Safety and Proof of Concept Demonstrated with a Novel Prep-Less X-Ray Imaging Capsule for Colon Cancer Screening

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Background

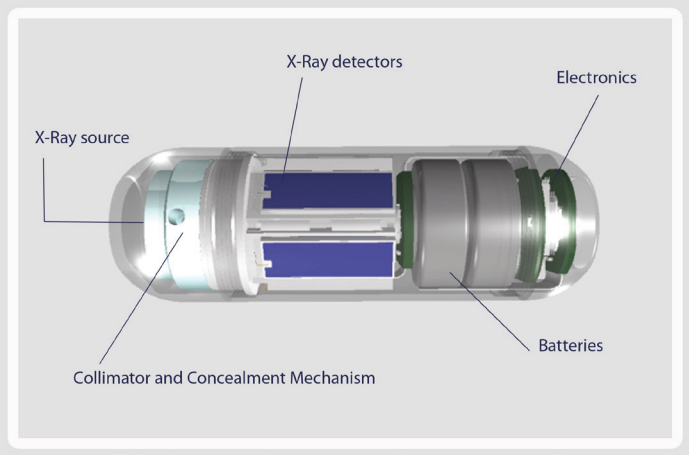
One of the major obstacles (~30%) of screening colonoscopy is the hurdle of preparation. The standard technologies demands aggressive bowel cleansing, which hamper patient's compliance.

Aim

To test the safety and proof of concept of a novel prep-less X-Ray imaging capsule (Check Cap Ltd, Israel) for colon cancer screening.

Material and Methods

The capsule (approximately 34 mm in length and 11.5 mm in diameter, similar in size to optical imaging capsules) utilizes a novel ultra-low dose (0.03 mSv) low energy (56 – 70 Kev) X-ray-based imaging technology to safely generate high resolution 3-D imagery of the colon without bowel cleansing or other aggressive preparation.



10 capsules were swallowed by volunteers M=7 (ages 37 - 66) and were tracked during the whole passage of the capsule in the body using radio frequency telemetry and an Electromagnetic Localization System (ELS). The capsules were programed to perform scans when movement in the colon is detected and transmit the imaging data to an external recorder unit worn by the patients. The study was approved by the IRB of the Tel Aviv Medical Center.

Total transit time and total X-ray exposure to the patients were calculated to assess the safety profile of the x-ray capsule imaging technology in human subjects.

Results

All capsules were swallowed and naturally exerted by the volunteers without any minor or major side effect with average transit time of 68 hours and Stdev 31 hours. The volunteers were exposed to an ultra-low total radiation dose (Average total exposure (0.03 mSv), Std (0.007 mSv), two orders of magnitude less than CTC. (with 1 outlier due to manufacturing fault). Data from scans in the colon combined with ELS positioning information was used to reconstruct 3D colon segments in un-prepped colon. Fig1 and Fig.2 are examples of such 3D scans.

Laboratory data form synthetic colon phantoms with and without polyps as well as data from cow colon phantom with induced tissue made polyp Fig.3 and Fig.4 have shown reconstruction accuracy of 2 – 3 mm in colon diameter measurements. (All figure dimensions in mm)

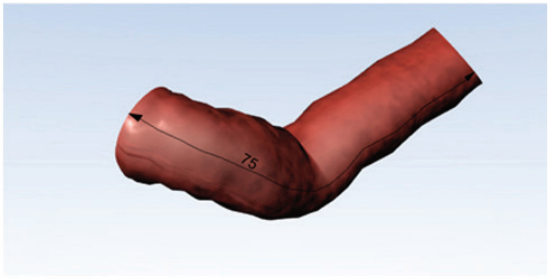


Fig.1 - Scan data combined with ELS position data in the descending colon

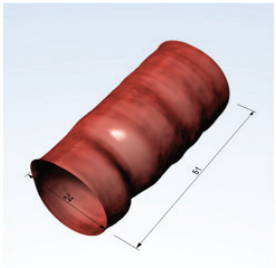


Fig.2 - Scan data combined with ELS position data in cecum

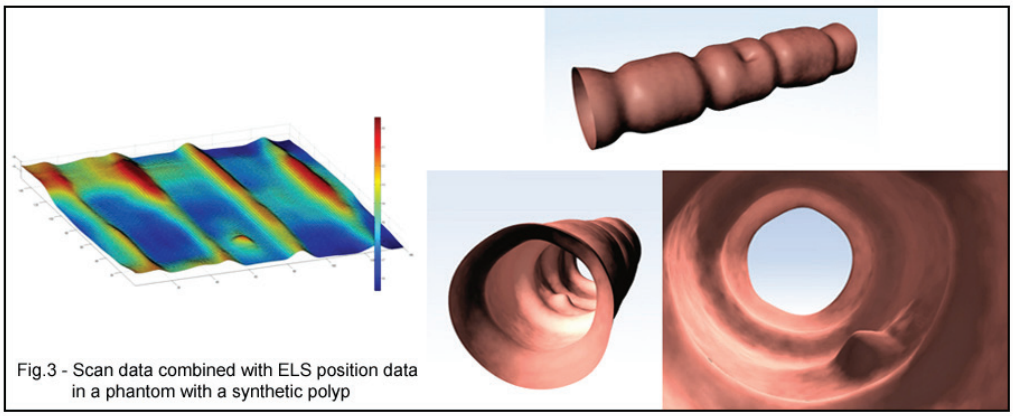


Fig.3 - Scan data combined with ELS position data in a phantom with a synthetic polyp

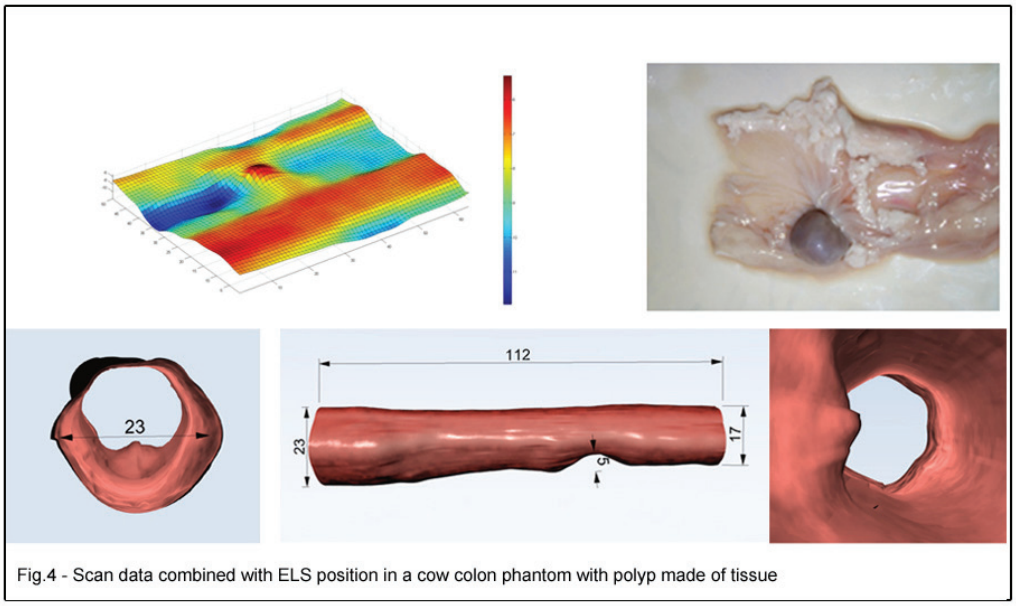


Fig.4 - Scan data combined with ELS position in a cow colon phantom with polyp made of tissue

Conclusions

A safety and proof of concept study has been performed using a novel prep-less x-ray imaging capsule for colon cancer screening. Quantitative ultra-low dose x-ray 3D imaging was achieved in the colon of human subjects. The efficacy will be confirmed in a multi-center study.