Measuring Arterial Strain Induced by Endovascular Stents

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Abstract

Endovascular stents are expandable, fenestrated tubes which are threaded in their collapsed state through an artery to a site of occlusion, plastically enlarged, and left as permanent implants to scaffold the artery open. The stent induces large-scale vascular strains which are difficult to measure *in vivo*, yet may be critical determinants of stent-vessel biology.

We developed a method to measure the strain tensor developed on the surface of an artery as a stent is expanded *in vivo.* Arterial sections were marked with reference points and imaged as the stent was expanded. An axially symmetric parametric model of the artery was determined for each expansion timepoint, and these reference points were back-projected onto this surface. The back-projected reference points were grouped and analysed to determine the circumferential, axial, and torsional strain tensor components in each arterial subsection. The method was characterised *in vitro* using bovine artery segments and a latex phantom, and then tested on rabbits to demonstrate its feasibility *in vivo*

In vitro experiments on stented bovine arteries showed typical post-stenting strains of 0.60, -0.26, and 0.08 mm/mm in the circumferential, axial, and torsional directions, respectively, sampled every 1 mm along the length of the stented region. Phantom experiments characterised the rms error of system measurements as 0.1mm/mm. The system was shown capable of measuring strains of straight, accessible vessels in the presence of respiratory/cardiac motion and visual glare *in vivo*.

1 Introduction

Endovascular stents are expandable, fenestrated metal tubes of variable length and diameter, made from a variety of materials and designed to hold open the lumen of obstructed arteries. Stents are mounted in their compressed state on catheters that can be threaded through the vascular tree to a site of narrowing, where they are enlarged in diameter by 50% or more. Nitinol stents expand as they are freed to resume their natural enlarged shape as dictated by a thermally-triggered shape memory effect, and stainless steel stents are plastically deformed under the influence of a cylindrical balloon inflated within the stent to 8-20 bar of pressure. Once the catheter is withdrawn the stent is left as a permanent implant within the artery.

Stent implantation imparts extreme vascular strains and focal mechanical injury to the vessel wall, ranging from denudation of the endothelial cell monolayer that covers the interior of the lumen, to progressive laceration of deeper vascular structures (EDELMAN and ROGERS, 1996, SCHWARTZ et al., 1992). The amount of injury inflicted by the stent is not only a function of the final vessel enlargement ratio but also of the stent geometry (ROGERS and EDELMAN, 1995) which dictates whether the stent axially contracts or twists as it circumferentially expands. This suggests that a more complete characterisation of the form and extent of strain imparted by stents may deepen understanding of the vascular response to strain, and may also lead to improved endovascular implant designs that minimise injury.

To fully characterise the deformation of the arterial surface by the expanding stent, the circumferential, axial, and torsional components of the strain tensor must be determined. In general, these components vary as a function of location along the stent, and change with time as the stent is expanded. The ability to measure these *in vivo* is constrained by two factors not addressed by techniques presently in use. First, although it is necessary to track the three-dimensional locations of arterial markers over the curved arterial surface, the surgical incision required to expose the artery for imaging without altering its orientation and environment is deep and narrow, making a multiple-camera approach impractical. Second, as the strain field tensor varies along the length of the stent, it must be determined locally as a function of position along the artery. We now report on the development of a method using a single camera to measure the dynamic, local Green strain tensor developed along the surface of a cylindrical wall as it deforms in an axisymmetric manner. Testing was performed *in vitro* on excised bovine arteries deformed by stenting to determine the method's suitability to measure stent-induced arterial strain. Accuracy was determined using a large-scale inflatable latex phantom. The feasibility of using this system to measure arterial strain *in vivo* was assessed on a rabbit undergoing stenting in both femoral arteries.

2 Methods

2.1 Experimental

A system was developed to track arterial deformation. The surface of the artery was imprinted with a fine grid of high-contrast ink marks by mounting an ink-jet printer cartridge (Cannon CJ-3A) in a handheld stylus and driving it with a low-impedance squarewave. Benchtop testing showed the cartridge formed regular 50 μm to 250 μm marks when driven by a 24 V pulse train using a pulse-on duration from 1 to 20 μs. A 10 Hz train of 5 μs pulses was used to produce 150 μm arterial markings.

Experimental data were recorded using an imaging system (Fig. 1) consisting of a deep-field zoom lens (Computar 18-108 mm, f2.5) with attached polarising lens mounted on a CCD camera with 640x480 pixel resolution (Hitachi VC-C370). The camera's NTSC signal was recorded on an S-VHS system, channelled to a frame grabber (Raster-Ops 24XLTV) via S-video cable, and digitised to 640x400 pixel resolution. The strain measuring system was first tested using excised bovine coronary arteries deformed by a stainless steel endovascular stent (Advanced Cardiovascular Systems/Guidant) mounted on a 3 mm polyethylene balloon catheter (Advanced Cardiovascular Systems/Guidant). The arterial surface was marked using the ink-jet system and imaged as the catheter was inflated to a maximum pressure of 8 bar in 2 bar steps. To determine the accuracy of the strain measurements, a large-scale latex phantom artery was imaged as it underwent deformation using the same setup shown in Fig. 2. We hand-marked a grid upon the phantom, and recorded

data as the tube was inflated in step increments from an average diameter of 46 cm to 175 cm. After each step the tube was allowed to stabilise for 1 minute to reduce creep or other viscoelastic effects that might confound manual measurements. The distances between 60 pairs of markers were hand-measured, yielding the circumferential, axial, and torsional strain components at 20 locations on the phantom's surface. The image was concomitantly digitised with a comparable field-of-view to the bovine coronary experiment, and the digitised data were processed with the strain measuring system for comparison.

In vivo feasibility was demonstrated by measuring the arterial strain in a rabbit undergoing stent implantation in both femoral arteries. A 3.4 kg New Zealand rabbit was anaesthetised with ketamine (35mg/kg IM) and sodium pentobarbital (Nembutal, 4mg/kg IM), and a length of each femoral artery was exposed and cleaned of fascia in preparation for the arteriotomy (Fig. 2). The length of artery isolated was approximately 5 cm longer than required for the arteriotomy, and after the incision was performed a hemicylindrical black plastic cradle was placed behind the excess length to improve contrast of the arterial envelope. The artery was marked in a gridded fashion using the inkjet stylus and a corrugated-ring stainless steel stent (Advanced Cardiovascular Systems/Guidant multilink 3mm x 12mm) mounted on a 3mm compliant balloon angioplasty catheter was advanced to the marked section. The balloon catheter was slowly pressurised to 8 bar, expanding the stent while the artery was imaged with the same apparatus used for the *in vitro* experiments.

2.2 Analytical

Strain data were extracted from the raw digitised images through several intermediate processing steps. To determine three-dimensional locations of the markers from each two-dimensional frame, the artery was assumed to be axisymmetric; i.e. in {*r, θ, z*} cylindrical co-ordinates of equation *r = f(z).* The outer envelope of the vessel was digitised and a general two-dimensional quadratic equation fit to the envelope. The general quadratic equation, of the form $Ar^2 + Brz + Cz^2 + Dr + Ez = 1$, was chosen to model the vessel's envelope because of its flexibility; with few coefficients it can model two line segments that are parallel, converging (a section cut from an ellipse), or diverging (a hyperbola of two sheets). The coefficients were determined using the Nelder-Meade non-linear least-squares algorithm (NELDER and MEADE, 1973) implemented in the Matlab programming language. Once the two-dimensional equations describing the stent envelope were determined, their paths were swept around their longitudinal axis to create a three-dimensional axially-symmetric quadratic surface model. The locations of the reference marks from each two-dimensional frame were back-projected onto this three-dimensional model and the three-dimensional locations stored for strain analysis.

The surface strain components {$\varepsilon_{\theta\theta}$, ε_{zz}, $\varepsilon_{\theta z}$} can be determined within a uniformly-strained triangular region if the change in distance between the vertex points are known (MCCULLOCH, 1987). Triads of reference points were automatically grouped by computer under the assumption that the strain, although highly non-uniform over the 12mm length of the stent, varied in space

sufficiently gradually between neighbouring markers so that a good local approximation could be found using adjacent markers located 0.5-1.0 mm apart. The algorithm that grouped the reference points assigned a weighted score to each potential triad. A positive weight was associated with triads including points separated by an empirically-determined optimal distance. Points separated too widely average-out the locally varying tensor field, reducing the spatial resolution of the system. Points grouped too closely together suffer from a high error-to-measurement ratio caused by additive uncertainties in position. A negative score was associated with triads constraining points progressively closer to the edge of the artery model as they generate exaggerated position measurement error because of the sensitivity of the back-projection. In a typical artery, approximately 40 reference marks were formed, providing nearly 60,000 possible triads. Of these, 50 possibly overlapping triads were chosen as optimal. Once chosen, the strain tensor within each reference-point triad was determined and associated with the corresponding area on the arterial surface. Areas of the arterial surface that lacked suitable reference point triads were associated with the strain tensor from the nearest reference point triad. If the earlier assumption of axial symmetry was valid each axial slice should have the same strain tensor, independent of θ. The strain tensor for all segments within each axial slice was therefore replaced with the average tensor for the entire slice, and an alert was generated if any of the values varied from the average by more than 10%.

3 Results

3.1 In vitro artery segment

The system was able to accurately measure large strains in a 2mm diameter excised bovine coronary artery expanded by a 3mm balloon-expandable stent. At 2 bar of pressure (Fig. 3) the stent had not yet expanded sufficiently to contact the arterial wall. There was so little circumferential expansion at this point that both proximal and distal ends appear slightly bowed *inwards*, although this is likely measurement error since the system's measurements have a standard deviation of approximately 10%. As the balloon catheter pressure was increased to 4 bar the proximal (left in Fig. 4) end of the stent began to inflate first, with relatively small gain in luminal area compared to the initial diameter. At 6 bar both proximal (left in Fig. 5) and distal sides enlarged, leaving the centre of the stent less expanded. Torsional strain components remained near zero, while the axial strain became clearly negative, reflecting arterial shortening during circumferential expansion. As the pressure increased to 8 bar the balloon/stent unit expanded to fully contact the arterial wall along its length and the arterial surface regained a cylindrical appearance (Fig. 6). The proximal end relaxed inwards, becoming slightly less open than the distal region. The small torsional component of strain indicates that twisting around the longitudinal axis remained nearly zero throughout the expansion, although the negative axial component indicates the artery contracted 10% to 20% in length.

3.2 Latex phantom

To examine the errors inherent in the strain measuring system, a large scale cylindrical latex phantom was inflated, and strain was measured both by the imaging system and directly by hand. Measuring inter-mark distances by hand eliminated errors due to both the limited resolution of the imaging system and the modelling assumptions inherent in backprojection. Six sets of measurements were taken at incremental stages of increasing balloon radius. The system error was defined as the difference between the computed Green strain tensor and the true strain tensor as determined by direct hand-measurement. It is zero mean ($p<0.03$) and its standard deviation is plotted as error bars over the true strain components (Fig. 7).

The assumption that the artery is axisymmetric and has a quadratic surface of revolution was also examined. Table 1 shows the standard deviation σ_e of the measured arterial/phantom radii r_i around the least-squares fit quadratic surface $r(x_i)$ as a percentage of the average radius. The standard deviation was calculated as $\sigma_e = \left(\frac{1}{N-1} \sum_i (r_i - r(x_i))^2 \right)^{1/2}$ for N = 10 equispaced points along the sample's length. The standard deviation of the error is a small fraction of the average radius, indicating that the arterial/phantom surfaces are nearly quadratic.

3.3 In vivo artery

The feasibility of using this system *in vivo* was demonstrated by deployment of an endovascular stent within both femoral arteries of a rabbit. The results of arterial marking are shown in Fig. 8. The moisture on the arterial surface did not impede marking, and there was negligible mark spread due to diffusion. There was a notable circumferential mark spread post-expansion proportional to circumferential strain. An example of the calculated arterial strain tensor is shown in Fig. 9 for a balloon expansion pressure of 6 bar. This pressure corresponded to the maximum end-first expansion timepoint for both arteries, and both can be seen opening proximal (left) side first, in a similar manner to the *in vitro* experiments. The limited field of view imposed by the surgical environment did not impair the ability of the system to measure the strain tensor, although glare caused by the surgical lamps did require installation of a polarising lens on the camera.

4 Discussion

We sought to measure the strain imparted to arteries by endovascular stents, as this may be an important determinant of the biological response to these implants. We chose to use the Green tensor formulation (FUNG, 1965) as have several other investigators of biologic strains (HOFFMAN and GRIGG, 1984; HUMPHREY et al., 1987; FUNG and LIU, 1991; MCCULLOCH et al., 1987; WALDMAN et al., 1985).

Of the nine components of triaxial, or solid strain that exist, four can be measured using surface marks alone, and of these biaxial or surface strains, three components are independent. As defined in cylindrical co-ordinates {r, θ, z} these are: circumferential $\varepsilon_{\theta\theta}$ which will tend to make the cylinder increase in diameter, torsional $\varepsilon_{\theta z}$ which will tend to make the artery twist around its axis, and longitudinal ε_{zz} which will tend to make the artery lengthen.

4.1 Approaches to measuring strain in biologic materials

The determination of surface strains in low-modulus biological materials such as arteries is not a new problem, and recent advances in imaging and computation systems have made several new measurement methods possible. The large deformations experienced by compliant tissues favour the use of non-contact systems that image tissue-bound markers using a variety of media, including: light (FUNG and LIU, 1991; HUMPHREY et al., 1987; MCCULLOCH et al., 1987; and others), ultrasound (SKOVORODA et al., 1994), x-rays (WALDMAN et al., 1985; YIN et al., 1972), and phase-contrast magnetic-

resonance (DRACE and PELC, 1994). The most common method used to measure strain in compliant tissues involves marking the specimen before optically imaging the displacement. Ink has been applied to specimens both directly (WEIZSACKER, 1988) and by sprinkling using the bristles of a toothbrush (YU, et al., 1993). Others have used inert particles such as vanilla-bean pieces pressed into the specimen surface (VITO et al., 1991) or fluorescently-labelled microspheres (BARBEE et al., 1994) to achieve the high-contrast needed to identify the markers amidst the visual noise of ambient glare and the irregular surface of moist tissue. Displacement over curved surfaces has been measured using multiple cameras (HSU et al., 1994; WALDMAN et al., 1985) to gain three-dimensional displacement information.

Our characterisation of the locally-varying strain field imparted by an expanding stent to an intact artery has two unique requirements not addressed by the above techniques. First, although it is necessary to track the three-dimensional locations of arterial markers over the curved arterial surface *in vivo*, the surgical incision required to expose the artery for imaging is deep and narrow, making a multiple-camera approach impractical. Second, the strain field tensor varies along the length of the stent, and so it must be determined locally as a function of position along the artery.

As shown in Figs. 3-6 the strain measuring system described in this article satisfies these criteria, and was used to quantify patterns of stent-induced arterial deformation in both *in vitro* and *in vivo* environments. Consistent with behaviour in clinical settings, the test stent opened from its extreme distal and proximal ends inwards which created a slightly dog-bone shaped surface as the

balloon catheter was inflated to 6 bar. The centre region deployed once the balloon pressure increased to 8 bar, which created a more uniform cylindrical envelope. The expansion of the centre region from 6-8 bar was accompanied by the first significant levels of observed axial shortening. The nonuniform strain along the length of the stented artery and the presence of negative axial strains separate stent expansion from the expected uniform behaviour of balloon-alone expansion.

The system's ability to measure arterial strains in a surgical environment was demonstrated by the *in vivo* experiments, which showed more extreme examples of end-first opening than occurred *in vitro*. The primary factor complicating measurements was glare from the surgical lamps that interfered with the camera. The addition of a polarising filter reduced but did not eliminate glare. Slight translations and rotations of the artery caused by cardiac and respiratory cycles did not affect measurement accuracy, since the strain tensor is calculated by noting the change in the distance between mark positions, not the change of the mark positions themselves (BARBEE, 1994).

4.2 Error analysis

The three primary contributors of error in the computed strain tensor (henceforth called calculated strain) are lack of arterial axial symmetry, poor fit of the longitudinal envelope to a quadratic model, and measurement inaccuracies from limited resolution of the digitised image. The magnitudes of these errors are difficult to measure directly on the 2mm diameter artery, and the highly non-linear method of marker association into triads does not lend itself to theoretical

methods of error analysis. For these reasons we constructed a large-scale latex phantom which allowed us to hand-measure the distance between markers.

The assumptions that the artery is axisymmetric and fits the quadratic envelope of a cylinder, elliptic section, or hyperboloid is surprisingly small for the *in vitro, in vivo*, and phantom samples we investigated (Table 1) and contributes less than 10% of the total error. This would not be the case for tortuous arteries such as the human coronary that display little symmetry; backprojection of marker locations in this type of vessel would require a more generalised model of arterial shape. The primary source of error in our investigations arises from the limited resolution of the camera and has two components: spatial quantization that is a function of the finite number of CCD elements within the camera, and the limited line resolution of the S-video standard used to encode the analogue video signal. These sources are hardware-dependent and difficult to reduce. Although increasing the magnification to make the stented region completely fill the field of view of the camera would decrease this error, it would be hard to do so *in vivo* because of motion between the camera and stent from natural cardiac and respiratory cycles, and movements of the catheter during inflation.

The standard deviation of the strain tensor error components is calculated as

$$\sigma_{\varepsilon} = \left(\frac{1}{N} \sum \left(\varepsilon_{actual} - \varepsilon_{calculated} \right)^2 \right)^{1/2} \qquad (1)$$

and are shown plotted as error bars over the mean strain components in Fig. 8. These data show that the system measures all three components of the strain tensor accurately to a standard deviation of approximately 0.1. Since the error is primarily derived from camera quantization error which is not a function of strain, we expect similar measurement errors in an *in vivo* environment.

The strain tensor computed as a function of three specific markers represents the average strain experienced within that marker triad. The system's spatial resolution, or ability to localise changes in strain, is therefore limited to the average distance between these markers. We chose to examine marker triads separated by 0.75 -1 mm which struck a reasonable balance between spatial resolution and the effect of digitisation error on strain measurement accuracy. This spatial resolution allows us to examine macroscopically how vascular implants expand and move, although it does make the system insensitive to large changes in strain over a short distance such as might occur in the immediate vicinity of a 0.25 mm strut. Spatial resolution may be improved through the use of higher magnification at the expense of limiting the field of view.

4.3 Luminal vs. Exterior Surface Strain

The system described measures strain on the exterior surface, however the region of interest often lies on the interior. Using endovascular stenting as an example, laceration, scraping, and stresses are greatest on the luminal surface of the artery, and therefore luminal arterial strain may be a stronger determinant

of arterial response than the strain induced on the external arterial surface. The following calculation derives this luminal strain tensor from the exterior strain tensor measured by the system reported in this paper for vessels that are axisymmetric and do not experience torsion. Although the *in vitro* and *in vivo* samples described in this paper have axisymmetric lumens, diseased arteries in primates typically do not, and are instead stenosed with an irregular, heterogeneous mass of smooth muscle and inflammatory cells, necrotic debris, calcified deposits, and lipid pools. Detection of luminal strain in such vessels would require either observation of the luminal surface such as with intravascular ultrasound, or use of more invasive procedures such as described in (MCCULLOCH, 1987).

Consider a cross-section of a vessel with outer and inner radii R_0 and r_0 before stent expansion, and R_1 and r_1 after expansion. Let two reference marks exist on the surface of this slice that are separated before and after expansion by chord length d_0 and d_1 respectively and by the constant angle θ. By the definition of strain,

$$\varepsilon_{exterior} \equiv \frac{d_1^2 - d_0^2}{2d_0^2} = \frac{R_1^2 - R_0^2}{2R_0^2} \tag{2}$$

and similarly,

$$\varepsilon_{interior} = \frac{r_1^2 - r_0^2}{2r_0^2} \tag{3}$$

If the vessel wall is assumed incompressible, i.e. $r_1^2 = R_1^2 - R_0^2 + r_0^2$, then (2,3) may be solved yielding

$$\varepsilon_{interior} = \varepsilon_{exterior}\left(\frac{R_0}{r_0}\right)^2 \quad (4)$$

The strain induced on the luminal surface is always greater than the measured strain developed on the exterior wall.

5 Conclusion

Advances in prosthetic science and engineering have spurred the rapid development of many new remotely-deliverable permanent implants such as arterial reinforcement grafts, hepatic pressure shunts, and stents that strengthen and scaffold the biliary duct, urethra, veins, and arteries. As use of these implants grow more common, it has become increasingly important to be able to understand how these devices mechanically interact with tissue in their native *in vivo* environment. Endovascular stents, for example, engender a tissue response that is likely a function of the extreme levels of strain they impose, yet these have not been rigorously measured *in vivo*.

The technique described in this paper is an important step towards this goal. This method can determine the complete surface strain tensor developed along any straight and observable axisymmetric surface undergoing large-scale deformations, and can describe how the tensor changes in space and time. It can do so in an *in vivo* environment using a single camera. Further, the development of a system that can create marks as small as 100μm permits this method to be used with fine structures such as vessels of several millimetres diameter.

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FIGURE LEGENDS

Fig. 1 Schematic diagram of the strain measuring system. An image acquisition subsystem records and analyses a sequence of digitised video

images of an artery marked with ink reference points as a stent is expanded inside the marked region. For the phantom experiments, a large marked latex tube was inflated by a compressed air source as it was imaged by the same system.

Fig. 2 *In vivo* feasibility study. The femoral arteries of a rabbit were exposed, gently cleaned of loose facia, and ligated. A 3mm endovascular stent mounted on a compliant 3mm balloon catheter was inserted into an arteriotomy. The stented region was marked in a gridded fashion and imaged while the stent was slowly expanded to 8 bar.

Fig. 3 Arterial surface strain tensor components after *in vitro* stent expansion to 2 bar. The horizontal axis represents distance along the length of the artery.

Fig. 4 Arterial surface strain tensor components after *in vitro* stent expansion to 4 bar. The stent has begun to expand proximal end first.

Fig. 5 Arterial surface strain tensor components after *in vitro* stent expansion to 6 bar. Both stent ends have deployed leaving the centre of the artery unsupported.

Fig. 6 Arterial surface strain tensor components after *in vitro* stent expansion to 8 bar. The stent's middle region has expanded and circumferential strain is

now evenly distributed along the length of the stent. Notice the degree of axial contraction that has occurred as the centre expanded.

Fig. 7 The accuracy of the strain measuring system was demonstrated by comparing the magnitude of the strain tensor it calculated on the oversize latex phantom of Figure 7 with a hand-measured reference. The mean of each strain component is shown as the strain tensor varied over the length of the artery. The error bars represent one standard deviation of the measured strain about the true strain.

Fig. 8 The ink-jet marking method was tested in an *in vivo* environment. A rabbit femoral artery has been exposed and is shown here proximal to the site of arteriotomy before and after marking with 150μm dots. The artery is clear in a live animal and showing the underlying corrugated ring stent.

Fig. 9 The system can measure strains in an *in vivo* environment. Here strains are shown generated in two rabbit femoral arteries by 3mm stents mounted on a balloon catheters pressurised to 4 bar. The end-first opening characteristic can be clearly seen, accompanied by slight axial shortening and relatively minor torsion, similar to that seen *in vitro* at similar pressures.

Table 1 Determining the validity of the assumption that the artery and phantom are axisymmetric and have a quadratic surface. The standard deviation of the error is shown as a percentage of the mean radius. Values tending toward zero indicate close agreement of the quadratic envelope to the measured envelope.

Phantom		Bovine coronary		Rabbit left femoral	
Step number	$\frac{\sigma_e}{\bar{r}}$	Pressure (bar)	$\frac{\sigma_e}{\bar{r}}$	Pressure (bar)	$\frac{\sigma_e}{\bar{r}}$
0	0.023	0	0.016	0	0.032
1	0.16	2	0.018	2	0.042
2	0.10	4	0.11	4	0.091
3	0.044	6	0.15	6	0.10
4	0.032	8	0.061	8	0.052