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Appendix E1

A. Accuracy of 3D Printed Models as Compared with Cadaveric and Surgically Exposed Tissues

The accuracy of 3D bone models based on bones imaged in situ with CT, as compared with dry bone after debridement, was measured in three studies (17,49,55). Gelaude et al (55) reported that the models of 15 cadaveric femurs were, on average, 1.14-mm larger when they were segmented from in situ CT images for printing versus 0.65-mm larger when they were segmented from CT images of the dry bone. Chang et al (17) reported a roughly twice as large maximal difference (8.7 mm), compared with investigators in similar studies involving dry bone, between 3D models of the skull and cadaveric specimens (Table 3). Ogden et al (49) created 3D models of the lumbar vertebrae and also reported larger differences than those in the majority of related studies (Table 3), but less than 2 mm at maximum.

Weinstock et al (14) compared MR angiogram–derived 3D models of intracranial AVMs in children with intraoperative AVM measurements. Average differences were within less than 5.4% of the in situ dimensions, within 0.2 mm for vessel size, and within 2 and 3 mm for distance from the AVM nidus to the ventricle and feeding artery, respectively. Santana et al (53) compared the length of the anterior loop of the mental nerve in STL models of 12 fresh cadaveric mandibles imaged with cone-beam CT with the length of the surgically exposed nerve. The mean difference between the nonenhanced CT–derived STL model and surgical specimen length was 0.39 mm (23.8% of the actual length), and the mean difference between the contrast-enhanced CT–derived STL model and surgical specimen lengths was 0.35 mm (21.3% of the actual length).

B. Accuracy of 3D Printed Models, as Compared with Imaging Measurements, for Craniomaxillofacial and Orthopedic Applications

Printing the skull from CT images by using nylon SLS (57) or SLA (58) 3D printing technology has yielded accuracies similar to those of cadaveric studies, with differences of 1–2 mm compared with image measurements. Wu et al (59) reported a difference of less than 0.2 mm in the average size of the cervical vertebrae of 45 patients between measurements performed on source CT images and those performed in FDM-printed models, with intraclass correlation coefficients higher than 0.8 for 39 (88.6%) of the 44 anatomically relevant dimensions and equivalent results for the thoracic and lumbar vertebrae. Regarding the accuracy of models used for neurosurgical applications, six printed skull models were successfully registered with a computer-guided neurosurgical navigation system (60), indicating that dimensional inaccuracies of the models, as compared with imaging measurements, were within the tolerance of the navigation system (<5 mm), in agreement with cadaveric study results. Regarding the accuracy of models used for interventional radiology procedures, printed models of the cervical vertebrae yielded an average difference of less than 0.2 mm (maximal difference, <0.7 mm) when the model was imaged with CT and of less than 0.7 mm (maximal difference, <1.5 mm) when the model was imaged with MR imaging (39).

C. Accuracy of 3D Printed Models, as Compared with Imaging Measurements, for Cardiovascular Applications

The intracardiac defect diameters in nine ventricular septal defect and periprosthetic valve leak models derived from 3D transthoracic echocardiography were highly correlated (Pearson *r*, >0.98) with image measurements, with a mean absolute difference of 0.88 mm ± 0.65 (71). The models of individual patients in that study differed by up to 2.1 mm—for example, one model depicted a perivalvular leak that was 1.6 mm in short-axis diameter to be 3.4-mm wide. Similarly, when models of the aortic root in 16 patients undergoing transcatheter aortic valve replacement (TAVR) who were examined with CT angiography were created, there was a small average signed difference in annulus diameter (<0.4 mm) between the model and image measurements. However, individual patient models differed by as much as 4 mm (65), a variation large enough to potentially lead to the selection of a different prosthetic valve size for implantation. In 10 TAVR models derived from CT angiography, absolute differences in annulus diameter measurements between the model and radiologist image measurements were, on average, smaller than 0.85 mm (maximal difference, 2.1 mm), offering a better gauge of model fidelity than the mean signed difference of −0.06 mm that would have been observed for the same measurements (66) (Fig 11).

Differences between the 3D printed models and image-based measurements have also been considered within the context of the intra- and interobserver variability of image-based measurements. In the study involving the 10 TAVR models (66), the mean absolute difference in aortic annulus diameters between two expert readers was 1.17 mm, or 23% larger than the mean absolute difference between the 3D printed model and average reader measurements. The same result was observed for another parameter used for TAVR planning—namely, the height of the coronary ostia from the annular plane. The average discrepancy between the model and image measurements was smaller than 1.62 mm (maximal difference, 2.66 mm); however, the same measurement was also more variable between readers (average difference between readers, 1.98 mm) (66) (Fig 11). However, this is not always the case; printing the abdominal aorta from CT angiograms is relatively accurate, with investigators in one study (68) reporting a mean absolute difference in measurements of 0.82 mm ± 1.05 across 19 landmarks. However, in another study (69), half of 10 measurements (location and angle of visceral branches) in seven abdominal aorta 3D printed models were not significantly correlated with the average of three surgeons' measurements for those patients. In contrast, the intraclass correlation coefficient between the three surgeons performing the measurements (to modify fenestrated endografts for aneurysm repair) was greater than 0.9 for seven of the 10 measurements (69). Although it is possible that models are more accurate for this application, this will need to be established with an appropriate study design.

The models used for cerebrovascular applications also suggest similarly high accuracy. In a series of 10 cerebral aneurysms, the mean absolute difference in aneurysm longest diameter measured on models versus on source digital subtraction angiograms was small (0.34 ± 0.23) and no larger than 0.9 mm (67). In another study (18) in which 3D printed models of 22 cerebral aneurysms were derived from CT angiograms and included both the skull and the vasculature, the artery and aneurysm dimensions were accurate to within 1.1 mm. However, for more than 25% of the patients, three of 21 microsurgical anatomy sites and four of 22 arteries visualized on the source CT angiograms were not reproduced on the models (18), illustrating the difficulty in reproducing fine (bone or vascular) detail on 3D printed models. This difficulty arises from the difficulty in performing accurate segmentation and the limitations of the 3D printing technology. For example, with FDM printing, bulk inaccuracies such as false lumen occlusion and imperfections in the form of surface blebs simulating small aneurysms have been reported (19). The difficulty in reproducing fine details possibly explains the subjectivity in some assessments. As an example, in one study (62), one clinician believed that the models of stenotic middle cerebral arteries, as compared with the depictions of these vessels on the source MR angiograms, were probably misleading, whereas seven clinicians not only considered the models to be consistent but also believed that they provided additional information.

D. Functional Accuracy of 3D Printed Models, as Compared with Imaging Measurements, for Cardiovascular Applications

In a study (70) in which eight models of aortic valves in patients with severe aortic stenosis were derived from CT angiograms and printed by using flexible material for the aortic wall and rigid material for calcifications, the investigators reported mean transvalvular gradient, peak velocity, stroke volume, and aortic valve area measurements that were comparable to the in vivo echocardiographic measurements, with the largest relative difference (5.7%) observed in peak velocity measurements. In another study (61) in which hollow vessel lumen models were created to plan catheter angiography procedures, the lumen dimensions in carotid aneurysm models attached to flow loops at digital subtraction angiography differed from the dimensions measured on in vivo images by an average of 0.12 mm (maximal difference, <1 mm). Finally, in a series involving 10 cerebral aneurysms (19), the aneurysm volume measured by using 3D rotational angiography of a model attached to a flow loop differed from that measured on the source angiograms by a mean of 21.2 mm^3 ± 28.5, or 6.4% ± 6.2, and by no more than 84.3 mm^3 (18.2%).