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A Novel Preparation-Free X-Ray Imaging Capsule for Colon Cancer Screening:

Correlation between Capsule and Colonoscopic Clinical Findings

Nathan Gluck (1), **Menachem Moshkowitz** (1),
Beni Shpak (2), **Seth A. Gross** (3), **Nadir Arber** (1)

(1) Tel Aviv Sourasky Medical Center, Tel Aviv, Israel
(2) Laniado Medical Center, Netanya, Israel
(3) NYU Langone Medical Center, New York, NY, United States.

Background:

Bowel preparation is likely the most significant reason for low participation in screening colonoscopy, while poor preparation impairs adenoma detection.

A CRC screening method that would generate structural data of the colon,

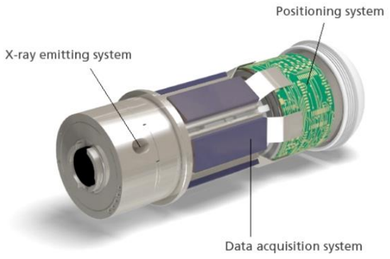
without cathartic cleansing or diet restrictions, would offer an attractive alternative for many patients from the target population that are not willing to undergo colonoscopy.

Aim:

To evaluate the safety and correlation between the **Prep-less capsule** (Check-Cap, Mt. Carmel, Israel) and colonoscopic clinical findings.

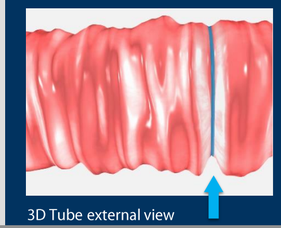
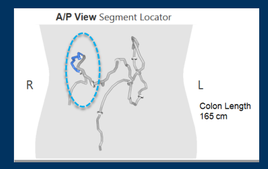
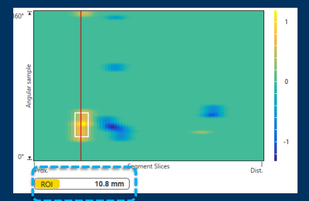
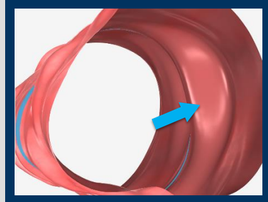
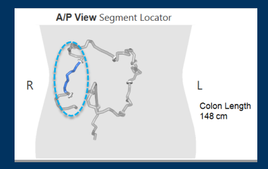
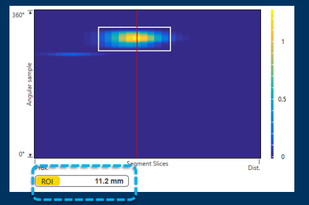
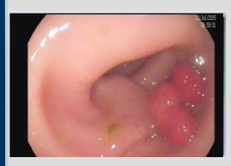
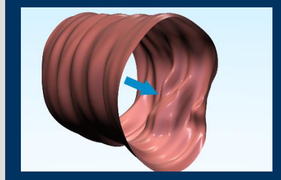
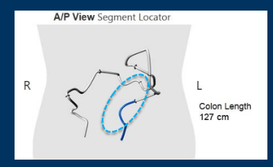
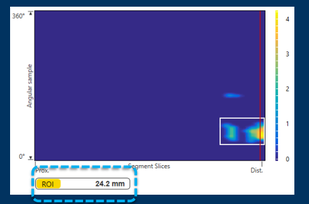
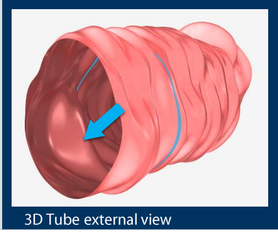
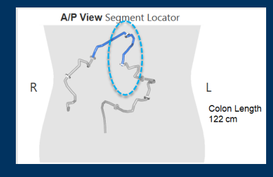
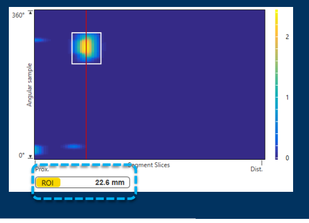
Methods:

A novel ultra-low dose X-ray based imaging capsule, generates high-resolution 2D and 3D imagery of colon segments, without bowel preparation.



Volunteers drink a small amount of contrast agent (~1 TBSP) with each meal during capsule passage. As the capsule moves naturally, it scans the inner lining of the colon in a 360 degree arc, scanning only when in motion.

Capsules were swallowed by 66 volunteers aged 41-74 years. The capsule localization system tracked its movement, using RF telemetry. The system performed scans upon detecting effective capsule motion in the colon and transmitted imaging data to an external recorder unit attached to participants' lower back. Combined data from colon scans and the localization system were used to reconstruct 2D and 3D colon segments in non-prepped colons. Total transit time and total X-ray exposure were calculated to assess the safety profile of the capsule in human subjects.

Case Study		Colonoscopy Finding: Picture taken during colonoscopy	Colonoscopy Finding: Polyp type, size, location	Screening Capsule Finding: 3D Tube - Reconstruction of the inner lining of the colon	Screening Capsule Finding: Segment Locator on reconstructed colon model	Screening Capsule Finding: 2D segment height map with Polyp measurement tool
1	Male Age : 52 Weight: 75 Kg Height: 170 cm Transit Time: 88 h		Pedunculated polyp **5 -10** mm **Ascending** colon	 3D Tube external view		
2	Male Age : 62 Weight: 70 Kg Height: 172 cm Transit Time: 42 h		Flat sessile polyp on a haustra **12 - 14** mm **Ascending** colon	 3D Tube Flythrough view		
3	Female Age : 49 Weight: 60 Kg Height: 161cm Transit Time: 50 h		Pedunculated polyp **30** mm **Sigmoid** colon	 3D Tube Flythrough view		
4	Male Age : 62 Weight: 97 Kg Height: 170 cm Transit Time: 43 h		Sessile polyp **20-30** mm **Sigmoid** colon	 3D Tube external view		

Results:

The volunteers were exposed to an ultra-low total radiation dose 0.062 ± 0.042 mSv (equivalent to 1 dental X-Ray) for the entire procedure. The capsule detected polyps of different size, shape and location in the colon. Polyps were considered "same position" compared to colonoscopy finding if they were detected in the same colon segment. Polyps were considered "same morphology" if they presented similar features. Average total transit time was 62 hours. There were no reports of capsule malfunction or side effects which might have compromised the participants' safety.

Conclusion:

Safety evaluation of a novel, preparation-free, X-ray imaging capsule and correlation of clinical findings to colonoscopy has been performed. **Quantitative ultra-low dose X-ray imaging and detection of polyps of different sizes and polyp types was achieved in non-prepped colons of human subjects**.

Further efficacy validation of this X-ray based CRC screening technology will be performed in multicenter studies.

Dr. Nathan Gluck, Dr. Menachem Moshkowitz, Dr. Beni Shpak – No conflict of interest

Dr. Seth A. Gross is a member of Check-Cap's Scientific Advisory Board

Prof. Nadir Arber is a member of Check-Cap's Scientific Advisory Board, a Medical Director and a leading investigator in its multicenter clinical study

Contact information: nadira@tlvmc.gov.il