Evaluation of electrocardiogram-gated computed tomography angiography to quantify changes in geometry and dynamic behavior of the iliac artery after placement of the Gore Excluder Iliac Branch Endoprosthesis

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BACKGROUND: The GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) is designed to treat iliac aneurysms with preservation of blood flow through the internal iliac artery (IIA). Little is known about the influence of IBE placement on the IIA geometry. This study aimed to provide detailed insights in the dynamic behavior and geometry of the common iliac artery (CIA) and IIA trajectory and how these are influenced after treatment with an IBE.

METHODS: Pre- and postoperative electrocardiogram-gated computed tomography angiography (ECG-gated CTA) scans were acquired in a prospective study design and analyzed with in-house written algorithms designed for aorto-iliac and endoprosthesis deformation evaluation. Cardiac pulsatility-induced motion patterns and pathlengths were computed by tracking predefined locations on the aorto-iliac tract. Centerlines through the CIA-IIA trajectory were used to investigate the static and dynamic geometry, including curvature, torsion, length and Tortuosity Index (TI).

RESULTS: Fourteen CIA-IIA trajectories were analyzed before and after IBE placement. Cardiac pulsatility-induced motion and pathlengths increased after IBE placement, especially at mid IIA and the first IIA bifurcation (P ≤ 0.04). After IBE placement, static and dynamic curvature, length and TI decreased significantly (P < 0.05). Furthermore, the average dynamic torsion increased significantly (P = 0.030). The remaining geometrical outcomes were not statistically significant.

CONCLUSIONS: The placement of an IBE device stiffens and straightens the CIA-IIA trajectory. Its relation with clinical outcome is yet to be investigated, which can be done thoroughly with the ECG-gated CTA algorithms used in this study.


KEY WORDS: Iliac aneurysm; Blood vessels; Computed tomography angiography.
The presence of a concomitant aneurysm of the common iliac artery (CIA), found in 20-40% of the patients with an abdominal aorta aneurysm patients, challenges standard endovascular aneurysm repair (EVAR) due to an insufficient distal sealing zone.1,2 The use of bell-bottom limbs is a valid option for concomitant CIA aneurysms with a diameter ≤24-25 mm, but is related to more complications during follow-up.3 Exclusion of the CIA aneurysm by covering the internal iliac artery (IIA), with or without IIA embolization, is considered a safe alternative.4 However, this strategy is related to ischemic complications, including invalidating buttock claudication (16-55%), erectile dysfunction (10-46%) and rarely spinal cord and colonic ischemia (<1%).5,6 To preserve pelvic circulation, and thus to reduce the incidence of pelvic ischemic complications, iliac branched devices were developed.6 One of these is the Iliac Branch Endoprosthesis (IBE) of the GORE® EXCLUDER® platform (W.L. Gore & Associates, Flagstaff, AZ, USA), which consists of an iliac branch component and a self-expanding IIA component of equal structure and composition. Short- and midterm results of the IBE are encouraging, with primary technical success rates of 94-100%,7-10 primary IIA patency rates of 90-95% at 6 months7-10 and 93.6% at both 12 and 24 months11 and overall freedom-from-reintervention rates of 95-100% at 6 months7-10 and 90.4% at 24 months,11 respectively. Long-term results of the IBE are still awaited.

In general, the implantation of an endoprosthesis causes a straightening of the aorto-iliac axis, especially in case of strong tortuosity of the native vessels.12 Advanced aortic-iliac aneurysmal disease is reflected in both an increased perirenal α- or β-angle and iliac tortuosity, which apply stresses to the endoprosthesis that may lead to complications, such as type Ia, Ib or III endoleaks, kinking and endoprosthesis thrombosis.13-16 Taudorf et al. showed a relation between the tortuosity of a vessel and the risk of limb occlusion in regular EVAR.14 Since the iliac arteries can exhibit severe tortuosity, iliac branched devices are subjected to higher tortuosity constraints than regular EVAR devices. Thus far, only one study investigated the static geometrical changes of the iliac arteries after IBE implantation.17 Albeit an IBE is placed to preserve flow through the IIA, the influence on the dynamic behavior and geometry of the IIA remains unknown. Dynamic behavior, *i.e.* cardiac pulsatility-induced motion and geometrical changes, can be analyzed using electrocardiogram (ECG)-gated computed tomography angiography (CTA) scans. These type of analysis have provided useful insights for other endoprostheses.16,18-23

The aim of this study was to quantify dynamic behavior and geometry of the CIA-IIA trajectory before and six weeks after implantation of an IBE, using dedicated analysis algorithms on ECG-gated CTA. This may lead to a better understanding of dynamic and geometrical behavior of IBE devices and provide insight into the mechanisms of underlying potential endoprosthesis failure. Ultimately, this may aid to further improvement of future devices and procedural planning.

**Materials and methods**

**Study design and population**

Between July 2017 and April 2020 fifteen patients scheduled for implantation of an IBE device were prospectively enrolled in this exploratory two-centered study. Procedures were performed according to the hospital’s standard practice. After IBE placement, patients received dual antiplatelet therapy for six months followed by single antiplatelet therapy. Procedural details and further device descriptions of the IBE have been described previously.17 ECG-gated CTA scans were acquired prior to and six weeks after the procedure as substitute for the routine CTA scans. Approval was obtained from the ethical committee and the institutional review boards. The trial was registered on ClinicalTrials.gov (NCT03762525). All patients provided written informed consent before participation. No exclusion criteria were defined.

**Image acquisition**

All ECG-gated CTA scans were performed on a 256-slice CT scanner (Brilliance iCT 256; Philips Healthcare, Best, the Netherlands) with a standardized arterial scan protocol. Scan parameters were as follows: tube voltage, 100-120 kV; tube current time product, 205-956 mA·s; collimation, 80x0.625 mm; rotation time, 0.27-0.33 s; slice thickness, 0.8-0.9 mm; slice increment, 0.4-0.7 mm; reconstruction matrix, 512×512 pixels; pitch factor, 0.18-0.30. A total of 100 mL of radiocontrast agent (Xenetix 350) was intravenously administered at 5 mL/s, without medical premedication. The scans were obtained during a single inspiration breath hold after performing a standard breathing exercise. Retrospective gating was applied to obtain 10 equally binned phases of the cardiac cycle from 0% to 90% of the RR interval.

**Image processing**

Image processing was conducted in Python programming language (version 3.7) using a previously established combined image registration and segmentation algorithm.24-26
The processing steps include registration of the 3D volumes of all 10 phases to obtain a motion compensated, 3D volume (i.e. static, mid cardiac cycle, CT volume) and 10 deformation fields describing the displacement of each voxel in an individual phase with respect to mid cardiac cycle.

Motion patterns

To quantify the cardiac pulsatility-induced motion of the native and stented iliac anatomy in x-, y- and z-direction, a set of points was manually selected in the pre- and postoperative static CT volume. In the preoperative scan, points were selected on the following anatomical structures: the native aorta bifurcation, CIA bifurcation, halfway between the origin and the first bifurcation of the IIA, and the first IIA bifurcation (Figure 1A). In the postoperative scan, these points were represented by the bifurcation of the main endoprosthesis, the IBE flow divider, the distal markers of the IIA component, and the first IIA bifurcation (Figure 1B). It should be noted that, although in close proximity, the selected points differ slightly between pre- and postoperative scans. However, they do resemble the same anatomical locations, including new (endograft) bifurcations at which similar hemodynamic forces are expected to be exerted. For all selected points, the motion in x-, y- and z-direction for each phase of the cardiac cycle was automatically obtained by applying the deformation fields through backward mapping. Also, the sum of displacement for each individual landmark during the cardiac cycle, hereafter pathlength, was obtained. The inter- and intra-observer variability were determined by additional point selection in all patients by the initial and a second observer.

Geometrical changes

The aorto-iliac tract and endoprosthesis were segmented using the static CT volume with a thresholding operation of respectively 150-350 and 500-650 Hounsfield units. Subsequently, centerlines of the vasculature were obtained as detailed elsewhere. Postoperatively, start and end of the centerline were defined at the origin of the CIA and the first bifurcation of the IIA, respectively. By referencing anatomical landmarks, similar start and end were selected in the preoperative CTA scan, making the obtained pre- and postoperative centerline comparable for analysis. Each centerline consisted of a number of points at a set distance of 1 mm. This centerline served as a basis for the subsequent static geometry analysis. The course of the centerline at each phase of the cardiac cycle was obtained after backward-mapping by applying the deformation fields. These centerlines were used for subsequent dynamic geometry analysis.

Curvature is used to describe the bending of the vessel centerline and was calculated for each centerline point. Torsion describes to what extent the centerline twists out of the plane of the curvature for each centerline point. First, curvature and torsion were calculated for each point on the static centerline. The average and maximum static curvature and torsion were computed by taking the average and maximum of all values. Next, curvature and torsion were calculated for each point on the dynamic centerlines, resulting in 10 values per point. The difference between the smallest and largest value per point was defined as the dynamic value. Subsequently, the average and maximum dynamic curvature and torsion were obtained by taking the average and maximum of all dynamic values. Initially torsion values can be either positive or negative, indicating the direction of twisting. To avoid disregarding of negative values when computing the maximum static or dynamic torsion, the absolute value was taken. In addition, the location of maximum static and dynamic curvature and were categorized based on visual inspection of color-coded centerlines (Figure 2).

The length of the centerline was calculated as the sum of all individual distances between consecutive points on the centerline. The Tortuosity Index (TI) was defined as the length of the centerline divided by the straight distance be-

![Figure 1—3D volume representation of a patient before (A) and after (B) treatment with an iliac branch endoprosthesis (IBE). The selected points are presented in blue in the online version. The corresponding landmarks are: 1 and 2: aorta bifurcation/flow divider main device; 3 and 4: common iliac artery bifurcation/flow divider IBE; 5 and 6: mid internal iliac artery (IIA)/distal marker of IIA component; 7: IIA bifurcation distal to the IBE.](image)
between start and end of the centerline. Dynamic length and TI were defined as the difference between the minimum and maximum value of length and TI over the 10 phases.

Statistical analysis

Normality of the data was assessed using the Shapiro-Wilk Test. Continuous data are presented as median (interquartile range, IQR), while categorical data is given as number (%). Differences between pre- and postoperatively obtained variables were tested with a paired samples t-test for parametric data and a Wilcoxon signed-rank test for non-parametric data. P values <0.05 were considered significant. Statistical analysis was performed using IBM SPSS statistics 26 (IBM corporation, Armonk, NY, USA).

Results

After visual inspection of all ECG-gated CTA scans of the fifteen patients, three patients were excluded for further analysis; one patient did not receive the dedicated IIA component, and two patients had insufficient CTA scans due to improper contrast distribution and retrospective gating (Figure 3). Patient-, aneurysm- and procedural characteristics of the remaining 12 patients (with a total of 14 devices) are depicted in Table 1.

Motion patterns

Both pre- and postoperatively the most prominent motion is observed in the z-direction (Figure 4), especially at the aorta- and CIA bifurcation (points 1-4). Motion decreased downstream the aorto-iliac tract in all directions. Points selected on opposite sides of the artery (or stent), i.e. points 1 and 2, 3 and 4, and 5 and 6, show similar motion patterns, hence little to no pulsatile expansion is observed. Motion amplitude increased significantly after IBE placement in the y-direction at the distal marker of the IIA component (point 5; P=0.024) and at the first IIA bifurcation (point 7; P=0.040). Moreover, a significant increase was found in the z-direction at the IBE flow divider (points 3 and 4; P=0.031, P=0.030) and the IIA bifurcation (point 7; P=0.001).

The pathlengths reflect similar results (Figure 5). Preoperatively, the pathlength reduced significantly from 2.4 mm (IQR 2.1, 3.0 mm) at the aorta bifurcation (point 1) to 1.6 mm (IQR 0.8, 1.7 mm; P=0.009) at the IIA bifurcation (point 7). Postoperatively, the pathlength decreased significantly as well, from 2.8 mm (IQR 2.2, 3.1 mm) at the bifurcation of the main endoprosthesis (point 1) to 1.7 mm (IQR 1.5, 2.0 mm; P=0.005) at the first IIA bifurcation (point 7). For each point the median pathlength increased between start and end of the centerline. Dynamic length and TI were defined as the difference between the minimum and maximum value of length and TI over the 10 phases.
Table I.—Patient-, aneurysm- and procedural characteristics.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Values</th>
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<tbody>
<tr>
<td>Patient characteristics</td>
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<tr>
<td>Age (years)</td>
<td>68.5 (64.3-74.5)*</td>
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<td>Male sex</td>
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<tr>
<td>Cardiovascular risk factors (SVS grading)</td>
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<tr>
<td>Diabetes</td>
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<td>Tobacco use</td>
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<td>Hypertension</td>
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<td>Renal status</td>
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<tr>
<td>Hyperlipidemia</td>
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<tr>
<td>Cardiac status</td>
<td>10 (83.3) / 1 (8.3) / 1 (8.3) / -</td>
</tr>
<tr>
<td>Pulmonary status</td>
<td>11 (91.7) / 1 (8.3) / - / -</td>
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<td>Aneurysm characteristics</td>
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<tr>
<td>IIA aneurysm (right/left/both/neither)</td>
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<td>Vessel geometries, mm</td>
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<td>Diameter infrarenal aortic neck, mm</td>
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<td>Maximum diameter infrarenal aorta, mm</td>
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<td>Maximum diameter treated CIA, mm</td>
<td>36.6 (28.6-47.4)*</td>
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<td>Length right CIA, mm</td>
<td>58.8 (47.2-73.3)*</td>
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<td>Length left CIA, mm</td>
<td>51.7 (48.7-66.7)</td>
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<tr>
<td>Maximum diameter right IIA, mm</td>
<td>9.2 (7.3-16.3)</td>
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<tr>
<td>Maximum diameter left IIA, mm</td>
<td>9.6 (8.3-13.6)</td>
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<tr>
<td>Maximum diameter right EIA, mm</td>
<td>10.3 (9.6-12.3)*</td>
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<tr>
<td>Maximum diameter left EIA, mm</td>
<td>10.3 (8.7-12.0)*</td>
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<td>Procedural characteristics</td>
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<td>Side of IBE (right/left/both)</td>
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</tr>
<tr>
<td>Diameter IIA component, mm (7/8/10/12/13/14.5)</td>
<td>1 (8.3)* / 1 (8.3) / 4 (33.3) / 3 (33.3) / 1 (8.3)* / 4 (33.3)*</td>
</tr>
</tbody>
</table>

Data presented as median (IQR), indicated with * when normally distributed, or as number (%).
*All EVAR grafts implanted in conjunction with an IBE were from the GORE® EXCLUDER® platform; †Viabahn stents. Two patients received a self-expanding IIA component extended with a Viabahn, one patient received a Viabahn only.

after IBE placement, however, this increase was not statistically significant (P=0.056).

The inter-observer variability for motion amplitudes was median 0.000 mm (-0.028 to 0.029 mm, ICC 0.839 P<0.01) and for pathlengths median 0.007 mm (IQR -0.044 – 0.093 mm, ICC 0.982 P<0.01); the intra-observer variability for motion amplitudes was median 0.001 (IQR -0.024 to 0.027, ICC 0.853 P<0.01) and for pathlengths median 0.007 mm (IQR -0.044 – 0.093 mm, ICC 0.982 P<0.01). These are all well within the previously established maximum error of amplitude calculation of 0.3 mm.24

Geometrical changes

Average and maximum static curvature of the native CIA-IIA trajectory were respectively 49.8 m⁻¹ (IQR 43.2, 67.0) and 185.1 m⁻¹ (IQR 144.0, 234.1), Figure 6. After treatment both average and maximum curvature significantly decreased to 35.3 m⁻¹ (IQR 32.8, 40.6; P=0.006) and 122.5 m⁻¹ (IQR 86.8, 167.9; P=0.012), respectively. Furthermore, the average dynamic curvature reduced from 2.2 m⁻¹ (IQR 1.8, 2.6) to 1.6 m⁻¹ (IQR 1.3, 1.9; P=0.005) and the maximum dynamic curvature from 7.6 m⁻¹ (IQR 6.1, 8.6) to 4.9 m⁻¹ (IQR 4.3, 6.1; P<0.001). Preoperatively, the maximum curvature was found at mid IIA in 3 out of 14 iliac trajectories, whereas postoperatively 9 out of 14 trajectories showed its maximum curvature at this location.

Average and maximum static torsion of the native CIA-IIA trajectory were respectively 190.0 m⁻¹ (IQR 171.3, 207.4) and 2329.3 m⁻¹ (IQR 1551.3, 3032.4), Figure 7. Neither showed a significant change after IBE implantation (P=0.573 and P=0.140, respectively). The average dynamic torsion increased significantly after IBE implantation from 30.7 m⁻¹ (IQR 25.6, 34.8) to 38.2 m⁻¹ (IQR 24.0, 77.2; P=0.037). The maximum dynamic torsion increased as well from 1303.7 (858.0, 1868.6) to 1841.0 (604.6, 4314.5), however not significant (P=0.079).
The length of the native CIA-IIA trajectory was 170.5 mm (IQR 148.1, 206.5) and showed a variation of 0.9 mm (IQR 0.5, 1.1) during the cardiac cycle, Figure 8. Postoperatively, the length significantly decreased to 165.9 mm (IQR 139.6, 188.9; P=0.003) and its variation decreased to 0.6 mm (IQR 0.4, 0.7; P=0.035). The static TI reduced significantly from 1.28 (IQR 1.19, 1.30) to 1.18 (IQR 1.14, 1.23; P=0.002). The dynamic TI reduced significantly from 0.005 (IQR 0.004, 0.009) to 0.003 (IQR 0.002, 0.004; P=0.005).

**Discussion**

The present study performed detailed assessment of 3D cardiac pulsatility-induced motion patterns and geometrical changes of the CIA-IIA trajectory before and after IBE placement. Novel and in-depth analyses of ECG-gated CTA scans showed that after treatment with an IBE, motion increased especially at the distal end of the IIA component.
and the remnant native AII. This suggests less dampening of the cardiac pressure wave along the CIA-IIA trajectory and consequently increased forces on the IIA component, potentially challenging its durability. In terms of geometrical changes, a significant decrease in both static and dynamic curvature, length and TI of the CIA-IIA trajectory was observed. This observation supports previous claims of stiffening, straightening and shortening of the aorto-iliac tract when treated with an endoprosthesis. The observed straightening and stiffening of the CIA-IIA trajectory in the current study is further supported by the relocation of the maximum curvature to the transition from distal IIA component and remnant IIA in nearly all patients. This implies that the stiffening of the stented vessel is somehow compensated at the transition between the IBE and the native IIA distal to the endoprosthesis. Consequently, hemodynamic and mechanical forces may be transferred from the IIA component to the native vessel, which might eventually cause injury to the intimal layer and may potentially promote thrombosis.

While long-term clinical outcomes of the IBE are still awaited, midterm results reported by Schneider et al. indicate a stable IIA component patency of 93.6% at both 6 and 24 months postoperatively and 91.8% remained free from reinterventions through 2 years. Five percent of patients experienced an occlusion of the IIA component within 1 month, suggesting that occlusion occurs due to anatomical, technical or geometrical factors. Out of the 12 patients analyzed, 1 patient presented with an occlusion of...
the IIA component due to thrombus at the 6 weeks follow-up visit. Several differences compared to the remaining cohort were observed, namely a larger decrease in length, TI and curvature of the CIA-IIA trajectory after treatment. These findings might explain the early occlusion of the IIA component due to potential occurrence of flow disturbances, vessel damage and/or forces induced by the stiffness of the endoprosthesis. Consequently, patients with similar geometrical changes after graft placement might be at risk for occlusion. Nevertheless, the relation between clinical outcome and the dynamic and geometrical changes should be further investigated.

To the best of our knowledge conformability of the IBE is previously only addressed by Della Schiava et al.17 who did not find significant differences in static length and TI of the CIA and CIA-EIA trajectory after treatment. Contrary to their results, significant differences in these parameters were found for the CIA-IIA trajectory in the present study which may be explained by the difference in study design. The dynamic behavior of the IIA or the IBE were not investigated by Della Schiava et al.17 nor by other studies. Apfaltrer et al.31 demonstrated that dynamic CTA is useful in endoleak detection after EVAR and Koenrades et al.18 evaluated motion and deformation after endovascular aneurysm sealing with chimney grafts using ECG-gated CTA, while Ullery et al.32 evaluated renal artery motion after fenestrated and snorkel/chimney EVAR on respiratory gated CTA.

Like in these previous studies, the current study underlines the main benefit of ECG-gated CT scanning: the ability to investigate dynamic behavior of vascular structures and endografts. However, a drawback of these types of CT scans is the extra radiation dose to which patients are exposed. By comparison, a standard CTA scan provide a radiation dose of about 4.6 mSv to a patient, while the ECG-gated CTA scans radiation dose is about 11 mSv. Based on a the ICRP 103 publication, the radiation exposure of 11 mSv (i.e. 1 ECG-gated CT) induces a lifetime attributable risk of all cancer of approximately 0.04% in adults. Considering the included population in the present study, i.e. mostly patients with comorbidities >65 years old, this risk might even be lower.

The investigated parameters gave insight in the geometry changes induced by IBE. Pre- to postoperative decrease in length may suggest compression and, when in combination with decreased TI and/or curvature, straightening of the vascular segment.33 Ti and curvature give insight in the curving of a vascular trajectory, based on the centerline. However, TI a general presentation of the experienced curves, while curvature can give more in depth insights into where the bending is most severe. Moreover, both parameters have been linked to (different) complications after EVAR.15-17,34, 35 For example, Dowson et al.34 found that calculating TI over centerline segments of 10 mm aids to predict the likely success of EVAR and Spinella et al.36 used curvature to evaluate the adaptability of a Viabahn balloon expandable stent graft in an IIA. Although curvature is increasingly accepted as a metric in characterizing vasculature and believed to be more accurate than angulation,37 to fully describe the trajectory of a centerline in 3D, torsion should be considered as well.27 However, literature in vascular research using torsion is scarce. This study showed an increase in the average dynamic torsion during the cardiac cycle. This may suggest an enhanced torsion during the cardiac cycle as compensation for the decreased curvature and stiffening. Despite being an important addition, caution should be taken with this variable considering its sensitivity to slight centerline inaccuracies and the clinical interpretation of static and dynamic torsion remains to be elucidated.

Limitations of the study

The study is limited by a relatively small sample size. Unfortunately, 2 patients in the present study had to be excluded due to insufficient ECG-gated CT scans. The first patient was excluded due to lack of contrast agent in the iliac arteries on the preoperative scan, probably caused by a combination of insufficient triggering and a large volume of the iliac aneurysm sac. The second patient was excluded because of incorrect retrospective gating and subsequent reconstruction of the 10 cardiac phases volumes of the postoperative scan. Unfortunately, the raw CT data was no longer available when this issue was discovered. Nevertheless, statistically significant changes were observed. Considering the prospective study design, in depth analysis of the ECG-gated CT scans and low observer variability in the measurements, these results can be considered reliable. Since this study only included patients treated with an IBE, the current data may not be generalized for all iliac branched devices. The algorithm used to assess motion has an error threshold of at most 0.3 mm.38 Some of the observed motion patterns are close to or below this threshold and can therefore not be considered completely valid.

Conclusions

Treatment of an aorto-iliac aneurysm using an IBE to preserve blood flow through the IIA changes the dynamic and
static behavior of the treated trajectory, based on evaluation with dedicated ECG-gated CTA analysis algorithms. The IBE causes less dampening of the cardiac pressure wave and more motion of the IIA trajectory. Shortening and straightening of the CIA-IIA trajectory was reflected by the reduction in static curvature, length and TI. Furthermore, the curvature varied less during the cardiac cycle, indicating a stiffened trajectory. Whether these observations relate to loss of long-term integrity and patency of the IIA component remains to be elucidated.

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