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Original Research

Endoscopic stabilization device evaluation using IDEAL framework: A quality improvement study

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ABSTRACT

Objective: To determine whether clinical evaluation reporting using the IDEAL (Idea, Development, Exploration, Assessment and Long-term study) framework improves a novel double-balloon endoscopic stabilization technology.

Design: Observational registry 6 month study with no follow-up. Using the Prospective Development Study (PDS) format recommended by the IDEAL collaboration, we report on continued refinement and optimization of an endoscopic stabilization platform during a clinical study conducted by two clinicians from the first case onwards. Key outcomes (ability to reach cecum, inflation of balloons in the sigmoid and ascending colon, and complications) were prospectively reported for each patient sequentially. All changes to technique were highlighted, showing when they occurred and an explanation for the change.

Results: 30 colonoscopies were undertaken using the device from April to September 2017. Two patients were excluded from the analysis for protocol deviations. Cecum was reached in 89% of the per protocol population of patients in an average time of 13.5 ± 11 min. Therapeutic zone creation was successful in 89% of patients on the right side of the intestine and 100% in those that reached the sigmoid. There were five deliberate changes in technique that occurred during the study that enabled improved device technical performance. There were no serious complications and one polyp was removed successfully using the device. Clinicians reported endoscope stability and increased visibility of the intestinal mucosa increased when using the device.

Conclusion: The IDEAL framework provided a structured reporting of the changes made to technique. Those changes facilitated a device that is safe, has achieved stability with improved performance.

1. Introduction

An increasing number of patients in the United States undergo surgical resection for benign colorectal polyps despite the availability of advanced endoscopic polypectomy (AP) methods e.g. Endoscopic Mucosal Resection (EMR) and Endoscopic Submucosal Dissection (ESD) [1]. Formal surgical resection carry significant risks [2]. One reason for this trend is the technical difficulty in performing complex endoscopic polypectomy procedures [3,4]. Such challenges include difficulty in visualizing the appropriate mucosal and submucosal areas coupled with poor Flexible Endoscope (FE) tip stability, resulting in long procedure times [5], serious complications (e.g. perforation [5–7]), and increased rates of polyp recurrence [8].

Despite the recent rapid growth in medical device technology, the overall number of randomised controlled trials and systematic reviews evaluating these innovations remains small [9]. Success of the intervention often depends on the skill and judgment of the individual clinician and is not always applicable to the general specialist population. The reporting is often undertaken in such a way that omits the clinicians learning curve and decision changes, often including general data e.g. whole data set averages. Some recent medical technology has led to serious post-procedure complications [10,11], hence raising questions about how medical devices are evaluated.

The Idea, Development, Exploration, Assessment and Long-term study (IDEAL) methodology is a useful framework for early-stage medical device clinical evaluation [9]. This framework for device application was developed in collaboration with manufacturers [12] and subsequent FDA guidances are aligned with this approach [13]. The key principle in the IDEAL method is transparency with recommendations for structured reporting of first-in-human experience and early clinical usage (IDEAL stages 1- 2a) in a format termed the Prospective Development Study (PDS). There is a need to formally record unsuccessful interventions, so as to avoid unnecessary repetition by peers. In Stage 1 (Idea), all new procedures are reported automatically via an online registry. Such reports should include adverse events. Subsequent developmental stage (IDEAL 2a) should be prospective with reporting of all cases and outcomes without omissions, and, with clear explanations of when and how technique, design, or indications were changed.

We postulated that the inability to perform AP procedures efficiently was in a large part due to the challenges of FE stability and visualization and so we set about designing and building a device to meet these needs. In this study we outline our initial human experience to date with Doubleballoon Endoscopic Interventional Platform (DEIP). We aimed to determine outcomes of the device with primary (ability to

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reach cecum) and secondary endpoints (time to cecum, ability to set up a Therapeutic Zone (TZ) in both the colon right and left side). This study on IDEAL stage 1 reports our early experience with this innovative device.

2. Patients/materials and methods

2.1. Study protocol and design

This was an observational registry study of 30 patients to assess safety and feasibility. Institutional Review Board (IRB) approval was granted. Prior to the study, the DEIP had never been used in a human colon. The work was reported in line with the Standards for Quality Improvement Reporting Excellence (SQUIRE) criteria [14].

This was a PDS to determine (1) whether a colonoscope equipped with the DEIP could be advanced to the cecum successfully (primary endpoint) and (2) have its two balloon system deployed successfully in both the right and left colon to create TZ (secondary endpoint). Consecutive patients who were judged suitable for routine surveillance colonoscopy or advanced polypectomy without contraindications were eligible for the study. No restrictions were imposed on BMI or age. Patients with previous history of diverticulitis, strictures or previous abdominal surgery were excluded from the study.

2.2. PDS documentation

Following the IDEAL Recommendations, we documented sequentially all patients included in the study from the first case performed using the device and the principal outcomes of interest in each case. When we made changes to the procedural technique or indications, we annotated the point in the series where this occurred. For the patients undergoing the procedure, we documented procedural time, occurrence of any complications and any additional procedures performed.

2.3. Device description

The device was manufactured according to specific criteria and cleared for clinical use under 510(k) K162428 by the Food Drug Administration (FDA) in December 2016.

The DEIP (see Fig. 1) consists of a 168 cm flexible oversheath with two independently inflatable balloons of 6 cm maximal diameter. The Aft-Balloon (AB) sits behind the endoscope tip and is fixed in position whereas the ForeBalloon (FB) is able to be moved beyond the endoscope tip to provide variable inter-balloon distance control. The push-rods were used to deploy the FB from the endoscope tip (see Figs. 1 and 2). With the FB extended beyond the FE tip and both balloons inflated this was termed the TZ (see Fig. 2). The adult or pediatric FEs were passed through the sheath and locked at its base using water as a lubricant. The base was then connected to an inflation handle, permitting individual inflation or deflation of the selected balloon. The internal

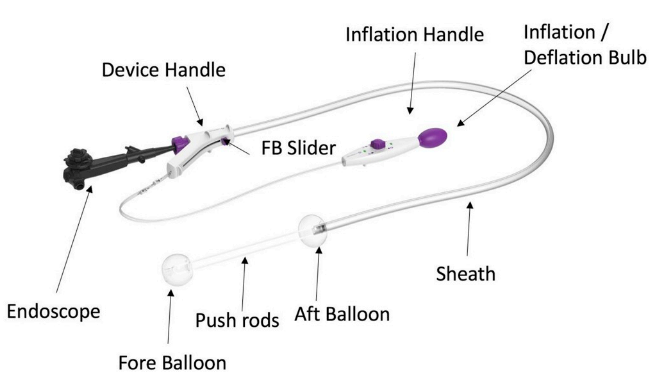

Fig. 1. Doubleballoon Endoscopic Interventional Platform overview.

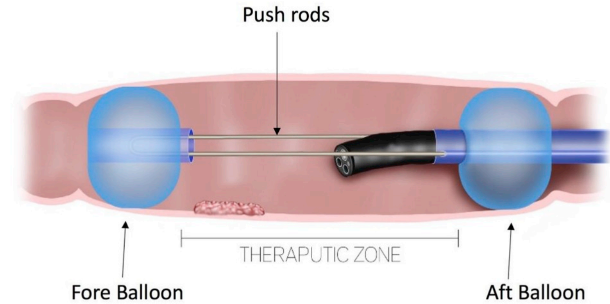

Fig. 2. Doubleballoon endoscopicl interventional platform therapeutic zone.

pressure of the balloons when fully inflated is approximately 55 mmHg. This inflation pressure is limited through the use of safety check valves within the inflation handle. The AB provided endoscope tip stability (and thus camera position), whereas the adjustable FB provided mucosal gripping, the ability to flatten folds and straighten flexures.

2.4. DEIP use

The patient was positioned in lithotomy (operating room only) or in left lateral orientation. After per rectum examination, the DEIP was mounted on the FE and both inserted into the anus after lubrication. The sigmoid colon was generously irrigated with water to traverse its generally smaller calibre through lubrication. The colonoscopy was completed as usual and upon reaching the cecum, appropriate pictures were taken and the terminal ileum intubated. After this the FE and device were retracted slowly towards the anus carefully noting the mucosal surface for any abnormalities e.g. polyps. During withdrawal, at both the ascending and sigmoid colon, both the AB and FB were inflated and deflated after TZ set-up (see Fig. 2). After this, the sequence was reversed and the FB re-docked onto the endoscope tip. When lesions e.g. polyps were encountered, the clinician would manage them in the normal fashion. Any difficulties in endoscopic navigation e.g. looping were managed in the typical fashion i.e. abdominal pressure and patient position change. After completing the procedure, the DEIP and FE were removed from the patient and the DEIP discarded (device is single-use).

2.5. Training and clinician experience

The clinicians at began using the platform in April 2017, after suitable training. The doctors developed their familiarity with the platform in both the Kyoto-Kagaku endoscopic trainer and an ex-vivo porcine intestinal model by performing basic and advanced procedures. Both doctors had over 10 years experience with advanced endoscopic techniques, one of whom practices as a board-certified therapeutic endoscopist and the other a board-certified colon and rectal surgeon. The endoscopy unit performs approximately 100 advanced endoscopic procedures a year (EMR and ESD).

3. Results

There were 11 men and 19 women included in this study, with age ranging from 35 to 83 years (mean 63.6 years ± 12 standard deviation). All cases were completed within a 6 month time period (April to September 2017) (see Table 1). Two patients were excluded from the analysis due to protocol deviations (safety concern due to diverticular disease precluded fufillment of protocol-patient 13, previous abdominal surgery – patient 26).

Primary endpoint - Reaching Cecum.

Cecum was successfully reached in 25 of the 28 (89%) patients (Intention to treat (ITT) group = 83%). Average time to reach cecum was 13.5 min, this was the same as the ITT group (Range: 3–48).

Table 1
Doubleballoon Endoscopic Interventional Platform Results: IDEAL format (Intention to Treat population).

Case Number	Time to Cecum (min)	Therapeutic Zone Right Side?	Therapeutic Zone Left Side?	Lesion(s)	Intervention with platform?	Comments
1	8	Yes	Yes	1 x biopsy - Ascending colon	Yes	Push rod malfunction (kink)
2	10	Yes	Yes	1 x biopsy - Splenic Flexure	Yes	Push rod malfunction (break)
3	12	Yes	Yes			Push rod malfunction (kink),. mucosal abrasions.
4	45	Yes	Yes			Push rod malfunction (kink),. mucosal abrasions.
5	20	Yes	Yes			Push rod malfunction (kink)
6	DNR	NE	NE			Push rod malfunction (kink)
7	12	Yes	Yes			
8	4	Yes	Yes			
9	8	Yes	Yes			
10	12	No				Push rod malfunction (break).
11	13	Yes	Yes			
12	4	Yes	Yes			
13	NE	NE	NE			
14	48	Yes	Yes			Mucosal Abrasions
15	26	Yes	Yes	3 x biopsy - Hepatic Flexure	Yes	
16	DNR	NR	NR			Push rod malfunction (break).
17	5	Yes	Yes			
18	5	Yes	Yes	2 x biopsy - Sigmoid	Yes	
19	10	Yes	Yes			
20	15	Yes	Yes			
21	10	Yes	Yes			
22	6	Yes	Yes			
23	15	Yes	Yes	1 x biopsy ascending colon and transverse colon	Yes	Mucosal Abrasions
24	15	Yes	Yes	1 x biopsy cecum-and transverse colon	Yes	
25	17	Yes	Yes			
26	DNR	NE	NE	2 x biopsy ascending colon	Yes	
27	8	Yes	Yes	4 x biopsy and 1 polypectomy	Yes	
28	DNR	NE	NE			
29	6	Yes	Yes			
30	3	Yes	Yes			Mucosal Abrasions

*NR = Not recorded.
DNR = Did not reach cecum NE = Not expected due to balloon inflation not attempted.

The reasons for inability to reach the cecum in three patients were as follows:

1) FE without DEIP could not reach cecum due to tortuosity and long length of colon (patient 6).
2) A long tortuous colon caused device malfunction (patient 16).
3) A long tortuous colon led to device removal (patient 28).

Additional procedures: Eight patients received additional interventions with DEIP due to findings observed during the procedure. These interventions were primarily previous site biopsies. One patient required polypectomy (EMR) which was successful.

Secondary endpoint – Therapeutic Zone creation (see Fig. 3).

In the Per protocol population, therapeutic zone creation was successful in 89% of patients where the device reached the right side of the intestine and 100% in those that reached the sigmoid.

There were no perforations, instances of bleeding post procedure, or deaths. Non-clinically significant mucosal abrasions were noted in five patients (17%). All patients were discharged on the same day of the procedure.

4. Procedure strategy evolution and lessons learned

During the whole series we made 5 changes to our procedural policy through the IDEAL methodology (see Fig. 4). These were:

1. At patient 2, we adjusted the position of the patient to left lateral as opposed to lithotomy with leg stirrups, this allowed greater flexibility in patient positioning whilst performing the procedure.
2. At patient 6, we altered our loading position of the DEIP on the FE to placing the DEIP device handle (see Fig. 1) back to the endoscope handle hilt. This was due to kinking of the push rods observed due to maximal retroflexion of the FE whilst traversing the sigmoid colon.
3. The loading position change was stopped after one case due to increased mucosal abrasions observed (case 7) and reverted to the original position (endoscope tip 1 cm proud of the FB).
4. From patient 12 onwards, we adopted the use of lubrication as a device mounting method (applying the usual water based surgical lubricant onto the endoscope) allowing the device to behave more as an overtube whilst maintaining endoscope functions.
5. From patient 12 onwards, we advocated the use of a primary endoscope prior to device use in order to assess intestinal anatomy, straighten out sigmoid colon and plan treatment if necessary. This method was supported by literature [15].

4.1. Change result

Prior to last change (patient 12), push rod kinking and breakage occurred in 7 out of 11 patients. After change was implemented, 1 push rod kinking and breakage was observed in 19 patients (P = 0.01).

4.2. Additonal subjective clinician observations

The clinician reported the balloons to be easily inflated and deflated in the ascending and sigmoid colon. Clinicians also reported increased stability of the FE tip upon balloon inflation and improved mucosal vizualisation in the TZ.

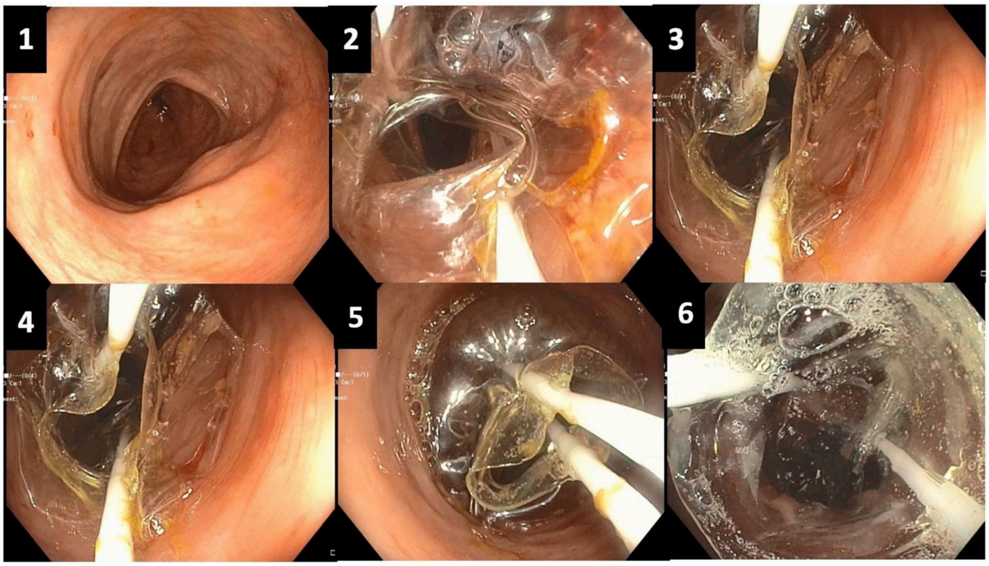

Fig. 3. Doubleballoon Endoscopic Interventional Platform Foreballoon deployment and re-docking. Top left – Lumen endoscopic view; Top middle – Foreballoon deployment; Top right – Foreballoon full extension; Bottom left – partial inflation of foreballoon; Bottom middle – full inflation of foreballoon; Bottom right – retraction of foreballoon and dock on endscope tip.

5. Discussion

In this study we determined the first-ever outcomes using DEIP in 30 patients following IDEAL PDS documentation format. We found that in 89% of cases in the per protocol population the cecum was reached which is in keeping with previous data on reaching the cecum without an add-on device [16,17]. The time taken to reach the cecum was again within normal limits.The vast majority of patients were able to have the TZ set up in the right and left colon.

Balloon use in the GI tract has predominantly focused on small bowel locomotion through the use of double-balloon enteroscopy. However, relatively recently, the utility of GI balloons in assisting advanced endoscopic procedures in the large intestine has been explored. Yamashina and colleagues recently reported on the use of double balloon assisted ESD (BAE) in achieving safe and reliable resection of superficial proximal colon tumors in colonoscopically difficult situations

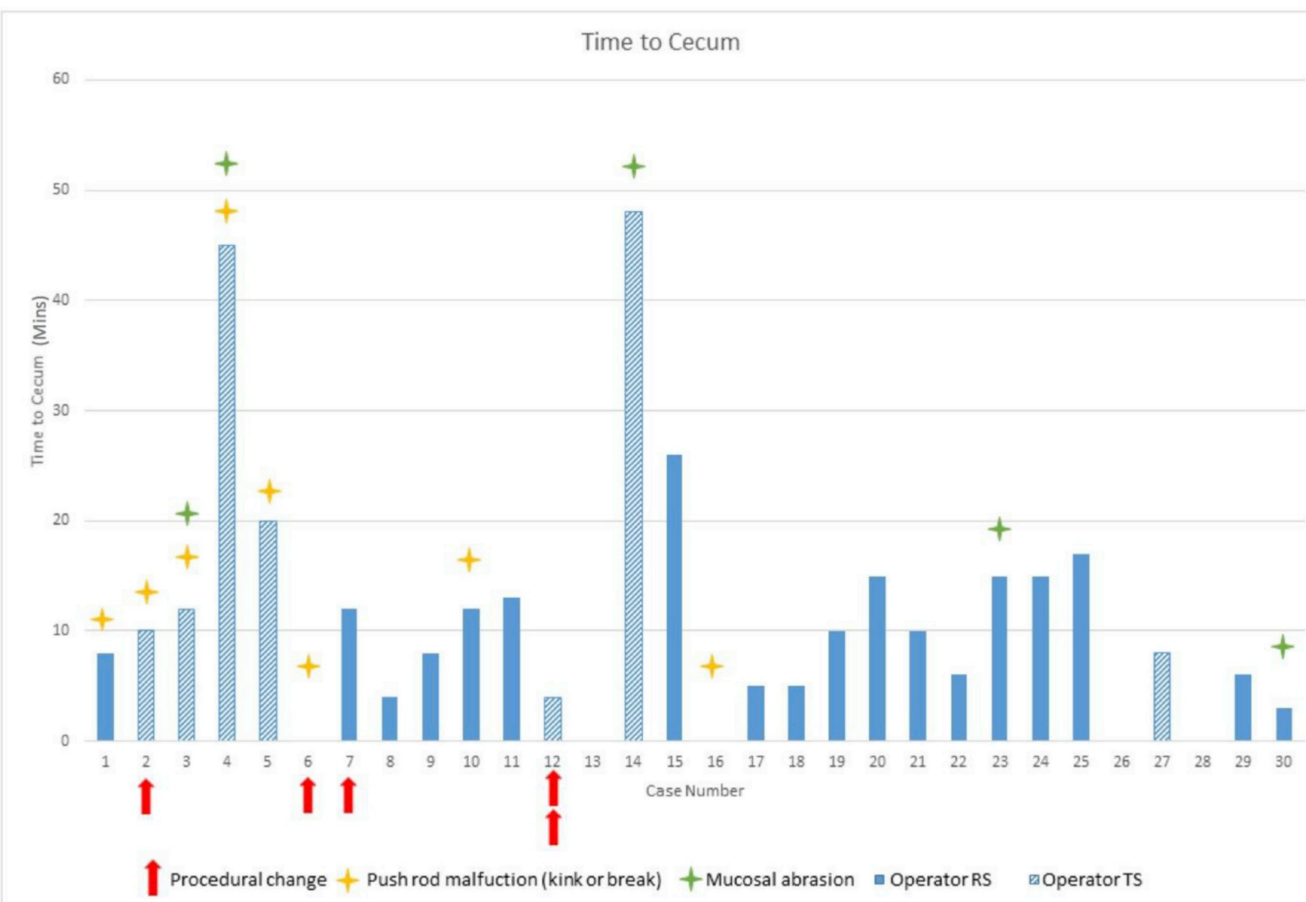

Fig. 4. Time to cecum with identification of complications with procedural change (Intention to Treat population).

[18]. They focused on patients with proximal colon lesions that had previous difficulty with routine colonoscopy, namely an inability to reach the lesion or unstable endoscope control. However, this study used a small bowel enteroscope with both balloons located behind the endoscope tip (short-type double-balloon endoscope EC-450BI5 with TS-13101 or BI-530B with TS-13101; Fujifilm). Here the procedure was generally performed by two people – an endoscopist and an assistant to control and hold the overtube. Hotta et al. has also previously reported that BAE is effective for polypectomy, EMR, and biopsy of all colorectal tumor locations [19].

DEIP builds on the key concepts of endoscopic stability and visualization, but adding novelty to the field through the use of a deployable fore-balloon which is extended out in front of the endoscope tip. This provides tissue tension, fold flattening and the straightening of flexures. In addition, DEIP procedures were single clinician operator and only required assistance with balloon inflation.

Through systematic implementation of five procedural changes we found that these modifications resulted in increased device stability and performance:

1. Use of the DEIP over a standard adult or pediatric colonoscope appeared safe in traversing the entire colon.
2. In both the right and left side of the colon the FB can be deployed off the tip of the endoscope and a TZ established.
3. Mounting position of the device on the FE is critical.
4. The device has value in allowing improved stability and visualization.
5. The position of the patient should be kept flexible as in conventional colonoscopy, both in the endo suite and OR.
6. The use of lubrication as a mounting medium (compared to water) may add favourable movement characteristics to the endoscope.
7. The use of a primary endoscope prior to device use reduced kinking of the pushrods and difficulty traversing the sigmoid colon.

There are several limitations with this study. This was a single center study in a tertiary referral center with two clinicians of significant experience. Whereas training was provided, clinicians may have still been on their respective device learning curve. The number of patients included in the study are small and although these results do add confidence regarding the overall safety of the device, this evaluation is still on-going.

Looking to the future, we would envisage expanding to IDEAL Stage 2a, as this would allow facilitated progression to an Randomised Controlled Trial (RCT) by addressing learning curves, consensus on indications where the device appears to have superiority, patient selection criteria and patient/clinician willingness to participate. A formal device registry will continue to record DEIP cases throughout the US. We plan to continue to assess the clinician learning curve and evaluate the use of the device in advanced polypectomy methods such as EMR and ESD.

In describing our experience with the device to date, we believe we have demonstrated initial safety and effectiveness of DEIP in its primary functions. We have also outlined the initial problems encountered in device use and the remedies taken at both a methodological and research and development standpoint to solve such issues in a concise manner. We conclude that the technology has achieved stability and improved performance and is now ready for use with larger number of clinicians.

Ethical approval

Cornell Irb (Number: 1610017641).

Author contribution

SHARMA: study design, data collections, data analysis, writing.
MOMOSE: data collections, data analysis.
SEDRAKYAN: data collections, data analysis, writing.
SONODA: study design, data collection.
SHARAIHA: study design, data collections, data analysis, writing.

Conflicts of interest

None.

Research registry number

Clinicaltrials.gov registered (NCT03113578.

Guarantor

DR. REEM SHARAIHA.

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Sam K. Sharma: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Writing - original draft, Writing - review & editing. **Kota Momose:** Investigation, Writing - review & editing. **Art Sedrakyan:** Investigation, Writing - review & editing. **Toyooki Sonoda:** Investigation, Writing - review & editing. **Reem Z. Sharaiha:** Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Writing - original draft, Writing - review & editing.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijsu.2019.02.010.

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