

Title: Computerized 3-dimensional localization of a video capsule in the abdominal cavity: validation by digital radiography

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Background: Video capsule endoscopy has become the gold standard for examining the small bowel and defining pathological lesions, however, localization of a specific lesion remains largely guesswork. We report the validation of a new 3D localization software using radiological localization in volunteers.

Methods: 30 volunteers with no known prior history of gastrointestinal disease swallowed the EC-10 video capsule. A sensor array with six radiopaque markers was placed on the anterior abdominal wall. Once the capsule was visualized to be in the small intestine using a real time viewer, five sets of low dose x-rays were taken every thirty minutes. Distances between sensor points and the capsule were measured on the x-rays to provide X, Y, and Z coordinates and compared with the distances calculated by the software from the same points.

Results: Data from 27 of the 30 subjects were suitable for analysis. There were three technical failures. Our study evaluated the accuracy of the "Capsule 3D Track function" which calculated the capsule position based on the signal strength received at the sensor array. The accuracy of the position was compared to the actual position of the capsule as determined by radiographic images obtained during the capsule's transit through the small bowel. The average error for the software measurement for each of the three coordinates was: X -2.00 cm (SD 1.64 cm), Y --2.64 cm (SD 2.39 cm), and Z --2.51 cm (1.83 cm).

Conclusion: The localization error reported here is comparable to the existing system for localization, however, it provides localization across all three spatial dimensions which has never been achieved before. The potential utility of this technology is yet to be seen, however, as it needs to now be studied in a prospective clinical trial for patients with suspected small bowel pathology