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Establishment of an Automated Algorithm Utilizing Optical Coherence Tomography and Micro-Computed Tomography Imaging to Reconstruct the 3D Deformed Stent Geometry

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Abstract

Percutaneous coronary intervention (PCI) is the prevalent treatment for coronary artery disease, with hundreds of thousands of stents implanted annually. Computational studies have demonstrated the role of biomechanics in the failure of vascular stents, but clinical studies in this area are limited by a lack of understanding of the deployed stent geometry, which is required to accurately model and predict the stent induced *in vivo* biomechanical environment. Herein, we present an automated method to reconstruct the 3D deployed stent configuration through the fusion of optical coherence tomography (OCT) and micro-computed tomography (μ CT) imaging data. In an experimental setup, OCT and μ CT data were collected in stents deployed in arterial phantoms ($n = 4$). A constrained iterative deformation process directed by diffeomorphic metric

mapping was developed to deform μ CT data of a stent wireframe to the OCT-derived sparse point cloud of the deployed stent. Reconstructions of the deployed stents showed excellent agreement with the ground truth configurations, with the distance between corresponding points on the reconstructed and ground truth configurations of $184 \pm 96 \mu\text{m}$. Finally, reconstructions required < 30 minutes of computational time. In conclusion, the developed and validated reconstruction algorithm provides a complete spatially resolved reconstruction of a deployed vascular stent from commercially available imaging modalities and has the potential, with further development, to provide more accurate computational models to evaluate the *in vivo* post-stent mechanical environment, as well as clinical visualization of the 3D stent geometry immediately following PCI.

Keywords

Optical coherence tomography; coronary artery disease; vascular stent; diffeomorphic metric mapping; biomechanics

I. Introduction

Percutaneous coronary intervention (PCI) is the prevalent treatment for coronary artery disease with an estimated 434,000 inpatient PCI procedures with stents performed in the United States in 2014 [1]. Despite the success of this minimally invasive procedure, the failure of these devices has been reported to be as high as 30% for bare-metal stents and 12% for 2nd-generation drug-eluting stents depending on disease location and severity [2], [3]. Notably, studies have demonstrated a direct link between biomechanics and the failure of these devices. Alterations in the fluid mechanical environment post-stenting have been correlated with thrombus formation and neointimal hyperplasia, and stent-induced wall stress has been correlated with neointimal hyperplasia [4]–[6]. Whereas these studies have advanced the understanding of the role that biomechanics has in stent failure, they are limited by construction of computational models of ideally deployed stents and thus lack direct application in the clinical setting to predict the *in vivo* post-stenting mechanical environment. This limitation is a direct result of a lack of an accurate and high spatially resolved reconstruction of a deployed vascular stent. Therefore, the establishment of an algorithm to reconstruct a vascular stent *in vivo* would increase the accuracy of stented artery computational models and may lead to the development of pre-interventional planning and patient-specific stenting strategies.

Recent advances in stent strut detection techniques from optical coherence tomography (OCT) image data have shown promise in reconstructing *in vivo* stent geometries. OCT is an intravascular imaging technique used for coronary plaque characterization and post-procedural analysis of PCI [7], [8]. In comparison to intravascular ultrasound (IVUS), OCT has superior spatial resolution ($\sim 10 \mu\text{m}$ axial resolution, and $20\text{--}40 \mu\text{m}$ lateral resolution, [7]), capturing images with an axial spacing of $100\text{--}200 \mu\text{m}$. The high reflectance and opacity of stent struts provides advantageous characteristics for identification of struts from the acquired image data. Numerous methods have been developed to identify stent struts, as well as segment lumen contours, from OCT image data (see references within [9, Tab. 1]). In general, automatic strut detection and lumen contouring algorithms include image pre-

processing, A-line classification/contouring based on pre-defined characteristics, and refinement (e.g., removing strut false positives, smoothing lumen contours). Depending on the segmented OCT feature of interest, processing methods vary to exploit optical signatures of these features. Some have used a classification algorithms with parameters set with the use of training data [10], whereas others have bootstrapped the data using bagged decision trees [11]. The most comprehensive study to date accounted for variability of shadow features within images due to malapposition/coverage and depth from the catheter with a Bayesian network and considered 3D factors by incorporating minimum spanning trees on the *en face* projection of the pullback [12]. Whereas these methods have demonstrated high accuracy in detecting stent struts from clinical OCT data, reconstructing a complete and spatially resolved stent geometry has been limited by the axial spacing (i.e., gap) between the OCT images. Due to the complex three-dimensional (3D) geometry of commercially available stents, interpolation to link struts in adjacent images proves challenging, particularly at the accuracy and resolution required for computational models. To compensate for these absent (or blind) regions, studies have sought to combine *a priori* knowledge of stent design with OCT-derived stent strut point clouds [13], [14]. Although these studies have demonstrated the promise of integrating novel stent reconstruction methods with computational fluid dynamics (CFD) techniques to evaluate the flow patterns and predict wall shear stress (WSS) values in deployed vascular stents, these studies are not without their limitations and disadvantages. Specifically, one proposed method lacks validation to assess the accuracy of the reconstructed stent [13], and the other method requires manual manipulation (i.e., the methods are semi-automatic) to create the reconstructed deployed stent geometry [14]; these shortcomings each limit the value in integrating these reconstruction methods into the clinical setting. The development of an automated and validated reconstruction method has far greater potential to translate into the cardiac catheterization laboratory to advance 3D visualization of a deployed vascular stent, as well as advance computational efforts in stented artery biomechanics.

Herein, we propose a fully automatic rule-based (constrained) method for the 3D reconstruction of a vascular stent from OCT image data and *a priori* stent design knowledge from high-resolution micro-computed tomography (μ CT) data. The method was developed in a well-controlled *in vitro* framework to mitigate the impact of potential *in vivo* imaging artifacts and provide a comprehensive and orderly data set to establish an accurate reconstruction technique. First, an image segmentation algorithm, which was specific to the *in vitro* OCT data characteristics, was developed to detect stent struts from the acquired OCT image data. Second, a novel reconstruction method was established that employs diffeomorphic metric mapping (DMM, [15]) to automatically deform the μ CT-derived stent wireframe to the OCT-derived stent strut point cloud. Finally, the morphed geometry was constrained to ensure the reconstructed stent form was not distorted following the mapping (i.e., the stent retained its distinct geometry following DMM). To evaluate the accuracy of the developed 3D stent reconstruction technique, resulting data were validated against μ CT data as the ground truth for measurement.

II. Methods

Our algorithm for 3D stent reconstruction are summarized as illustrated in Fig. 1. Briefly, acquired OCT image data from a stented phantom artery were segmented to define a sparse 3D geometry of strut centroids (section II: B). Separately, a stent of the same design was deployed in open-air, imaged with μ CT, and parameterized into a wireframe model (section II: C). The wireframe model and sparse OCT-defined stent geometry were co-registered in space and a constrained iterative deformation process directed by DMM placed the model in the configuration of the OCT-defined stent geometry (section II: D). Finally, volume thickening of the deformed wireframe resulted in a 3D reconstruction of the geometry at the resolution of the μ CT scan. OCT segmentation, wireframe creation, co-registration, and the constrained iterative deformation process were implemented in Matlab (R2017a, The MathWorks Inc., Natick, MA) and run on a personal computer with an Intel® Core™ i7–4790 processor (3.60 GHz).

A. Experimental Setup and Image Acquisition

Silicone arterial phantoms were manufactured to provide a well-controlled experimental system to acquire multimodal imaging data of a deployed vascular stent. Straight phantoms were fabricated using an injection molding process, and two versions of arterial phantoms were manufactured: models with a constant diameter (i.e., healthy model) and models with a focal stenosis approximately 66% by diameter (i.e., stenotic model). Briefly, an outer mold (diameter = 3.4 mm) was machined out of an aluminum block on a 4-axis CNC machining center (Hurco VM1, Buckinghamshire, U.K.). A stainless-steel wire (diameter = 3.0 mm) was positioned concentrically within the outer model. For the stenotic models, a notch (diameter = 1.0 mm, length = 10 mm) was machined out of the wire center on a lathe. A two-part silicone elastomer mixture (Elastosil® M 4641 A/B, Wacker Chemie AG, Munich, Germany; mix ratio 4:1 by weight) mixed with 20% silicone fluid (Notcutt, Surrey, U.K.) was used to create the phantom wall. Previous uniaxial tensile testing using this formulation yielded a material with a Young's modulus of 800 kPa. The silicone mixture was degassed and injected into the void space between the outer mold and wire. Once cured, the flexible silicone model was carefully removed off the wire resulting in a thin-walled straight artery phantom with dimensions consistent with human epicardial coronary arteries.

Phantoms were mounted at an axial stretch of 1.05 to an experimental platform and connected in-line to a flow circuit filled with saline via barbed fittings.¹ A 0.014" guidewire (Hi-Torque Pilot 50, Abbott Vascular, Santa Clara, CA) was introduced and guided across the length of the phantom, and stents were deployed to a nominal diameter of 3 mm under manufacturer guidelines. Two stent designs were evaluated: Integrity® BMS (Medtronic, Minneapolis, MN) and Xience Alpine™ (Abbott Vascular). Each design was deployed in both a healthy and stenotic model for a total of 4 stented artery phantoms.² Both Integrity® stents were 18 mm in length, the Xience™ stent deployed in the stenotic model was 18 mm long, and the Xience™ stent deployed in a healthy model was 8 mm long. Following deployment, an OCT catheter (Dragonfly™ OPTIS™, St. Jude, St. Paul, MN) was

¹See Supplemental Fig. 1 of the online supplementary materials available in the supplementary files /multimedia tab.

²See Supplemental Fig. 2 of the online supplementary materials available in the supplementary files /multimedia tab.

introduced, advanced across the stented region, and bi-plane angiographic image data were collected prior to catheter pullback. An automatic motorized pullback was performed, and OCT image data were acquired along 54 mm (i.e., High Resolution Mode) throughout the stented region.

Following clinical image data acquisition, the stented phantom was removed from the experimental platform, and phantom material beyond the stent edges was carefully cut away. The stented phantom segment was stabilized in a 6 mm OD sample holder, and μ CT image data were acquired (μ CT 40, Scanco Medical, Bassersdorf, Switzerland). Scanner settings (energy: 90 kVp, current: 155 μ A, power: 14 W, integration time: 350 ms) yielded an isotropic voxel size of 14.8 μ m. Raw scan data were automatically reconstructed to 2D slice tomograms using a standard cone beam filtered back projection algorithm. In addition, identical stent designs to those deployed in the phantoms were deployed in open-air and μ CT image data were collected as described above.

B. Automated Strut Detection from OCT Image Data

Following image acquisition, raw 16-bit OCT image data (.oct file type), which are defined in polar coordinates, were transferred from the OCT console (IllumienTM OptisTM PCI OptimizationTM System, St. Jude). Prior to axial line (A-line) classification, image data were windowed, so as only to evaluate data between the catheter and perivascular boundaries (Fig. 2). The catheter boundary was identified through a Hough Transform of the Cartesian-transformed image tuned to detect circular objects near the image center with diameter of 2.7 ± 0.5 Fr. The final boundary was then defined 30 μ m outward radially from the detected catheter sheath. The perivascular boundary was estimated by measuring the (radial) depth at which the normalized summation of pixel intensities over θ in the B-scan (i.e., cross-sectional tomograph) image were less than $1.5 \times$ the background intensity level. The background level was calculated separately for each analyzed B-scan as the mean intensity of a region of interest (ROI) at the furthest 60 pixel depths from the catheter of the B-scan (Fig. 2).

Windowed A-line data were classified as either defining a stent strut or the lumen boundary (i.e., phantom wall). An initial estimation of A-lines containing struts was determined by detecting the stent shadow, which arises due to complete reflection of light off the metallic surface of the stent. The shadow was identified by enumerating along each windowed A-line the number of pixels with intensity values at least $2 \times$ the background level. Local minima were then used as candidate locations for stent struts. Classification was performed on neighboring A-lines to each candidate by characterizing them with a set of features based on the experimental imaging data. The features considered were: 1) peak prominence, 2) number of prominent peaks, and 3) mean signal intensity between peaks (herein, wall level; Fig. 2). The two A-lines shown in Fig. 2 highlight the differences between these features in strut and phantom vessel A-lines. The strut A-line has a high-intensity peak at the strut depth and a shallower peak ($>1 \times$ background level) from speckle noise, whereas the phantom vessel A-line has two prominent peaks with a wall signal $3 \times$ higher than the background level. Classification was performed until all contiguous strut A-lines from the verified candidates were identified. Depth from the catheter was identified by the most prominent

peak in strut A-lines. Strut reflection width (S_w) and height (S_{HT}) were determined by the number of contiguous strut A-lines and the range of depths in those A-lines, respectively (Fig. 2). Subsequently, the strut centroid was defined as the midpoint of S_w and S_{HT} with an addition of half the thickness of the strut (Xience™: 81 μm ; Integrity®: 91 μm) to the depth to compensate for the fact that the detected centroid is the reflection of the abluminal strut surface. The guidewire reflection was removed post classification and was identified as being the widest contiguous ‘strut’ A-line group, as well as being at a consistently shallower depth than other defined struts and at similar angular positions in neighboring images. Following application of the A-line classification scheme across all images in the OCT pullback, a sparse 3D point cloud (herein, OCT_{PC}) of the stent struts was generated in Cartesian coordinates using the physical dimensions of pixels (5 $\mu\text{m}/\text{pixel}$ in radial direction) and distance between acquired B-scans (100 μm ; Fig. 1).

C. Micro-CT Wireframe Parameterization

An image processing framework previously defined to quantify osteocyte topology was adapted to parameterize the 2D tomography data of the stents deployed in open-air into a wireframe [16]. As performed in [16], which was a study that quantitatively evaluated osteocyte network organization from volumetric confocal microscopy image data, an intensity threshold was applied to the μCT tomograms of the stents deployed in open air to create a binary volume with the object of interest in the foreground. Note that the threshold value was defined so that the cross-sectional area of the thresholded struts matched manufacturer dimensions. A homotopic thinning algorithm was applied to extract the medial axis of the volume, forming a skeleton of individual neighboring voxels, and the voxel skeleton was converted into a graph network, where voxels with more than two neighbors were defined as nodes and groups (or chains) of voxels with two neighbors each were defined as links. Additionally, the graph network was modified by redefining critical points along sinusoidal links as nodes, sectioning the links further. Thus, the resulting open-air μCT wireframe (*wireframe-OA*) skeleton was structured in a graph representation with data on link length and node orientation alongside node connectivity and location. This same parameterization process was performed on the μCT images of the stents deployed in the phantom arteries (*wireframe-P*) to serve as the ground truth for validation of the reconstruction methods.³

D. Constrained Iterative Deformation Process Directed by Diffeomorphic Metric Mapping

The parameterized *wireframe-OA* was deformed to the geometry of its corresponding OCT_{PC} in a constrained iterative process directed by DMM (Fig. 3). Each sparse OCT_{PC} and corresponding *wireframe-OA* were spatially co-registered by applying the method of moments to center the geometries and align their smallest inertial moment with the z-axis. Rotational differences were minimized through cross-correlation of the rotational frames ($z\theta$ - coordinates). Deformation of the wireframe to the OCT_{PC} was accomplished by directing displacement via DMM and constraining the stent form by the data in the graph structure in a stretched graph method. These two steps were iterated until the distances between the centroids of OCT_{PC} and their nearest points on the wireframe were minimized.

³See Supplemental Fig. 2 of the online supplementary materials available in the supplementary files /multimedia tab.

1) Diffeomorphic Metric Mapping—The application of diffeomorphism to our reconstruction technique is based on established algorithms for sub-manifold matching, which are described in detail elsewhere [17], [18]. Briefly, DMM finds the transformation (ϕ) that minimizes the difference between two point clouds, a source and target, while minimizing the energy it takes to displace the original source configuration to its final mapped configuration. In general, the optimization functional ($J(\phi)$) is,

$$J(\phi) = \gamma_R D^2(e, \phi) + E(\phi(x), y), \quad (1)$$

where the dissimilarity term, $E(\phi(x), y)$, is a function of the source and target point clouds, $x \in (x_1, x_2 \dots x_m)$ and $y \in (y_1, y_2 \dots y_m)$ respectively, in $\mathbb{R}^3$ and is defined as,

$$E(\phi(x), y) = \sum_{i=1}^m \sum_{j=1}^m K_I[\phi(x_i), \phi(x_j)] - 2 \sum_{i=1}^m \sum_{j=1}^n K_I[\phi(x_i), y_j] + \sum_{i=1}^n \sum_{j=1}^n K_I[y_i, y_j], \quad (2)$$

where K_I is a 3D Gaussian kernel with variance σ_I^2 . The dissimilarity kernel (2) is minimized as $\phi(x)$ approaches the target point cloud, y (i.e., as $\phi(x) \rightarrow y$, $E(\phi(x), y) \rightarrow 0$). The regularizing term, $D^2(e, \phi)$, is defined as,

$$D^2(e, \phi) = \sum_{j=1}^n \left\langle \frac{dx_j}{dt}(t), \alpha_j(t) \right\rangle, \quad (3)$$

where $x_j(t) = \phi(t, x_j)$ are the deformed source points at time discretization step t , and $\alpha_j(t)$ are unknown variables called momentum vectors [19], [20]. The momentum vectors are related to the deformed source points by,

$$\frac{dx_j}{dt}(t) = \sum_{i=1}^n K_V(x_i(t), x_j(t)) \alpha_i(t), \quad (4)$$

where K_V is a Gaussian kernel with variance σ_V^2 . Thus the regularizing term, $D^2(e, \phi)$, is minimized when there is the least displacement between the mapped and original source (i.e., if no mapping occurs, $\phi = e$). To decrease computational effort a k-d tree was implemented to approximate the Gaussian kernels. A factor, γ_R , was introduced to weight the contribution of the regularizing term. The variances σ_V^2 and σ_I^2 along with γ_R tune the DMM for the application of interest; σ_V and σ_I augment interactions between points in terms of source regulation and target matching, respectively. Initial assumptions were that σ_V and σ_I would optimally be on the interval $[0, 500]$ (i.e., when a point 1.5 mm from the center of the Gaussian kernel has 5% of full effect) and γ_R would be the interval $[0, 1]$. A Monte Carlo parameter analysis narrowed these intervals for σ_V , σ_I and γ_R , by randomly selecting parameter sets from uniform distributions over these intervals and identifying when DMM

mapped the source to the target across 1 iteration (i.e., DMM allowed the source to deform). Final optimal parameter selection was determined by a 5-step parameter sweep (i.e., 125 parameter sets) of the narrowed intervals through the full deformation process.

2) Stent Form Constraint—To ensure that the DMM-derived point displacements did not violate the form of the stent (i.e., displacements did not result in a physically ill-conceived stent geometry), a stretched grid method was implemented to constrain the form. Following each DMM (Fig. 3), displaced point positions for each node from the resulting mapped source configuration were imposed on the wireframe model. The links between new node locations were either stretched or compressed from their original lengths, and node orientation changed. The stent form was constrained by anchoring the node nearest the axial center and applying a greedy stretched grid minimization on its nearest (connected) neighbors that solved the system of equations describing hard constraints on link length (i.e., distance between nodes) and absolute $z;\theta$ -orientation (e.g., node i remains above and counter-clockwise to node j following DMM) and soft constraints on relative $z;\theta$ -orientation that were proportional to link length, as compared with original wireframe lengths and orientations (i.e., the amount and degree that node i is above and counter-clockwise to node j following DMM). Nodes in this neighborhood were then anchored in space and from each node at the border of this neighborhood, new neighborhoods were defined, constrained, and anchored. Conflicts between neighborhood solutions were handled by unfixing a neighborhood around the conflict and solving for a minimum with the border nodes anchored in space. After all nodes positions were anchored, links associated with each node were translated and rotated into their final position.

Following DMM and stent form constraint, the resulting configuration was compared against the OCT_{PC} by calculating the Euclidean distance from each strut centroid to the nearest point on the deformed wireframe. If the average distance and standard deviation decreased from the previous iteration, then the deformed wireframe was used as the DMM source (i.e., x -point cloud) for the subsequent iteration. Once converged, the resulting deformed wireframe was identified as the DMM derived stent wireframe (herein, *wireframe-DMM*). Finally, the complete 3D stent reconstruction was established by thickening the wireframe through addition of a volume primitive to each point on the wireframe. A spherical primitive with a radius equal to half the strut thickness resulted in a circular stent strut cross section (Integrity®), and a cylindrical primitive with diameter and height equivalent to the strut thickness resulted in a square cross section (e.g., Xience™; Fig. 1).

E. Validation of Strut Identification Algorithm

The strut detection algorithm was validated by comparing results with manually detected struts identified by a trained observer. Manual detection was performed by defining bounding boxes around each stent strut in an OCT image (ImageJ; [21]). The trained reviewer, who was blinded to the results from the algorithm, manually identified struts in the acquired OCT images for all 4 OCT pullbacks. In addition, the reviewer re-identified stent struts in 200 randomly selected images (50 from each pullback) one month after the initial detection to evaluate intraobserver variability (i.e., repeatability). A second trained reviewer also manually identified stent struts in the same 200 selected images to evaluate

interobserver variability (i.e., reproducibility). The sparse OCT_{PC} was also compared against *wireframe-P*. Because it is not possible to precisely identify where an OCT-defined strut centroid is spatially located on the stent, comparisons were performed by determining the Euclidean distance from the nearest point on *wireframe-P* to each centroid.

F. Statistical Analysis

Agreement between automatically and manually detected stent strut centroids was analyzed with a confusion matrix, and the sensitivity and positive predictive value (PPV, i.e., precision) were calculated for all OCT images in the stented region of each phantom. A true positive corresponded to an automatically identified stent strut that resided within the manually defined bounding box for that strut. Differences between each *wireframe-DMM* and their corresponding *wireframe-P* were determined by calculating the Euclidean distance between the wireframes. Because both geometries were modeled as parametric frames, with the same node and link graph representations, node locations and points at 5% intervals along each link were identified and the Euclidean distance between corresponding points on each frame was calculated. Additionally, the 25th, 50th, and 75th percentiles of the distance distribution for each reconstruction was determined.

All results are reported as mean $\pm$ standard deviation. Euclidean distances between the constrained DMM deformation wireframe and OCT-defined strut centroids were statistically compared with a one-way ANOVA and Holm-Sidak post-hoc analysis to determine pairwise differences between iterations. Statistical analyses were performed using SigmaPlot (Systat Software, San Jose, CA).

III. Results

The experimental setup provided OCT scans that were consistent with expected measurements. Across all 4 scans, 2156 images were obtained (539 images per stent) and expert manual review determined that 635 of these images (~30%) contained struts. The number of images per stent that contained struts was consistent with stent length and the expected 0.1 mm gap between images (e.g., the 8 mm Xience™ stent deployed in a healthy phantom had 80 images containing struts; Table 1).

Manual review determined that in these images, there were 8262 struts, with strut density per image consistent with stent design. The Integrity® stents had 15 ± 1 struts per image, and the Xience™ stents had 10 ± 1 struts per image. In these images, 5232 struts were detected by the automated strut detection algorithm; 9 ± 4 struts in the Integrity® images and 7 ± 1 struts in the Xience™ images. The algorithm showed strong agreement with manual detection by a trained reviewer. Although sensitivity values for the automatic strut detection ranged from 40–76% across the 4 stented phantoms, the PPV of the algorithm for all stents was >90% and PPV exceeded 97% in 3 stents (Table I). Intraobserver and interobserver analyses demonstrated excellent repeatability and reproducibility, respectively, for manual identification of stent struts across independent evaluations and reviewers. Sensitivity and PPV were 97% and 99%, respectively, for both intra- and interobserver analysis. Further confirmation of the accuracy of the strut detection algorithm was observed when comparing the OCT_{PC} and *wireframe-P* (i.e., ground truth) for each stent design. For example,

qualitative agreement was clearly observed when comparing the OCT_{PC} and *wireframe-P* for the Integrity[®] stent deployed in a stenotic phantom (Fig. 4A).⁴ Quantitative comparison across all four stents revealed an average distance between the OCT-defined strut centroids (OCT_{PC}) and true medial axis of each stent (*wireframe-P*) of $97.5 \pm 54.4 \mu\text{m}$.

Monte Carlo parameter analysis narrowed the intervals of the parameter space down until the 5-step parameter sweep had a good degree of precision. The analysis revealed that DMM only mapped the *wireframe-OA* to the OCT_{PC} when $\gamma_R < 10^{-7}$ and that mapping occurred more frequently when $\sigma_V \in [25, 65]$ and $\sigma_I \in [5, 25]$. These intervals for σ_V and σ_I and an empirically defined interval of $[10^{-9}, 10^{-7}]$ for γ_R and an provided the refined 5-step parameter space. Across the parameter space sweep, the average distance from the resulting *wireframe-DMM* to the nearest point in OCT_{PC} was used as the metric to find the optimal parameters, which were $\sigma_V=55$, $\sigma_I=15$, and $\gamma_R=10^{-8}$.

The constrained DMM-directed deformation process quickly converged to a mapped solution for the wireframe to the OCT_{PC} . For all 4 stents, the process took an average of 5 ± 4 iterations to converge on a minimal solution; each iteration taking on average 62 ± 25 seconds. For example, the Xience[™] stent deployed in the healthy phantom rapidly converged after four iterations (Figs. 5 and 6). As demonstrated in this representative example, the majority of distance minimization (i.e., deformation) between the OCT_{PC} and nearest point on the deformed wireframe occurred in the first and second iterations, as the total distances (i.e., mismatch) between the bodies following these iterations were significantly larger as compared to subsequent iterations ($P < 0.001$), whereas minimal deformations occurred in the final 3 iterations ($P > 0.05$; Figs. 5 and 6). Specifically, the total distance mismatch following the first and second iterations decreased by 192 and 25 μm , respectively, whereas the total distance never changed more than 5 μm for the remaining iterations. Evaluation of the components of the displacement vectors revealed that iteration 1 was dominated by radial displacement of the deformed wireframe as it expanded to map to the OCT_{PC} (Fig. 5). In contrast, later iterations were predominantly circumferential and axial displacements as the constrained DMM deformation fine-tuned the mapping from source to target. These findings for the constrained DMM deformation process were similar across all stent designs.

Following solution convergence, the final deformed wireframes showed excellent agreement with the actual deployed stent geometry, as determined by comparing corresponding points on *wireframe-DMM* and *wireframe-P* (i.e., ground truth). Across all 4 stent designs, the average Euclidean distance between wireframes was $184 \pm 96 \mu\text{m}$. The Xience[™] stent deployed in the healthy phantom demonstrated the strongest agreement with an average distance of $110 \pm 51 \mu\text{m}$, whereas the weakest agreement was observed in the Integrity[®] stent deployed in the stenotic phantom ($228 \pm 107 \mu\text{m}$; Fig. 7). Evaluation of the distribution of corresponding point distances further revealed the considerable agreement between the wireframes (Fig. 8). Examining the 25th, 50th, and 75th percentiles of the distance difference between *wireframe-DMM* and *wireframe-P* revealed values of 112 ± 35 , 160 ± 48 , and $212 \pm 55 \mu\text{m}$, respectively, across the 4 stent designs (Fig. 8). Notably, in all cases except the

⁴See Supplemental Fig. 3 of the online supplementary materials available in the supplementary files /multimedia tab.

Integrity[®] stent deployed in the stenotic vessel, the 25%, 50%, and 75% of corresponding points on *wireframe-DMM* were within 120, 170, and 220 μm , respectively, of *wireframe-P*. For the Integrity[®] stent in a stenotic phantom, these percentile groups were defined at 155, 218, and 275 μm , respectively.

IV. Discussion

In this study, we presented a novel technique to reconstruct the 3D geometry of a deployed vascular stent through the fusion of OCT and μCT image data. The method utilized a constrained deformation directed by DMM to map a high-resolution μCT scan of the stent deployed in open-air (i.e., *a priori* knowledge of stent design) to a sparse strut point cloud derived from processing OCT image data acquired in stented phantom arteries. The algorithm was successfully implemented across multiple stent designs and phantom configurations, and the method converged quickly to a geometric configuration that demonstrated strong agreement with the ground truth geometry (i.e., the method was validated). Furthermore, the developed algorithm was fully automated (< 30 min. of computational time), only requiring the raw OCT and μCT image data, thus avoiding any subjectivity and minimizing the time commitment associated with offline analysis.

Other reconstruction methods have been developed that combine OCT image data and *a priori* knowledge of stent design to reconstruct deployed stents and the surrounding anatomy. O'Brien *et al.* used a nonrigid registration by coherent point drift on an idealized stent skeleton constructed from nonuniform rational b-splines to morph the stent skeleton to the OCT-defined geometry [13]. Although this study performed 3D reconstructions of stents deployed in healthy swine, the reconstructed stent geometries were not validated, but rather only a volume fraction (reconstructed to actual stent volume), which provides minimal information on reconstruction accuracy, was reported. Similar to the present study, Migliori *et al.* extracted a wireframe model from μCT data of a stent, but the wireframe was semi-automatically morphed using a commercial software to match the OCT-derived stent strut point cloud [14]. As a result, concerns with potential reconstruction variability and human error during the manual manipulation, as well as extended processing time, limit the routine use of the reconstruction algorithm on large-scale clinical data. Whereas the methods presented herein utilized similar methods to those previous studies, our reconstruction algorithm overcomes the aforementioned shortcomings through the use of a well-controlled experimental framework to validate the algorithm and a logical rule-based constrained DMM that provides an automatic and rational wireframe deformation process. In addition, by constraining the wireframe at critical points (i.e., nodes; Fig. 1) defined in the graph representation, the stent deformation during the mapping algorithm accurately resembles the physical deformation of the stent (e.g., increasing/decreasing the angle between straight links at the crown junction in repeating sinusoidal rings).

It is acknowledged that the developed OCT stent segmentation algorithm demonstrated lower sensitivity than previous studies. Compared to others (see references within [9, Tab. 1]), our strut detection algorithm used fewer classification features and identification schemes; however, our segmentation algorithm was uniquely design for the experimentally acquired OCT images. A similar study also developed automated OCT segmentation

methods for stents experimentally deployed in silicon phantom arteries [22]. Utilizing the rate of A-line intensity decay in the presence of strut shadowing, and defining regions of confidence to remove false positives, sensitivity values for stent strut detection were ~91%, which approach levels achieved strut detection in clinical image data [10], [12]. While modifications to the presented strut identification algorithm could improve sensitivity values to those reported by [22], analysis revealed no significant improvements in the reconstruction algorithm would be observed (Fig. 9). Specifically, we performed additional analysis and evaluated the Euclidean distance mismatch between the *wireframe-DMM* and *wireframe-P* when the OCT_{PC} was defined by the struts identified by the trained reviewer, who had a sensitivity value 20% higher than the algorithm. We observed that differences in the Euclidean distance mismatch between the *wireframe-DMM* and *wireframe-P* was only improved by $7.6 \pm 14.2 \mu\text{m}$ across the 4 stent designs. Thus, while others have presented state-of-the-art strut identification methods for both *in vitro* and *in vivo* OCT image data, inclusion of these methods in our presented reconstruction algorithm would provide minimal improvement. These data suggest that our proposed reconstruction method has the potential to be robust in the clinical setting, where conditions, such as faster OCT acquisition rates and partial image obstruction from blood/tissue artifacts, may lower the amount of detectable stent struts.

When comparing agreement metrics between the reconstructed (*wireframe-DMM*) and ground truth (*wireframe-P*) stent geometries, corresponding points were explicitly defined on the geometries to ensure an accurate validation of the reconstruction technique was performed. We emphasize the importance of validating the reconstruction technique against a ground truth measurement with the metric of total distance between these corresponding points, as opposed to utilizing a nearest neighbor approach (i.e., identifying the closest point on *wireframe-P* from a defined point in *wireframe-DMM* and determining that distance). Specifically, a nearest neighbor approach underestimates the actual distance between corresponding points between two geometries and suggests that a reconstruction algorithm is more accurate than in actuality. For stent reconstruction algorithms that incorporate OCT image data, a limitation of using OCT-defined struts as points to evaluate reconstruction accuracy is the lack of spatial understanding of where the image-defined strut is located on the stent. With the nearest neighbor approach, one may be comparing disparate points. As an example, we acknowledge the limitation of reporting the distance between *wireframe-P* and OCT_{PC} when performing the 3D validation of the strut identification algorithm (Fig. 4); however, a corresponding point approach is not possible due to this limited spatial understanding. By structuring the stent wireframes with a graph representation (Fig. 1), it was trivial to ensure that our validation method truly evaluated the accuracy of the established reconstruction technique. For completeness, we note that when implementing a nearest neighbor approach to compare *wireframe-DMM* and *wireframe-P*, there is a 42% reduction in the average Euclidean distance reported in Figure 7 (reduction from 184 ± 96 to $106 \pm 60 \mu\text{m}$ across all stented phantoms). Furthermore, the 25th, 50th, and 75th percentiles are reduced to 61 ± 17 (46% reduction), 90 ± 26 (44%), and $130 \pm 33 \mu\text{m}$ (39%), respectively. Whereas a similar stent reconstruction algorithm to that presented herein has been developed [14], the lack of clarity in stating whether a corresponding points or nearest

neighbor approach was implemented limits understanding of the true accuracy of the algorithm and a direct comparison between the two methods.

Whereas our reconstruction technique has been validated, it is important to note the scope and limitations of the method as presented herein. First, our stent strut detection algorithm was developed for the optical features of stents deployed in silicone phantom arteries; as such, our methods for A-line classification require modification to detect struts in OCT images that are acquired in vivo. Fortunately, there are several established methods for automated detection from clinical OCT images (see references within [19, Tab. 1]) that describe features (e.g. A-line FWPM; [10]) and methods (e.g. Bayesian network; [12]) for A-line classification. Second, in our well-controlled experimental setup, the OCT images were acquired along an approximately-straight line during catheter pullback. From this, we assumed that cross-sectional images were parallel to each other, evenly spaced, and had no rotational differences. These assumptions simplified the process of creating an OCT_{PC} . We acknowledge that further processing of the OCT_{PC} (e.g., fusion with angiography data; [23]) will be required to account for catheter rotation and vessel curvature when analyzing clinical OCT image data. These assumptions also allowed us to co-register a *wireframe-OA* to its corresponding OCT_{PC} using the method of moments and cross-correlation, as described herein. This co-registration technique is not effective when the OCT_{PC} is curved and the *wireframe-OA* is not, so different co-registration techniques will need to be employed (e.g. bending the *wireframe-OA* to the curvature of vessel). Third, we acknowledge the deformations on each *wireframe-OA* during the iterative deformation process were small ($< 500 \mu m$; Figs. 5, 6). These small deformations are a result of attributed to the experimental setup (i.e., deployment of stents in healthy, straight phantoms) and the strong initial rigid coregistration. Although the reconstruction techniques were not tested on conditions where large deformations may occur, our results demonstrate the importance of initial coregistration techniques to minimize the size of deformations between a *wireframe-OA* and OCT_{PC} across the DMM-directed process. Finally, our technique is able to accurately find the configuration of a single deployed stent; however, complex PCIs often require multiple stents to be deployed in the same anatomic region (e.g., bifurcation disease; [24]). Unless the deployed stents are distinct geometries, modifications to the proposed methods would be required to reconstruct the two, potentially overlapping, stents.

V. Conclusion

In conclusion, we present a fully automated reconstruction technique that integrates OCT image data and *a priori* stent design knowledge obtained via μCT to generate a high-resolution, 3D geometry of a deployed vascular stent. We established and validated the technique through evaluation of 4 experimental stented phantom artery scenarios, which evaluated two stent designs (Integrity[®] BMS and Xience Alpine[™]) and two phantom vessels (healthy and stenotic). We report that the algorithm accurately reconstructed the deployed stent geometries, as demonstrated by the excellent agreement between the final reconstructed configuration and ground truth geometry. Following extension of the presented reconstruction framework to manage clinical image data, future development of this technique has the potential to advance *in vivo* stented artery computational models, as well

as inform the strain state of deployed stents, that may better inform interventional treatment strategies and improve clinical outcomes.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Fig. 1.

Schematic of the automatic 3D stent reconstruction algorithm. Imaging data were collected of a stent deployed in an arterial phantom (OCT) and a stent, of identical design, deployed in open-air (μ CT). Parallel image processing methods established a sparse OCT-derived stent geometry and μ CT-derived wireframe. A constrained iterative diffeomorphic metric mapping algorithm was employed to deform the wireframe to the OCT geometry and volume thickening was applied to create a 3D, high-resolution reconstruction of the deployed stent geometry.

Fig. 2.

OCT strut detection algorithm. Raw OCT images were windowed, and only data between the catheter and perivascular boundaries were considered. A background pixel intensity level was calculated as the mean intensity of an ROI of the furthest 60 pixel depths (green bounding box). A-lines were classified as either a strut or lumen based on distinct features (peak intensity, number of peaks, and wall level) as illustrated. Final measurements of strut reflection width (S_W) and height (S_{HT}) were taken and the center of strut reflection (red asterisk) was determined. The strut half-thickness was added to the centroid depth before point cloud generation (yellow asterisk).

Fig. 3.

Iterative deformation process algorithm. After generation of the OCT_{PC} and parameterization of the μ CT wireframe (*wireframe-OA*), deformation of the wireframe to the point cloud was directed by DMM and constrained by a stretched graph method.

Fig. 4.

Three-dimensional (3D) validation of OCT-defined stent geometry. (A) Representative result of OCT-defined centroids derived from strut identification algorithm (blue circles) and *wireframe-P* (black lines) for the Integrity® stent design deployed in a healthy phantom. Illustration presented in a rotational view ($z\theta$ -coordinates) for qualitative visual ease. (B) Euclidean distances between *wireframe-P* and *OCT_{PC}* for the stented phantoms.

Fig. 5. Representative example of constrained DMM deformation across the iterative process. The initial coregistration (iteration 0), first iteration, and final *wireframe-DMM* (iteration 4) for the XienceTM stent deployed in a healthy phantom vessel are shown in two views against the *OCT_{PC}* (gray circles: *OCT_{PC}* centroids; solid lines: wireframes). The ‘down-the-barrel’ view ($r\theta$ -orientation) highlights the radial deformation of the stent in the first iteration, and the rotational view ($z\theta$ -coordinates) highlights the primarily circumferential deformation of the stent in later iterations. Note the large displacements that occur during the first iteration, as

compared to the final iteration where the constrained iterative DMM process is fine-tuning the mapping (see quantification in Fig. 6).

Fig. 6.

Wireframe displacement and distance mismatch between wireframe and OCT_{PC} during constrained DMM deformation of the Xience™ stent deployed in a healthy phantom (illustrated in Fig. 5). (A) Cylindrical components of point displacement vectors on the wireframe through the iterative process. Note that the circumferential displacement scale (arc length) is equivalent to the axial and radial displacements for the approximate radius of the deployed stents (1.4 mm). (B) Euclidean distance differences (i.e., mismatch) between the deforming wireframe and OCT_{PC} across iterations. The largest displacements, which were primarily in the radial direction, occurred during the first iteration, and displacements

in subsequent iterations were comparatively small as the DMM process fine-tuned the mapping until the process converged at iteration 4. * $P < 0.001$

Fig. 7.
Average distances between corresponding points on *wireframe-DMM* and *wireframe-P*.

Fig. 8.

Distribution of distances between corresponding points on the deformed wireframe and the wireframe derived from the μ CT of the stented phantoms (i.e., ground truth) for each deployed stent. (A) Xience stent deployed in healthy phantom. (B) Integrity[®] stent deployed in healthy phantom. (C) Xience stent deployed in stenotic phantom. (D) Integrity[®] stent deployed in stenotic phantom. Note that all distributions are positively skewed (i.e., the distribution is skewed towards greater agreement between wireframes).

Fig. 9.

Euclidean distance between corresponding points on *wireframe-DMM* and *wireframe-P* when OCT_{PC} is defined by the trained reviewer (manual detection) or strut detection algorithm (automated detection) across all 4 stents. Note that manual detection had a sensitivity 20% higher than automated detection, but did not significantly improve final reconstruction accuracy ($p = 0.29$).

TABLE I

Validation of Automated Strut Detection

Stent Vessel	# of Images Containing Struts	# of Struts	Sensitivity	PPV
Integrity® Healthy	187	2946	76%	99%
Integrity® Stenotic	184	2615	40%	92%
Xience™ Healthy	80	805	72%	97%
Xience™ Stenotic	184	1896	72%	97%

* The number of images containing struts and number of struts were determined by manual review.