Roentgen stereophotogrammetric analysis to study dynamics and migration of stent grafts

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CHAPTER

3

Roentgen Stereophotogrammetric Analysis: An Accurate Tool to Assess Stent-Graft Migration

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Abstract

Purpose: To evaluate in an in vitro model the feasibility and accuracy of Roentgen stereophotogrammetric analysis (RSA) versus computed tomography (CT) for the ability to detect stent-graft migration.

Methods: An aortic model was constructed from a 22-mm-diameter Plexiglas tube with 6-mm polytetrafluoroethylene inlays to mimic the renal arteries. Six tantalum markers were placed in the wall of the aortic tube proximal to the renal arteries. Another 6 markers were added to a Gianturco stent, which was cast in Plexiglas and placed inside the aorta and fixed to a micromanipulator to precisely control displacement of the stent along the longitudinal axis. Sixteen migrations were analyzed with RSA software and compared to the micromanipulator. Thirty-two migrations were measured by 3 observers from CT images acquired with 16×0.5-mm beam collimation and reconstructed with a 0.5-mm slice thickness and a 0.4-mm reconstruction interval. Measurements were made with Vitrea postprocessing software using a standard clinical protocol and central lumen line reconstruction. Results of CT were also compared to the micromanipulator.

Results: The mean RSA measurement error compared to the micromanipulator was 0.002±0.044 mm, and the maximum error was 0.10 mm. There was no statistically significant interobserver variability for CT ($p=0.17$). The pooled mean (maximum) measurement error of CT was 0.14±0.29 (1.00) mm, which was significantly different from the RSA measurement error ($p<0.0001$).

Conclusion: Detection of endograft migration by RSA is feasible and was significantly more accurate than CT in this nonpulsatile in vitro model.

Introduction

Endograft migration is a well recognized complication after endovascular aneurysm repair (EVAR) of an abdominal aortic aneurysm (AAA).[1,2] Contrast-enhanced computed tomographic angiography (CTA) is the current gold standard to detect endograft migration.[3] However, CT has several adverse effects, including high radiation dose and the use of nephrotoxic intravascular contrast. With the widespread use of EVAR, CT surveillance also places increasingly high logistical and economical burdens on hospitals,[4] considerations that have led many centers to reduce the frequency of CT after EVAR, especially if there is evidence of sac shrinkage.[5] Less frequent CT scans may be feasible; however, there is the risk of unnoticed migration. Clearly, there is a need for another type of imaging modality to follow the thousands of patients with aortic endografts.

Roentgen stereophotogrammetric analysis (RSA) was introduced by Selvik[6] in 1974 and became the gold standard for assessing micromotion of orthopedic implants[7-10]; the technique now is used widely across northern Europe. RSA is based on calculating the 3-dimensional (3D) position of markers from stereo images.[9] The technique is relatively simple, requiring only 2 standard Roentgen tubes, a calibration box with markers, and computer software for the analysis. The major advantages of RSA are the fact that intravascular contrast is not required and the radiation dose is only 0.3 mSv. Furthermore, RSA is a low-cost and time efficient method that can be performed by a trained technician.

Georg et al.[11] recently described the use of RSA to detect stent-graft migration in a model. However, they showed only reproducibility of marker position measurement with RSA in an endovascular setting. The accuracy of RSA to detect stent-graft migration is still unknown. To evaluate the possible role of RSA in the follow-up after EVAR, we tested the feasibility and accuracy of RSA in an in vitro model of endograft migration.

Methods

Aortic Model With Stent-Graft

An aortic model (Figure 1) was constructed from a 22-mm-diameter Plexiglas tube to simulate the aorta. The tube had 2 6-mm-diameter polytetrafluoroethylene tubes inserted to mimic the renal arteries with intravascular contrast, used for CT analysis. RSA requires the use of markers, so 6 1-mm-diameter tantalum markers were placed in the wall of the aortic tube proximal to the renal arteries. Another 6 tantalum markers were added to a Gianturco stent (Cook Inc.,

Figure 1. Model used in the experiments. The micromanipulator can displace the stent in a highly controlled manner along the axis of the aorta. Markers are placed on the stent and inside the aorta for RSA analysis. Renal arteries (arrow) are mimicked by polytetrafluoroethylene inlays in the wall of the aorta for CT analysis.

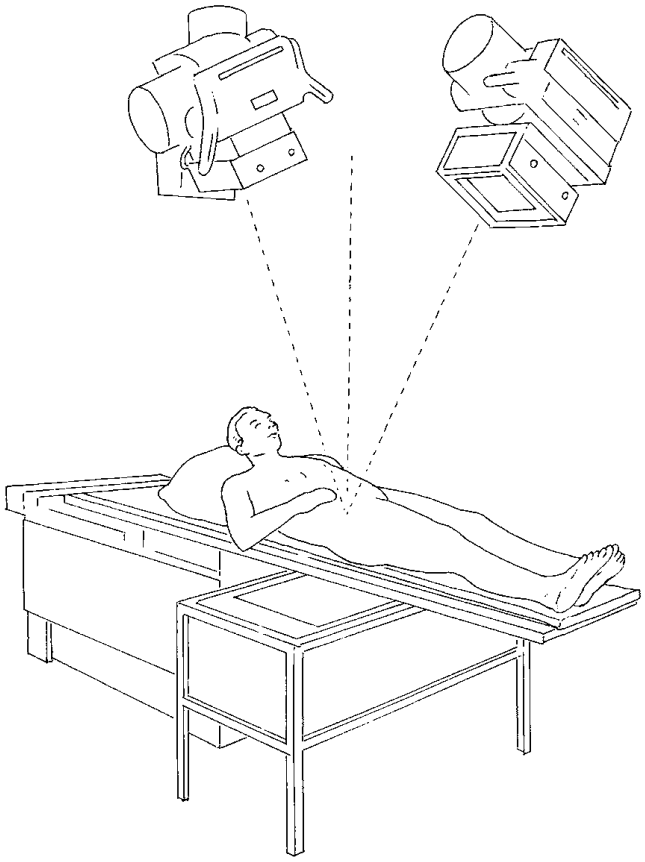

Figure 2. RSA imaging setup. The reference and control markers are in the box under the patient. The radiographic films are placed directly under the box.

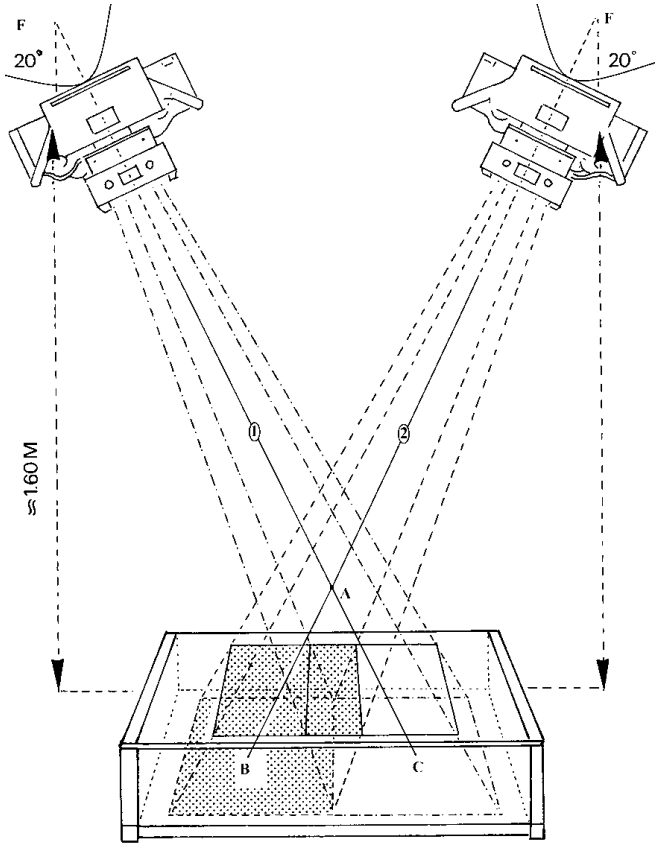

Figure 3. Schematic drawing of the RSA technique. The projection of the calibration box markers on the film is used to reconstruct the position of the Roentgen foci (F). Graft marker A gives projections B and C on the films. With a known focus position, projection lines 1 and 2 can be reconstructed. The calculation of intersection of 1 and 2 in space gives the position of A.

Bjaeverskov, Denmark), which was then cast in Plexiglas, making rotational movement and stent distortion impossible. The encased stent was placed inside the aorta and fixed to a micromanipulator (Thesa, Veenendaal, The Netherlands) to precisely control displacement of the stent along the longitudinal axis of the aorta. The increments of the micromanipulator were accurate up to 0.01 mm according to the manufacturer, which was confirmed by laboratory testing at our institution. To simulate soft tissue, 22 cm of Plexiglas was placed on top of the model during RSA imaging.[12]

RSA Imaging Technique

The RSA setup (Figure 2), identical to that used for orthopedic evaluation,[13] consisted of 2 Roentgen tubes (Philips Rotalix, 90 kV/100 mAs and a Philips Practix 2000, 90 kV/60 mAs; Philips Medical Systems Europe, Amsterdam, The Netherlands) positioned 1.5 meters above a

pair of 35×43-cm Roentgen cassettes (Kodak, Amsterdam, The Netherlands) at a 20° angle to the vertical. To define a 3D laboratory coordinate system, 50 1-mm-diameter tantalum reference markers were positioned in the lower plane of a calibration box. In order to calculate the Roentgen focus position, 24 1-mm tantalum control markers were positioned in the upper plane of the box. The films were placed directly under the box (Figure 3).

First, a reference RSA image was taken by simultaneously exposing the films, and then the stent was moved longitudinally in 0.1-mm increments up to 15 mm using the micromanipulator. One migration of 20 mm was also created. After each migration, an RSA image was taken. The 16 images were randomly numbered, and the reviewer was blinded as to the distance of migration induced. The RSA software determined the distance between the aortic markers and the stent markers. It then compared this distance to the reference image to determine the extent of migration. This measurement was then compared to the micromanipulator to calculate the measurement error of the technique. Figure 4 shows the RSA software reconstruction of the marker and x-ray focus positions in space in relation to the 2 images.

Subsequently, the radiographs were digitized by scanning with a Vidar VXR-12 scanner (Vidar, Lund, Sweden) at a 150-dots/inch, 8-bit grayscale resolution. The RSA-CMS software (MEDIS,

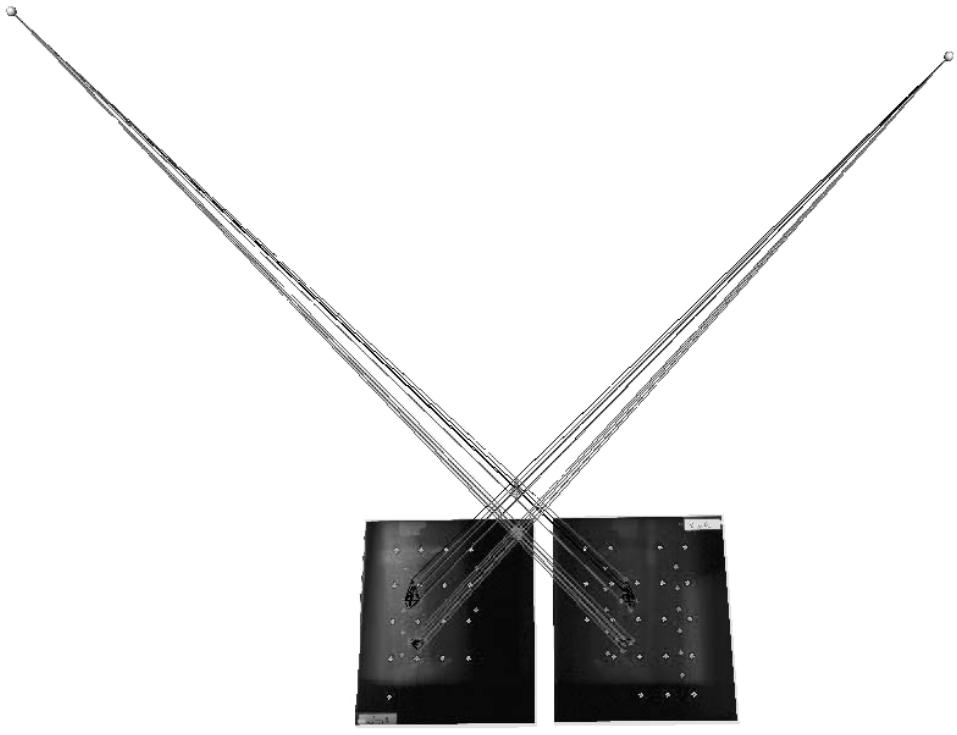

Figure 4. RSA software reconstruction of the position of the 2 Roentgen foci, the stent-graft markers, and reference markers in space (crossing lines). These positions were reconstructed from the 2 radiographs (black).

Leiden, The Netherlands) automatically measured the marker coordinates in the digitized radiographs from the 3D reconstruction of the marker positions to measure micromotion.[8-10]

CTA

The same techniques for acquiring, postprocessing, and analyzing CT data to measure endograft position were the same as those used for EVAR surveillance in our clinic The images were acquired with a Toshiba Aquilion 16 multidetector CT scanner (Toshiba Medical Systems Europe, The Netherlands) set to the following parameters: 80 kV, 200 mAs, 1-second rotation, pitch 0.7, and 0.5-mm collimation; images were reconstructed with a 0.5-mm slice thickness and a 0.4-mm reconstruction interval. A reference scan was made, and then the stent was moved longitudinally in 0.5-mm increments up to 15 mm using the micromanipulator. One migration of 20 mm was also created. After each migration, a CT scan was made, for a total of 32 CT scans. Because CT involves human action and possible interpretation error, the number of CTs created was double that of the RSA setup. The CT images were randomly numbered, and the observers were blinded to the amount of migration induced. Using the Vitrea2 postprocessing software (Vital Images Inc., Plymouth, MN, USA), the images were reconstructed along the central lumen line. The distance was measured from just below the most caudal renal artery to the level where the first circumferential view of the stent was obtained. The struts of the stent were used for orientation. No special markers were used for CT measurement. To correct for interobserver variability, the CT scans were evaluated by 3 medical specialists (2 interventional radiologists and a vascular surgeon who were all experienced with this protocol). The distances measured in the 32 CT images were compared to the reference image. The migration thus measured was compared to the micromanipulator to determine the measurement error of the technique.

Statistical Analysis

Levene's test for variance was used to detect statistically significant interobserver variability between the measurement errors of the 3 CT readers. An F-test was used to compare the pooled CT measurement errors to the measurement error of RSA. $P<0.05$ represented a statistically significant difference. The tests were performed using SPSS for Windows (version 11.0; SPSS Inc., Chicago, IL, USA).

Results

The mean measurement error for RSA compared to the micromanipulator was 0.002±0.044 mm, and the maximum error was 0.10 mm. Three observers measured endograft migration (Figure

5) in 32 CTA scans. Compared to the micromanipulator (Figure 6), the mean (maximum) errors were 0.15±0.26 (0.70) mm for observer A, 0.25±0.36 (1.00) mm for observer B, and 0.02±0.23 (0.70) mm for observer C. There appeared to be no significant interobserver variability (p=0.17). Pooling the CT measurement errors of the 3 observers resulted in a pooled mean (maximum) error of 0.14±0.29 (1.00) mm, which was significantly different from the 0.002±0.044-mm RSA measurement error (p<0.0001).

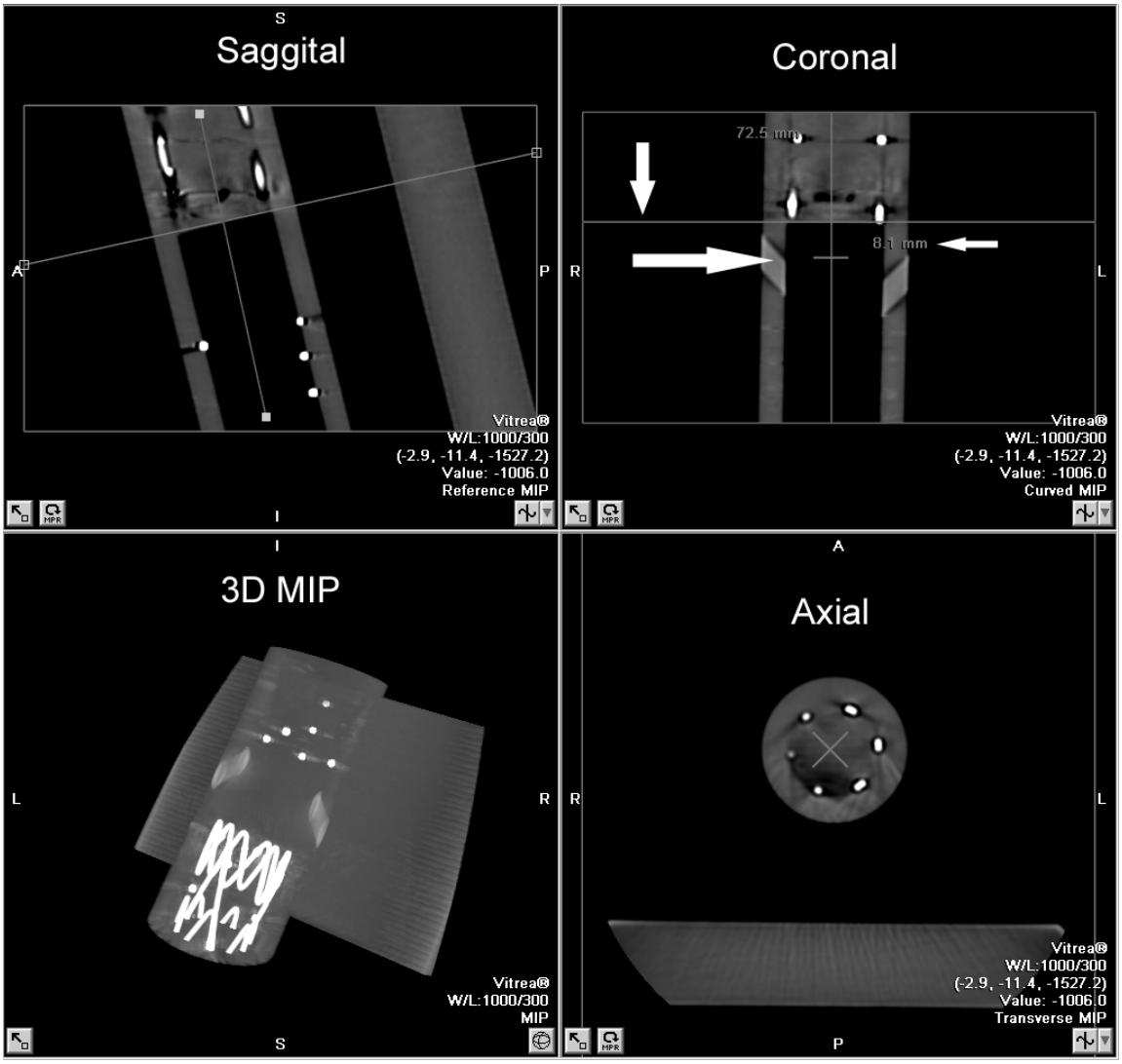

Figure 5. CT image reconstruction with Vitrea2 software. The caudal margin of the renal artery is identified (coronal image, largest arrow) on the axial image and the "ruler" is set to 0 mm. Afterward, the axial image is used to determine the first image with a circumferential view of the stent (axial image and coronal image, vertical arrow). The measurement is now taken (coronal image, smallest arrow).

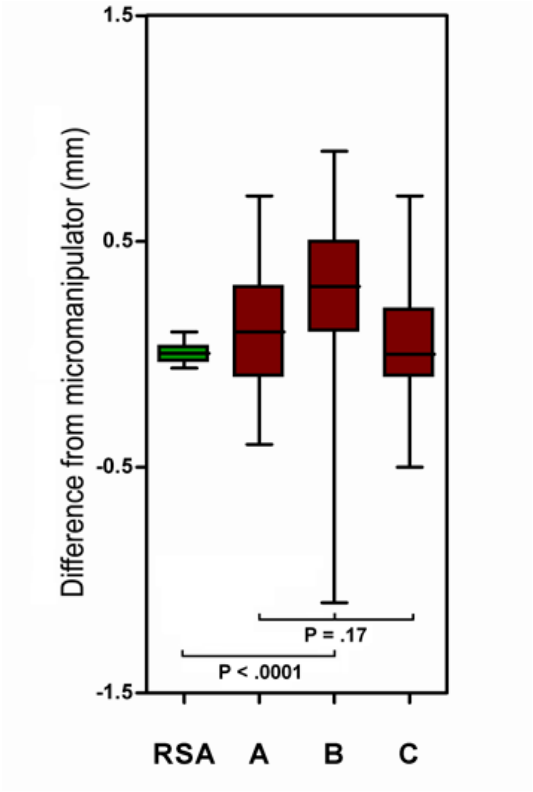

Figure 6. Box plot of the measurement errors of RSA and CT (observers A, B, and C) compared to the micromanipulator. The median, 10th, 25th, 75th, and 90th percentiles are given in mm.

Discussion

The use of RSA to evaluate endograft migration is promising for several reasons. Perhaps the most important advantage of RSA is that it does not require intravascular contrast to accurately determine stent-graft position, which is an asset in a patient population with a significant incidence of renal dysfunction. Plain CT without contrast enhancement may be used for stent-graft migration assessment, but it is likely that this reduces the accuracy of identifying the renal arteries consistently in consecutive scans.

Comparing radiation doses, RSA results in a radiation dose of only 0.3 mSv. In contrast, the radiation dose of CT is much higher, ~17 mSv for a complete triple-phase scan: 6.8 mSv for the unenhanced phase and 6.8 mSv for the early contrast-enhanced phase to measure stent-graft position. The RSA images can also be used to identify other adverse effects, such as possible stent fractures, so that RSA could replace the plain abdominal radiographs that are part of current routine follow-up in most centers.

RSA is a simple technique to use and does not require a large investment in special equipment. The imaging as well as the computerized postprocessing and migration measurement can be

performed by a trained technician instead of a dedicated medical specialist, which makes the investigation far less expensive in terms of logistical burden and healthcare cost. It could thus increase the cost effectiveness of EVAR by reducing the need for serial CTs.

Furthermore, there is the high accuracy of RSA. To our knowledge, no data exist in the literature about the accuracy of CT measurement of stent-graft migration. We used thin 0.5-mm slices for CT and 3D image reconstruction, which resulted in a significantly less accurate migration measurement by CT than by RSA. Thicker CT slices, as are the current practice in follow-up protocols, will undoubtedly result in larger errors of measurement by CT.

Another possible advantage of RSA is that it uses a single 90-ms exposure for the entire field of interest, which is minimally affected by the cardiac cycle and produces a high-definition image with high spatial resolution. Pulsatile changes in the aorta–stent-graft complex[14,15] will result in minimal measurement error due to this short acquisition time.

In terms of image postprocessing, RSA uses digital image processing that will distinguish the points of reference automatically with the help of a computer. To the contrary, CT requires observer-assigned reference points for measurement, which are sensitive to human variance. RSA reference points are constant, inherent metal markers, so accuracy of measurement is higher due to this consistent position.

Finally, there is the measurement of CT itself that can be performed in different ways, varying from workstation "image counting" multiplied by slice thickness to advanced postprocessing software, as used in our study. RSA is a consistent method using one well-established protocol for measuring the distance between reference points. In RSA analysis, the relative positions of markers do not change in the absence of migration. Any change in relative position indicates movement between the markers. Patient position is not critical, as the calibration box will facilitate the calculation of marker coordinates each time an RSA image is taken.

A potentially significant disadvantage of RSA compared to CT with intravascular contrast is the fact that at least one marker is required in the aortic wall as a reference point. Theoretically, one marker is sufficient to accurately measure axial migration. This marker would have to be placed as an additional procedure, preferably during EVAR. After secure fixation, migration of a reference marker is unlikely, as there is no significant dislocating force acting on it. The markers used to identify the endograft could be incorporated during manufacture of the stent-graft without many modifications. Certain endografts already have welding points that might function as markers.

In theory, remodeling of the aorta could lead to erroneous detection of migration. However, the amount of error will be minimal as the reference markers will be placed directly proximal to the stent-graft and renal arteries. The distance between the aortic markers and the stent-graft markers

will therefore be small, and slight changes in the aortic wall in this area will subsequently have minimal significance. The amount and design of the endovascular marker(s) needed for this application is subject to further study at our institution. We are confident that this issue can be resolved.

Currently, plain abdominal radiography may be used to detect endograft migration as an alternative to CT. In this investigation, the lumbar spine is used as a reference. Based on the protocol published by Murphy et al.,[16] a 2-mm margin of error has been reported by Hodgson et al.[17] in an experimental static model that eliminated any pulsatile axial movement of the aorta relative to the spine. Flora et al.[18] measured a pulsatile movement up to 1 mm in just 4 patients,[18] while Vos et al.[14] reported craniocaudal movement of up to 1.99 mm in 7 patients,[14] indicating that a wider range of movement is likely. The measurement error in a static situation versus the pulsatile motion of the aorta–stent-graft complex could significantly impair the accuracy of stent-graft migration assessment with plain radiography.

Other possible errors in the analysis of plain abdominal radiographs are changes in the vertebral column, e.g., due to osteoporosis or fractures, and possibly changes in neck angulation due to AAA shrinkage. RSA uses reference markers in the aorta and is therefore, in theory, not susceptible to pulsatile movement or changes in, or relative to, the vertebral column. Georg et al.[11] described the use of the transverse process of a vertebral body as a reference point to measure stent-graft migration. We believe that this will provide a significant source of error due to the pulsatile movement of the aorta.

When considering our model, it is obvious that all motion artifacts were eliminated in this static setup. To assess the impact of pulsatile motion on the accuracy of RSA, further studies are necessary. Axial movement of the aorta-endograft complex, as well as rotational movement, will probably have insignificant impact on RSA accuracy; endovascular reference markers are placed directly proximal to the endoprosthesis, which eliminates any significant movement between the two. With the use of endovascular reference markers, the vertebral column is no longer required as a reference, and all the abovementioned confounders regarding this structure and its relation to the endoprosthesis can be avoided.

Conclusion

Detection of stent-graft migration by RSA was feasible and significantly more accurate than CT in this nonpulsatile in vitro study. RSA combines high accuracy with low cost in terms of radiation, healthcare cost, and logistics. The absence of intravascular contrast is an additional asset of this method. Further studies are necessary to investigate the application of RSA markers in endovascular surgery and to investigate the influence of pulsatile motion on the accuracy of RSA.

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