



CADe (SKOUT®) Improves Adenoma Detection Without Increasing Resection of Non-Neoplastic Lesions

Research Goal

Investigate if colonoscopy with a real-time "CADe" device (SKOUT) is superior to standard colonoscopy in increasing the adenomas detected per colonoscopy (APC) without resulting in an increase in resection rates of non-neoplastic lesions, as measured by true histology rate (THR).

US-based multi-center randomized controlled trial

CADe (SKOUT) vs Standard of Care

Clinical Relevance

While colonoscopy is the gold standard of colorectal cancer screening, it is highly operator dependent, and studies suggest that up to 26% of adenomas are missed. Technologies that enhance adenoma detection could positively impact patient outcomes.

↑ 1% increase in ADR
↓ 3% decrease in risk of interval CRC²

Adenoma detection rate (ADR) is a common measure of colonoscopy quality, but APC allows for deeper understanding of CADe's ability to enhance detection of clinically significant polyps.

FIGURE 1: Computer-aided polyp detection (SKOUT)

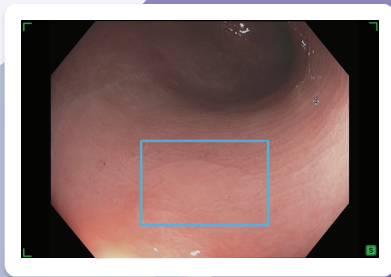
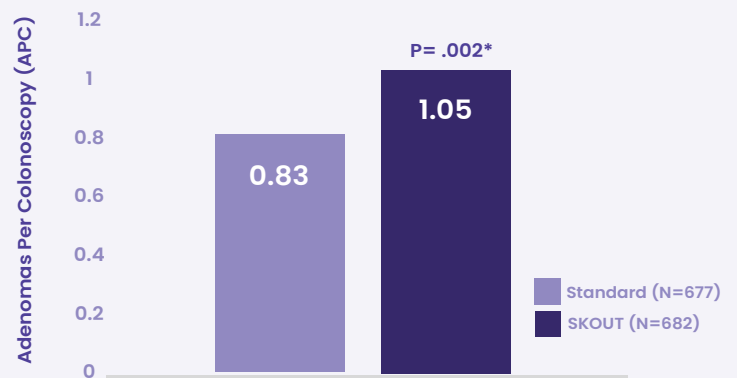


FIGURE 2: 27% relative increase in APC with CADe (SKOUT)



Computer-Aided Detection (CADe) Improves Adenomas per Colonoscopy for Screening and Surveillance Colonoscopy: A Randomized Trial¹

Aasma Shaikat, David R. Lichtenstein, Samuel C. Somers, Daniel C. Chung, David G. Perdue, Murali Gopal, Daniel R. Colucci, Sloane A. Phillips, Nicolas A. Marka, Timothy R. Church, and William R. Brugge, for the SKOUT Registration Study Team
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Methodology

Prospective randomized study designed to reflect the real-world, average risk US population

Primary endpoints:

adenomas per colonoscopy (APC) and true histology rate (THR)

Secondary outcome measures:

adenoma detection rate (ADR), polyps per colonoscopy, corrected withdrawal time, and more



1,359 screening and surveillance patients

Exclusions:

- Incomplete procedures
- Diagnostic indications
- Inflammatory adenomas
- Familial adenomatous polyposis



22 gastroenterologists

- US board certified
- Minimum ADR of 25% (actual baseline ADR: 44%)
- At least 1000 colonoscopies performed



5 US academic and community centers

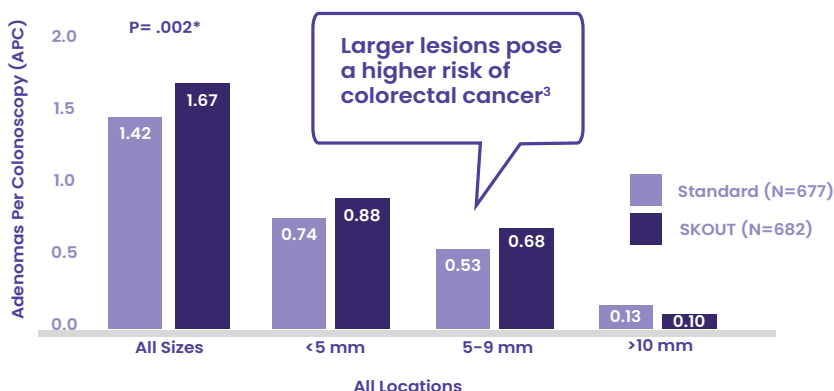
- Concord Endoscopy Center
- Mount Auburn Hospital
- Massachusetts General Hospital
- Boston Medical Center
- MNGI Digestive Health

Results

CADe (SKOUT) vs. standard colonoscopy among experienced endoscopists:

- Significantly improved APC in both screening and surveillance populations (27% relative increase), without a concomitant increase in resection of non-neoplastic lesions (THR).
- Increased ADR to 47.8%, from 43.9% in the standard arm (~4% absolute increase).
- Increased polyp detection per colonoscopy in the proximal colon (18% relative increase), including 5–9mm proximal polyps (44% relative increase).
- Had no significant impact on withdrawal or total procedure time.

FIGURE 3:
CADe (SKOUT) improves detection of 1–9mm polyps



“The colon has many challenges. Things can hide, and some polyps are hard to detect. SKOUT is enhancing our colonoscopy by allowing us to do the same thing in a more effective way.”

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1. Shaukat A, Lichtenstein D, Somers S, et al. (2022). Computer-Aided Detection Improves Adenomas per Colonoscopy for Screening and Surveillance Colonoscopy: A Randomized Trial. *Gastroenterology*. <https://pubmed.ncbi.nlm.nih.gov/35643173/>
2. Corley DA, Levin TR, Doubeni CA. Adenoma detection rate and risk of colorectal cancer and death. *N Engl J Med*. 2014 Jun 26;370(26):2541.
3. Bonnington, S. N., & Rutter, M. D. (2016). Surveillance of colonic polyps: Are we getting it right?. *World journal of gastroenterology*, 22(6), 1925–1934. <https://doi.org/10.3748/wjg.v22.i6.1925>