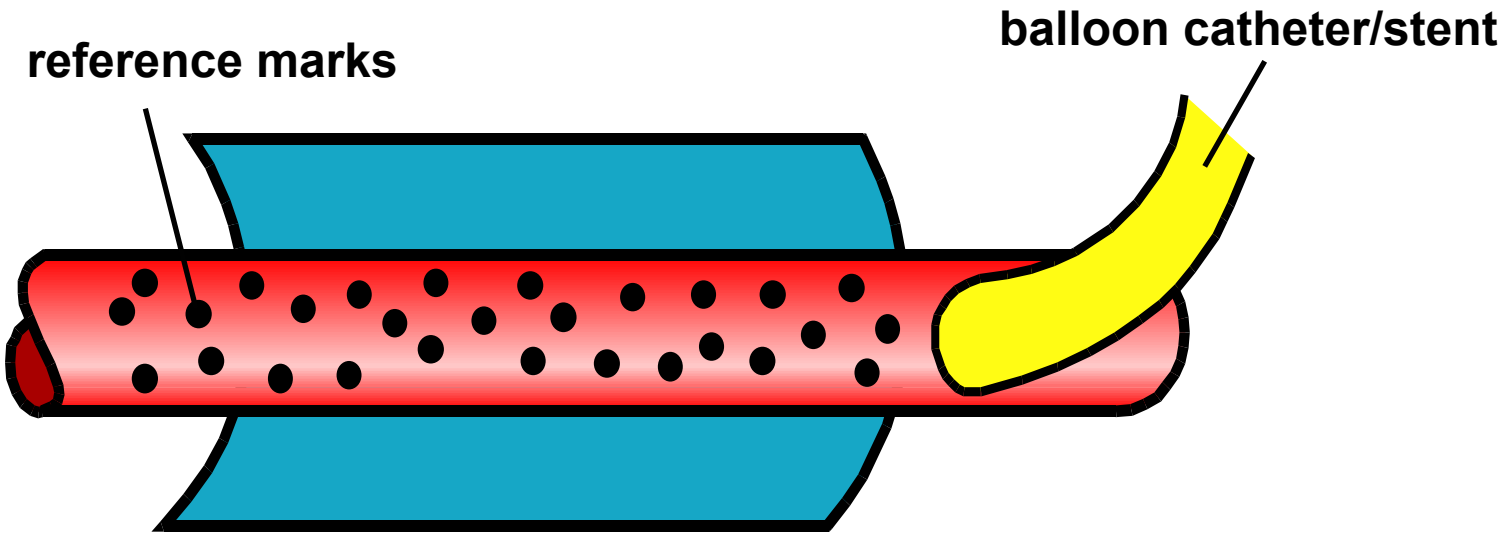
$\varepsilon_{zz} \Rightarrow$ lengthen

$\varepsilon_{\theta z} \Rightarrow$ twist

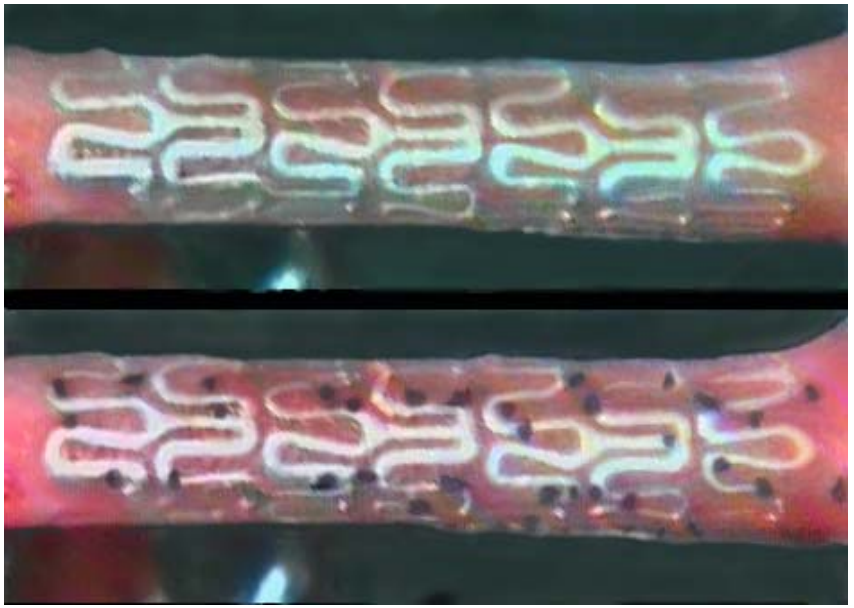
Surface strain is a tensor quantity with three independent components shown here in cylindrical coordinates. Each component varies with location along the artery.

IN-VIVO EXPERIMENTAL SYSTEM





INK-JET MARKING SYSTEM



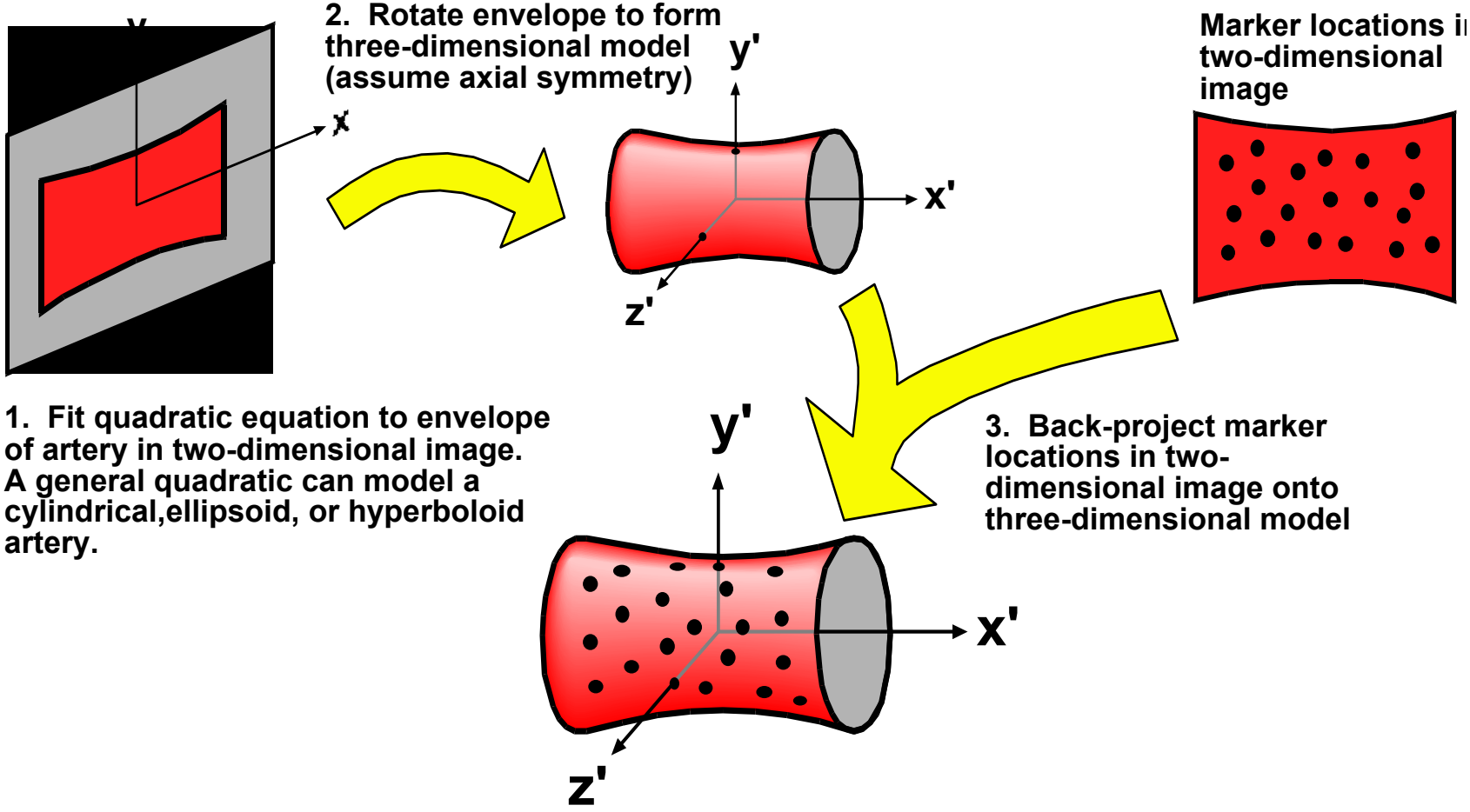
Bovine coronary *ex-vivo* before/after marking. Scale: 500μm/division.

Rabbit iliac marked *in-vivo* after 3mm Multi Link insertion. Same scale as left.

A hand-held unit incorporating a Cannon CJ-3A ink-jet head produced these marks.

By adjusting the input waveform duty cycle, marks from 75-500μm diameter can be produced.

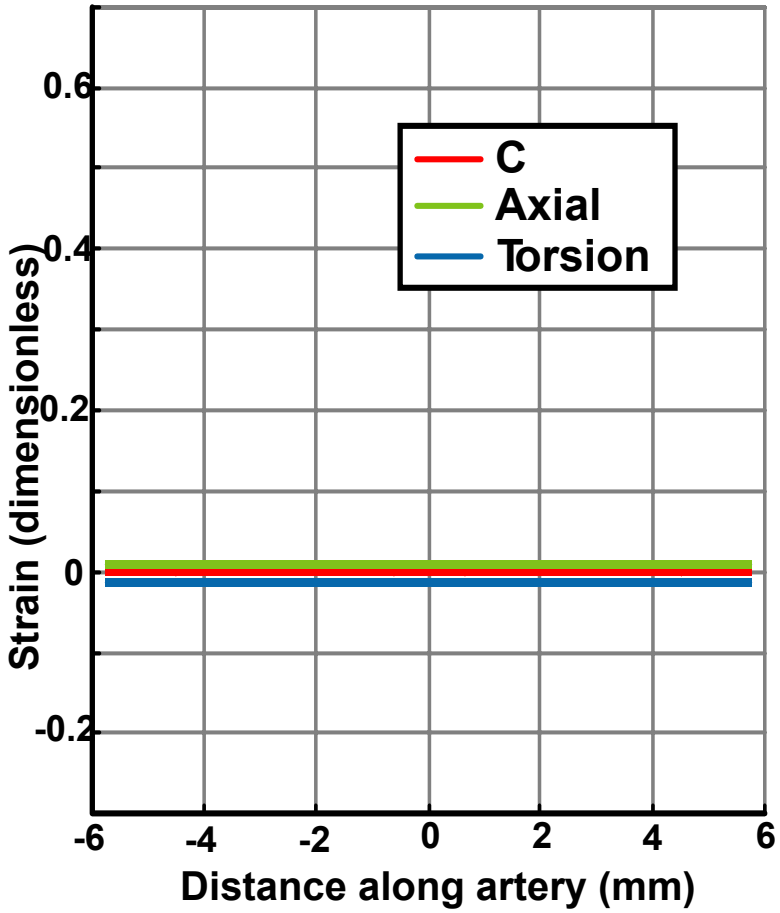
ANALYSIS



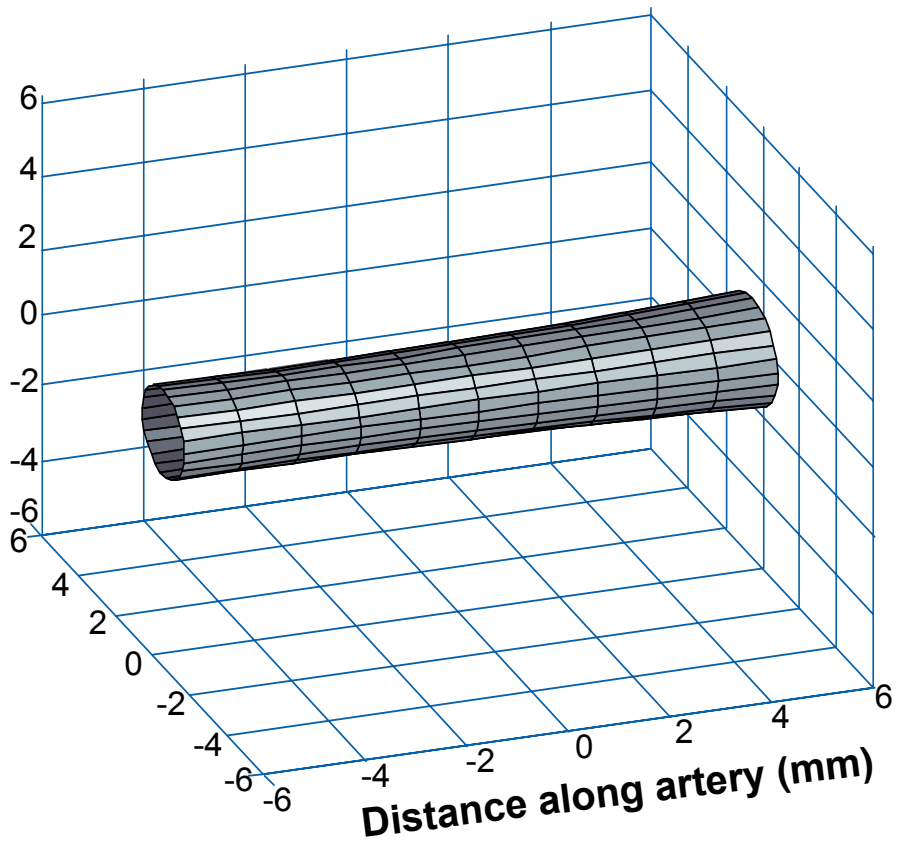
The three-dimensional displacements of the markers determines the strain tensor
As only one camera could be positioned in the surgical theater,
the above method determines the 3D marker locations given a 2D frame.

0 ATMOSPHERES

Strain tensor components

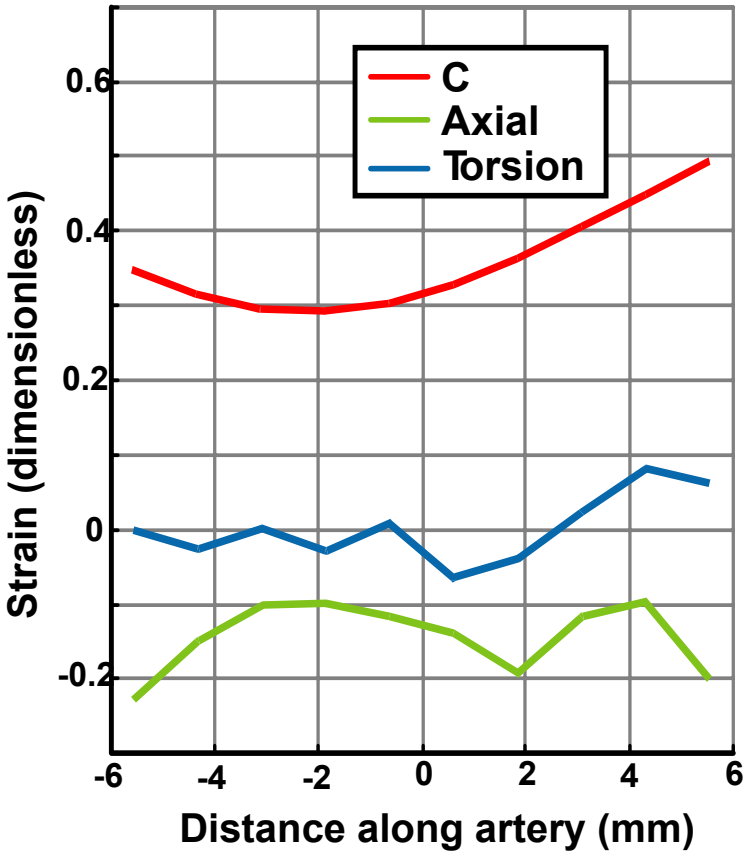


Model reconstruction

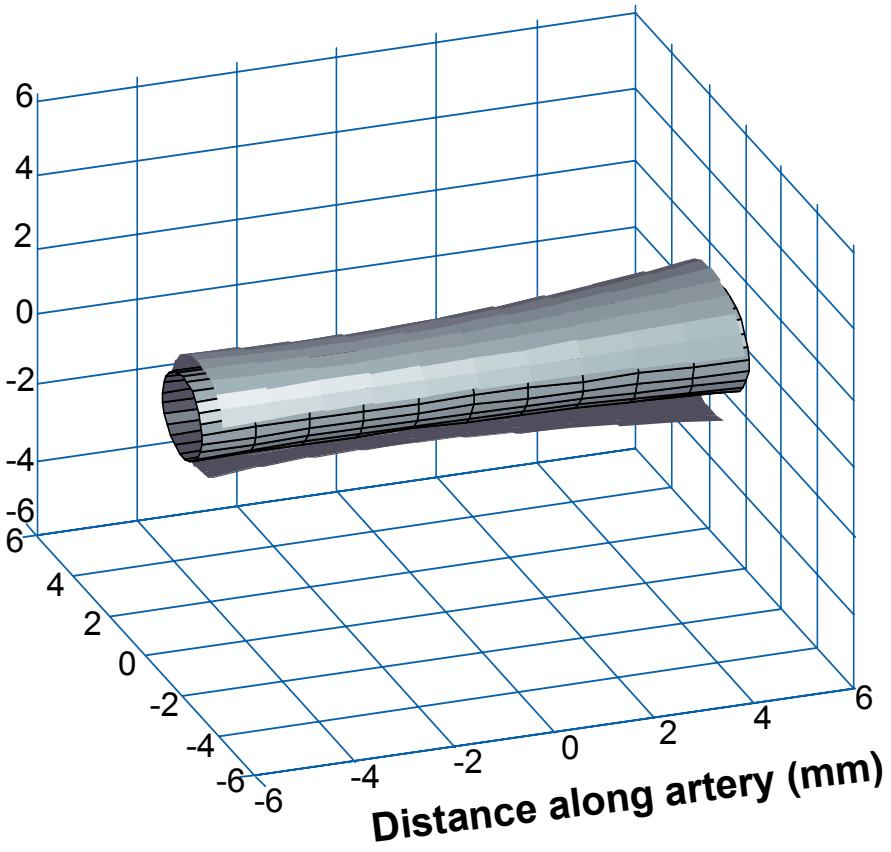


4 ATMOSPHERES

Strain tensor components

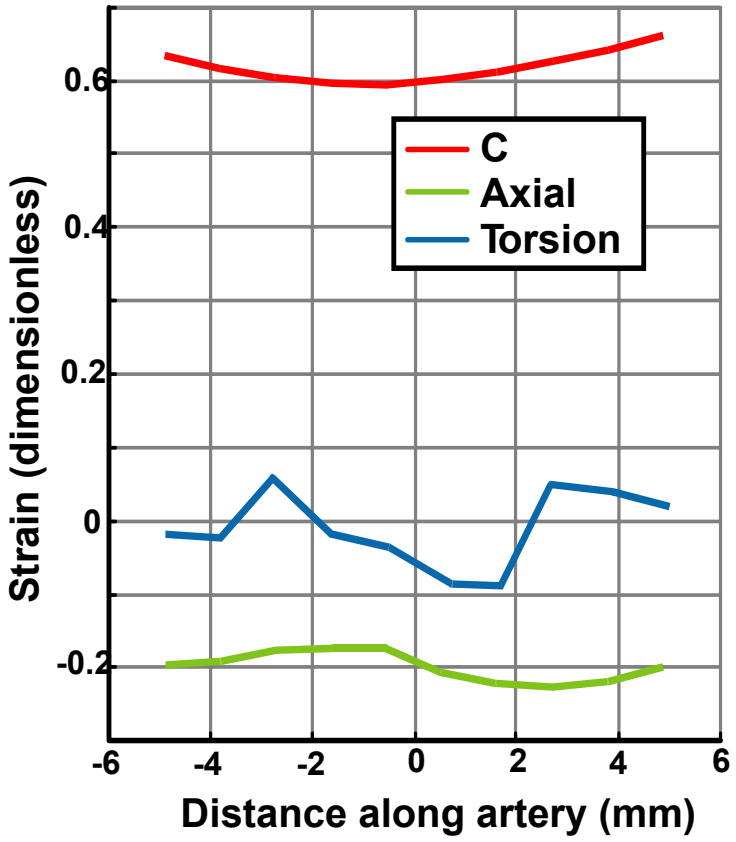


Model reconstruction

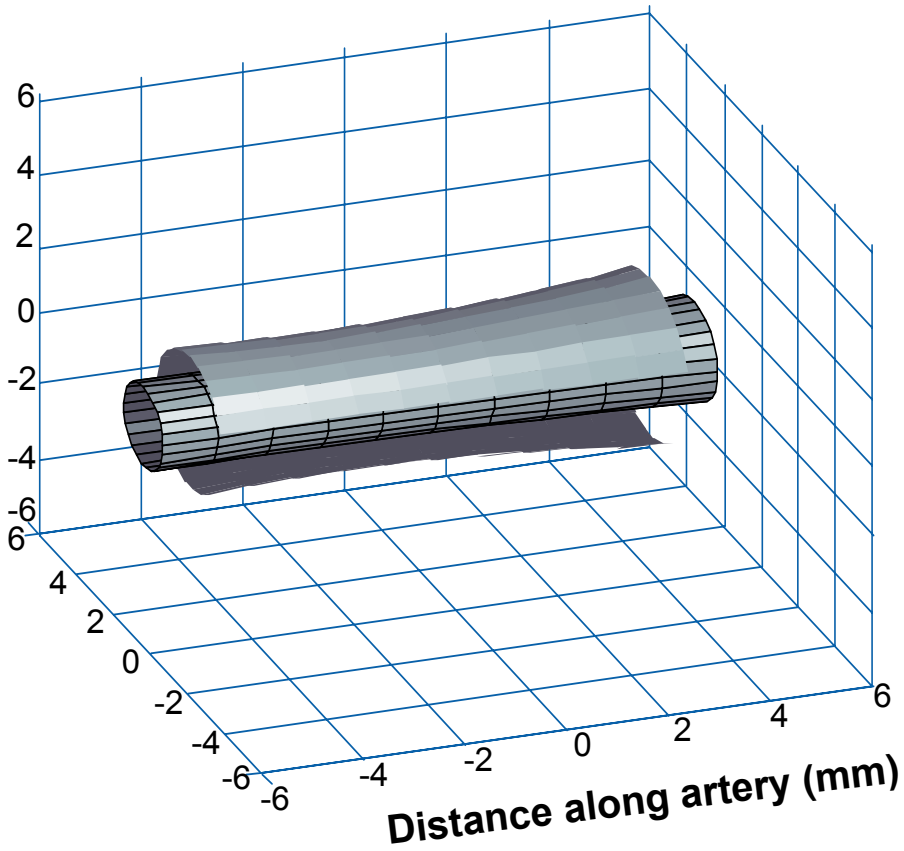


8 ATMOSPHERES

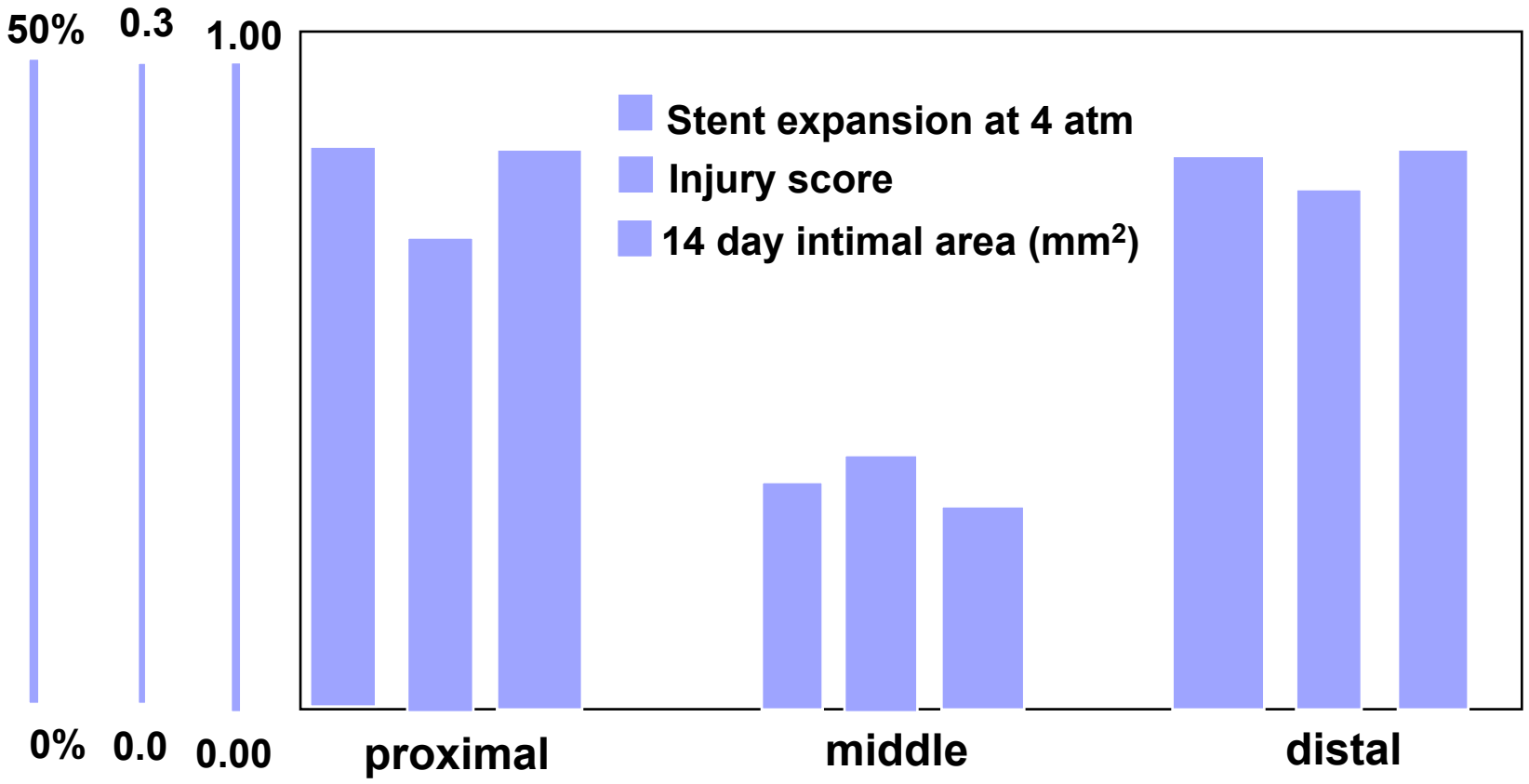
Strain tensor components



Model reconstruction

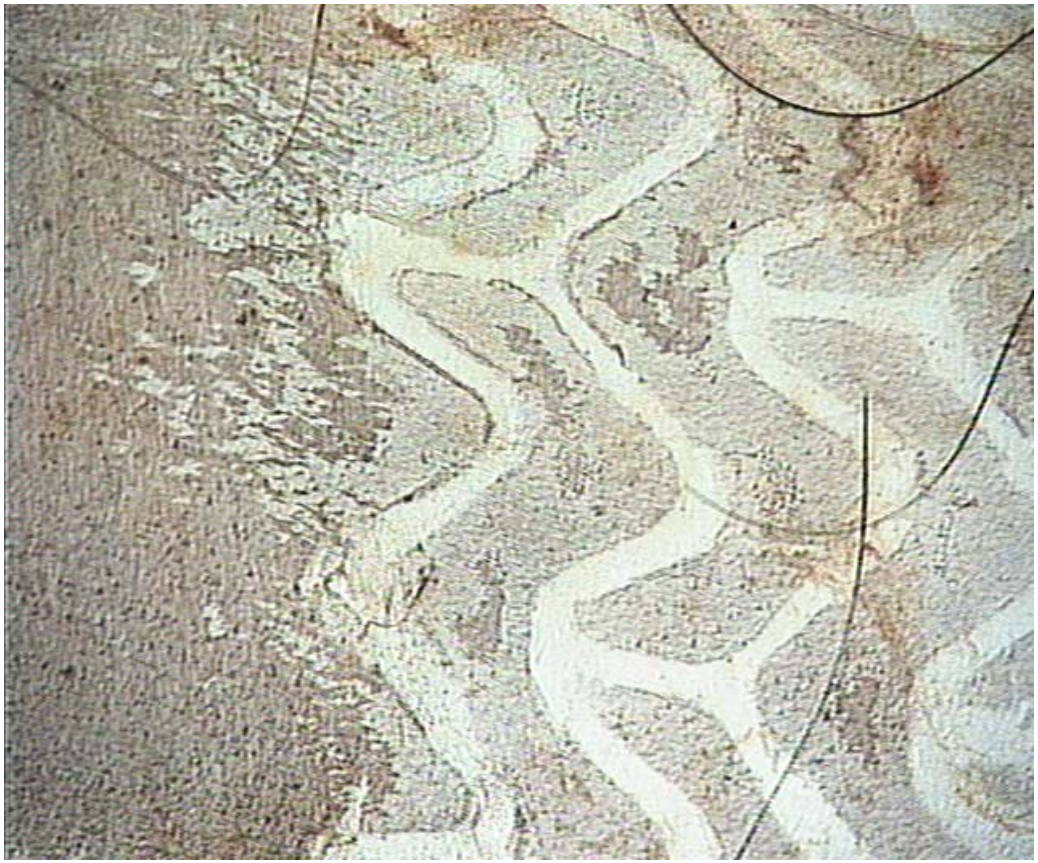


LOCALIZATION OF MEASURED INJURY



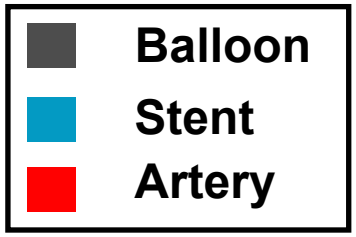
Damage incurred by non-linear expansion characteristics measured by comparing percent of circumferential expansion at the most uneven expansion timepoint: 4 atm

HISTOLOGY



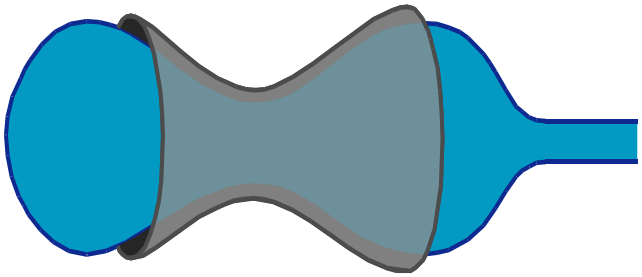
$AgNO_3$ *en-face* staining of rabbit femoral artery 15 minutes after stenting with a Multi-Link®

EDGE EFFECT



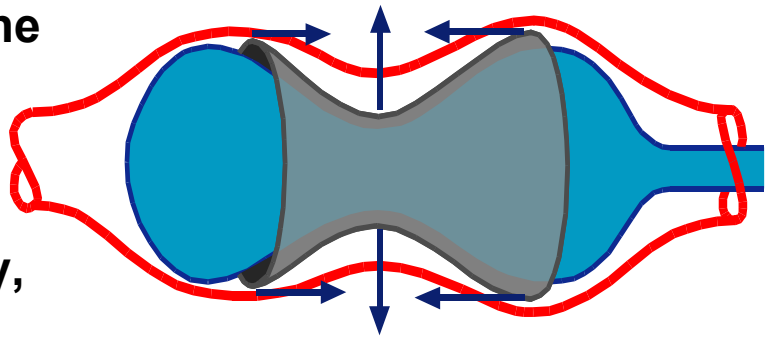
Unconstrained ends of balloon inflate first

Stent begins likewise end-first expansion

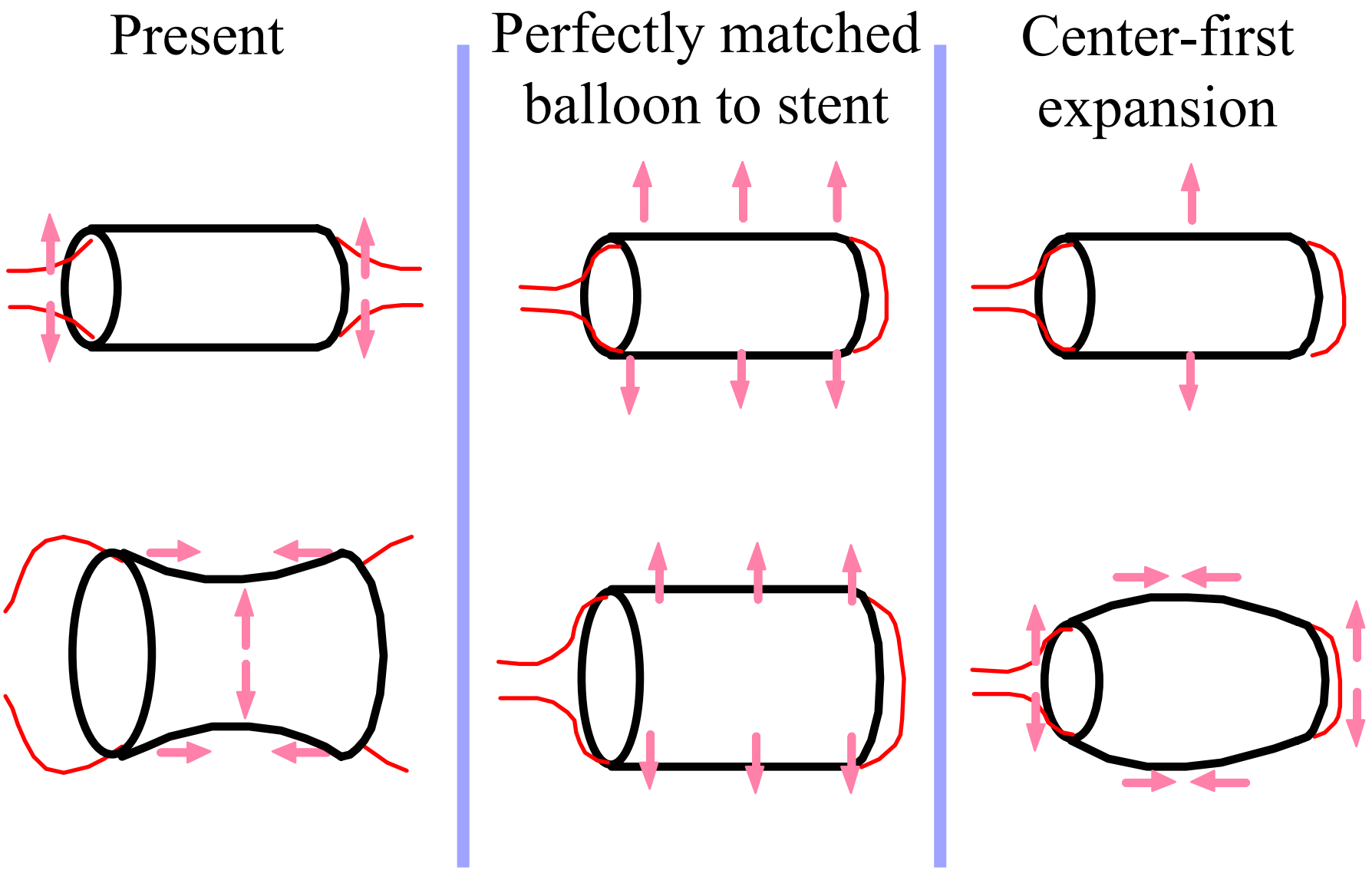


The stent ends expanding most contact the covering artery as two rings might, while the center remains comparatively uninflated

As the stent's center region expands circumferentially the stent contracts axially, scraping the ringed-ends against the arterial wall



INJURY REDUCTION



Stents dynamically open in a highly non-linear fashion. We name this the edge effect after the momentary ballooning of the proximal and distal edges

During expansion, this non-linear characteristic causes direct, acute mechanical damage to the artery

This mechanical damage may be measured using the endothelium as a marker, and correlates well with eventual restenosis

A means of limiting arterial damage from the edge effect has been proposed in a center-first opening stent

INTRODUCTION

METHODS

RESULTS / DISCUSSION

CONCLUSIONS