

Use of a Novel Articulating Knife with Advanced Endoluminal Surgical Platform for Colorectal Polyp ESD: Learning Curve Analysis of Skill in Expert and Novice Operators

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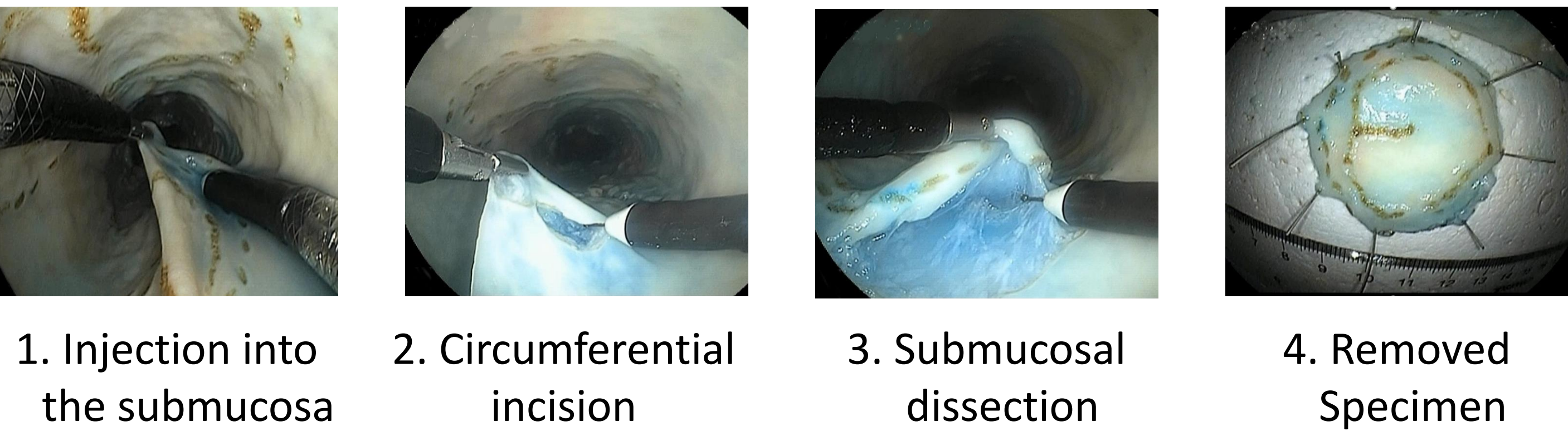
Background

- Complex colorectal polypectomy e.g. ESD is a challenging technique with high complication rate and long learning curve.
- We previously reported the feasibility of a unique endoluminal surgery method with endoscopic double balloon oversheath platform (Dilumen C2, Lumendi Ltd, Westport CT USA) to overcome the challenges of endoscopic complex polypectomy.
- We tested a unique ESD method with a novel endoluminal interventional knife (Ik, Lumendi) which was designed to use especially with DilumenC2.

Methods

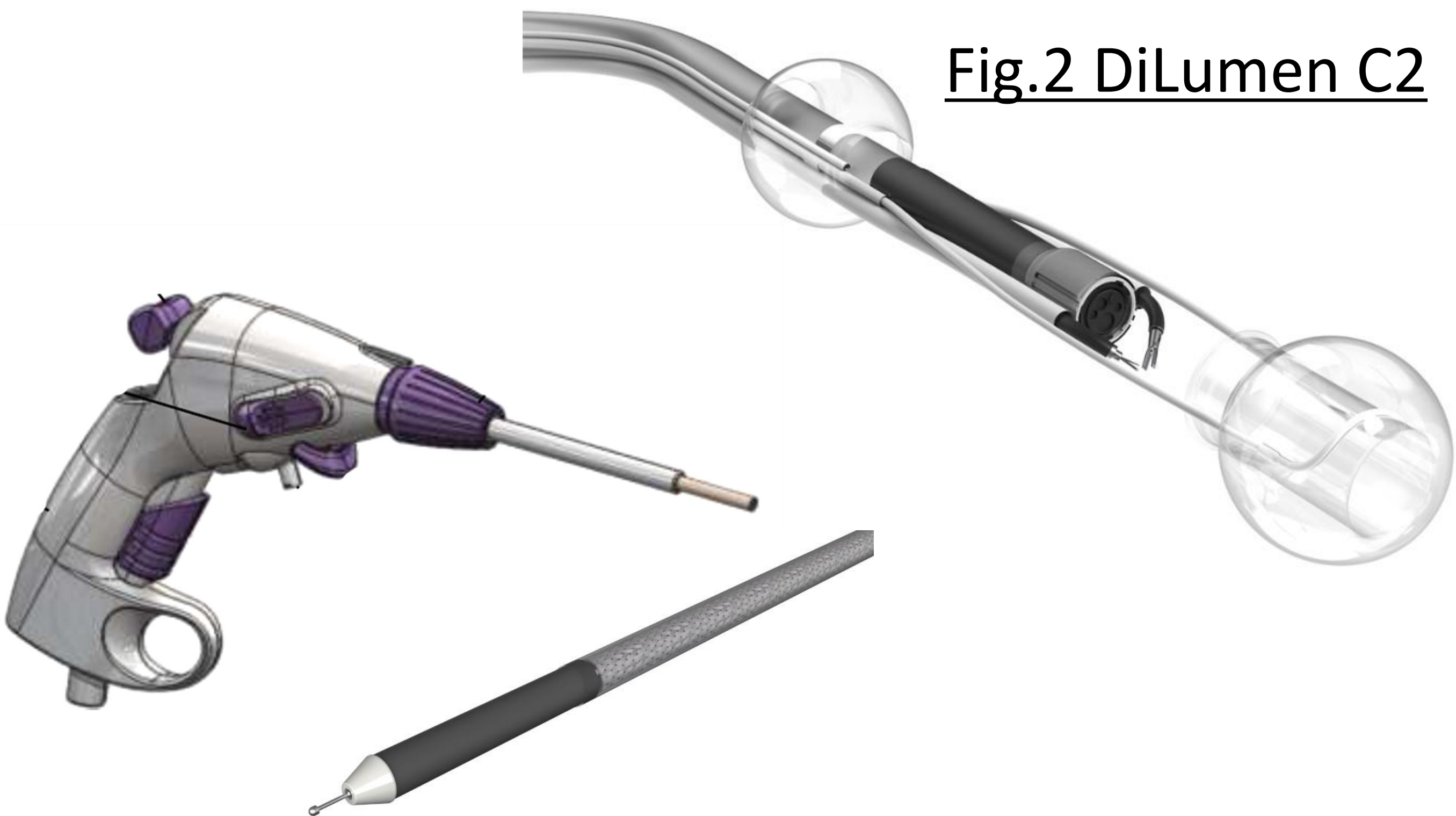
- a 2.5 cm pseudopolyp was created about 25-30 cm from the anus in ex vivo colon model.
- Ik and instrument grasper (Ig) was used to remove the pseudopolyp with a 5 mm margin (Figure1).
- We evaluated an early learning curve. Parameters measured: Procedure time and complications e.g. muscle layer damage and perforation

Fig.1 ESD procedure with DiLumen C2 and Ik



Platform and Instrument

- Dilumen 2nd generation overtube equipped with 2 instrument channels (Figure2).
- The endoluminal interventional knife (Ik), a flexible articulating and electrosurgical device, was newly cleared by the Food and Drug Administration (Figure3).



Conclusions

- ESD model using a colonoscope equipped with a double balloon oversheath and a novel articulating endoscopic knife (Ik) enabled complete, safe, and rapid polypectomy even by less experienced physicians.
- Using Ik with the endoscopic double balloon oversheath platform could become an effective option for ESD of large polyps.

Results

- 5 operators performed 5 procedures each in this study.
- Expert operators (n=3): significant experience with endoscopic polypectomy (>30) and with our endoluminal surgery platform (10).
- Novice oerators (n=2): a small number of endoscopic polypectomy experience (10) and no endoluminal surgery training.

Fig.4 Total procedure time

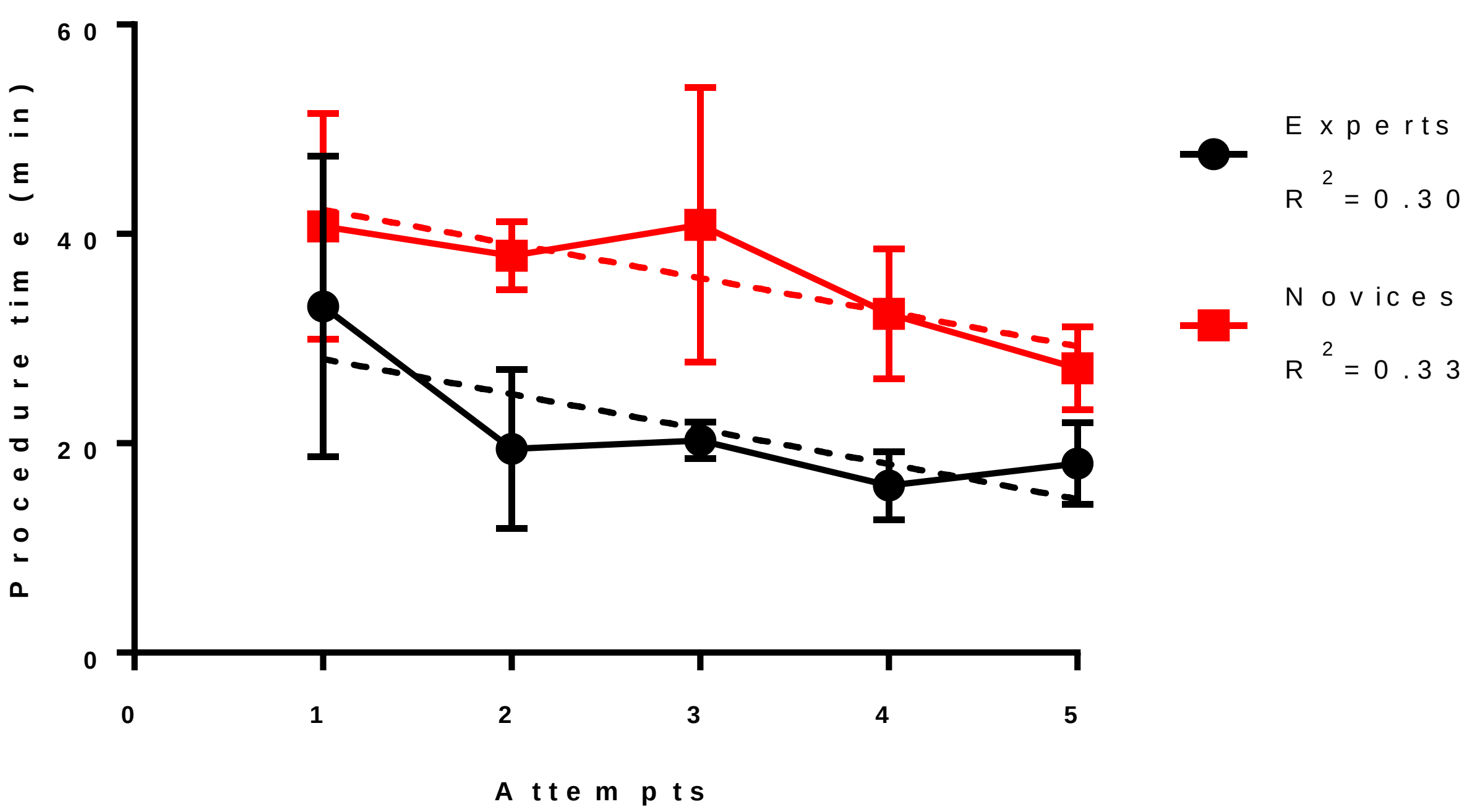


Table1 Performance and Complication

Parameters	Expert (n=3) Experience: polypectomy >30 Our platform ESD 10	Novice (n=2) Experience: polypectomy 10 Our platform ESD 0	p
Completion rate (%)	100% (15/15)	100% (10/10)	>0.99
Mean procedure time (min)	21.4 ± 9.0	35.8 ± 8.4	<0.01
Shallow muscle layer damage number (n)	3.6 ± 2.4	2.6 ± 1.4	0.38
Deep muscle layer damage number (n)	0.1 ± 1.0	1.4 ± 0.7	<0.01
Perforation rate(%)	0%	0%	>0.99