

(H25)

<学会発表 (海外) >

1. 1) & 2) Saito Y. 3) Saito Y and Nakamura K as assistant for ESD live demos. 1) Endoscopic treatment of T1 carcinoma: criteria and methods. 2) Resection of colorectal neoplasia: cold-and hot snares, EMR, ESD. 3) Live Demonstrations. 1) Lecture at the Mini symposium: Challenges for endoscopic management of colorectal neoplasia. Oral presentation. 2) Debates at the Breakout sessions, "Snack with the Experts". Oral presentation. 3) Moderator and Live demos at the Mini-Symposium, Live-Demonstrations IV. 15th Dusseldorf International Endoscopy Symposium, 1<sup>st</sup> - 2<sup>nd</sup> Feb, 2013, Maritim Hotel Dusseldorf, Dusseldorf, Germany.
2. Saito Y. Decision making in Early Gastric cancer. Session 9 - Guest Lectures, Oral Presentation. Endoscopy Update Course-Quality, Safety & the Team in Endoscopy, 20<sup>th</sup> Mar, 2013, All Nations Centre Cardiff, Cardiff, UK.
3. Saito Y. 1) Colorectal ESD or Laparoscopic Surgery in the Proximal Colon. 2) Setting Standards in Therapeutic Endoscopy. 3) Large Rectal Polyps - ESD. 4) Complex/Difficult Lower GI Cases. 5) Hands on Stations, ESD. 1) Lecture at the Session 6 - Controversies in the Lower GI Tract. 2) Debates at the Session 8 - Panel Discussion & Audience Interaction. 3) Lecture at the Session 2 - Focused Video Tutorials & Technical Tips. 4) Chair at the Session 3 - Clinical Case Conference - MDT. 5) Live at the Session 4 - Post Lunch Breakout Sessions, Breakout Meet The Experts Sessions & Hands On Stations. 1), 2) & 3) Oral Presentations. 4) Chair. 5) Live demonstration. **Advanced Endoscopy Symposium**, 21<sup>st</sup> - 22<sup>nd</sup> Mar, 2013, All Nations Centre Cardiff, Cardiff, UK.
4. Saito Y. 1) Advanced Therapeutic Colonoscopy. 2) Perforations During Colonoscopy. 1) Demonstrations at the ASGE Hands-On Workshop Session. 2) Lecture at the ASGE Clinical Symposium, Perforations and Fistulae: How Should You Manage Them?, Oral presentation. DDW 2013, 18<sup>th</sup> -20<sup>th</sup> May, 2013, Orange County Convention Center, Orlando, FL, USA.
5. Saito Y. 1) How to become a Master in Colorectal Polyp Resection. 2) Principles of Colorectal Endoscopic Submucosal Dissection (ESD). 1) "Meet the Professor" with the GI Fellows, Oral presentations. 2)

- Master Endoscopist Grand Rounds, Oral presentations. UAB Distinguished Faculty Congress for UAB Basil Hirschowitz master Endoscopist Award, 23<sup>rd</sup> May, 2013, University of Alabama at Birmingham (UAB) Medical Center, Birmingham, AL, USA.
6. Saito Y. 1) Traction of effective dissection: adjunctive methods are required. 2) Moderator for GIF: ESD/EMR Forum II. 3) Moderator for LGS-IV: Urgent Issues in Colon: When Do We Need Urgent colonoscopy? 4) Adjunctive methods for easier colorectal ESD: Sinkers, specialized clip, and others. 1) Debates on Colorectal ESD at the Session, LGS-II. 2) Video Lecture. 3) Session. 4) Lecture at the Session, LGS V: Tips and tricks for Better Endoscopic Treatment of Colorectal Tumors. 1) & 4) Oral presentations. 2) & 3) Moderator. IDEN 2013 with the 12th KJSGE, 8<sup>th</sup> - 9<sup>th</sup> June, 2013, Grand Hilton Seoul, Seoul, Korea.
7. 1) & 3) 齋藤 豊 2) 齋藤 豊、森 源喜 (ライブ助手) 1) 日本における大腸・直腸 ESD の現状—早期がん、大寸法がん、難部位がん、LST への対処法 国立がん研究センターにおける最近 10 年の治療実績 2) マスターコース (ライブ)、3) 大腸 ESD 時の合併症と誤謬の克服 1) & 3) 口演発表、2) ライブ
- デモ、イルクーツク州保健省 ロシア連邦保健省イルクーツク医師再教育アカデミー腫瘍学講座 露日セミナー「内視鏡学におけるイノベーションテクノロジー」、2013. 7. 29-30、州立がんセンター、イルクーツク市、ロシア (書類はロシア語から通訳者による和訳のみ。)
8. Saito Y. 1) How to perform submucosal resection and its potential. 2) How to improve detection and characterization of early colorectal neoplasms. 1) & 2) Lectures at Module 1: Colon cancer: "The best treatment for complex polyps". 1) & 2) Oral Presentations. II Latin American Symposium, ENDOSUR 2013, 20th Aug, 2013, Marriott Hotel, Santiago, Chile.
9. Saito Y. Image-Enhanced Endoscopy (IEE) in Japan. Lecture at WEO/A-PSDE/JGES, "Advanced Diagnosis Endoscopy Course (ADEC): Lower GI". Oral Presentation. GASTRO 2013 APDW/WCOG SHANGHAI, 23rd Sept, 2013, EXPO Convention Center, Shanghai, China.
10. Saito Y. 1) Live Endoscopy. 2) Screening strategies in the East. 3) Endoscopic treatment of dysplasia in IBD. 1) 3 Live Demonstrations at the UEG Week Live Demo experts. 2) Lecture at the Symposium, "East

- meets West: Colorectal cancer screening". 3) Lecture as expert at the Lunch Session. 1) Live demonstrations, transmission from the Sana Klinikum. 2) & 3) Oral presentations. UEGW 2013, 15th-16th Oct, 2013, ICC Berlin, Berlin, Germany.
11. Saito Y. 1) Introduction of training program in Japan. 2) Colorectal ESD: Oncologically safe? 3) Moderator at the Oral Presentation Session 1\_Lower GI. 1) Lecture at the Session IV "Colorectal ESD: Learning from Masters". 2) Lecture at the Debate Session II "Beyond Absolute Criteria of Endoscopic resection". 3) Moderator at the Oral Presentation Session 1\_Lower GI. 1) & 2) Oral presentations. 3) Moderator. The 7th Meeting of the Society of Gastrointestinal Intervention (SGI) 2013, 25th-26th Oct, 2013, Sheraton Grande Walkerhill Seoul, Seoul, Korea.
  12. 1) Saito Y. and Abe S. as assistant for ESD Live demos. 2) Saito Y. 1) Endoscopy Live. 2) What is the gold standard for the mucosa and submucosa? 1) Live demos. 2) Lecture at Endo Arena: High-endo endoscopy or histology. Oral presentation. ENDO CLUB NORD. 1st-2nd Nov, 2013, Congress Center Hamburg, Hamburg, Germany.
  13. 1) Saito Y. and Yamada M. as assistant for ESD Live demos. 2) Saito Y. 1) Colonic ESD and Therapeutic endoscopy. 2) Colonic ESD. 1) Live demos. 2) Lecture at State-of-the Art Lecture Oral presentation. 17th Digestive Endoscopy Course. 8th Nov, 2013, Minimal Access Surgery Training Centre, Hong Kong, China.
  14. Saito Y. 1) Japan experiences with colonoscopy screening. 2) Discussion with Asian neighbors. 1) Lecture at the Session II: For the Better CRC Screening Program in Asia. 2) Panelist at the Session III: Revision of Korean CRC Screening Guideline; Issues and Evidences. 1) Oral presentation. 2) Panelist. Colorectal Tumor Research Group Workshop. 4<sup>th</sup>-5<sup>th</sup> Jan, 2014, Alpensia Resort, Pyeongchang, Korea.
  15. Saito Y. 1) EAES Consensus Conference on Early Rectal Cancer. 2) ESD: Endoscopic Submucosal Dissection; Indications, Technique and Results. 1) Panelist as one of the selected expert. 2) Lecture and Live demo. 1) Oral Presentation and discussion. 2) Oral Presentation and Live demo. European Association for Endoscopic Surgery (EAES) Consensus

Conference on Early Rectal Cancer.

3<sup>rd</sup> - 4<sup>th</sup> Mar, 2014, University of Torino, Torino, Italy.

16. 1) & 2) Saito Y. 3) Saito Y. & Otake Y. as assistant for ESD Live demos.  
1) Working in the famous National Cancer Centre, Tokyo! 2) EMR vs ESD for colonic polyps, when and how? Japanese perspective. 3) Live demonstrations. 1) Lecture at Workshop Dinner, Special Dinner Lectures: 2) Lecture. 3) Live demos. 1) 2) Oral Presentation. 2) Live demos. ENDOSCOPY 2014, 29th -30th Mar, 2014, University of Malaya Medical Centre, Kuala Lumpur, Malaysia.

<学会発表 (国内)>

17. 齋藤豊: 大腸癌診断-色素・NB I 拡大内視鏡診断とESDに焦点を絞って-, 教育講演、第9回日本消化管学会総会学術集会、2013/1/26 京王プラザホテル本館5F「コンコードボールルームB」、東京都
18. 齋藤豊: Technical tips for success in advanced therapeutic colonoscopy-Current ESD indications and latest technical advances-. 講演 (英語)、大腸肛門病セミナー「7th Colorectal Disease Symposium in Tokyo」、2013/6/29 時事通信ホール、東京都

19. 齋藤豊: 大腸腫瘍の診断と治療 EMR/ESD の選択、講演、第26回日本消化器内視鏡学会関東セミナー、2013/7/21 都市センターホテル、東京都。

20. 齋藤豊: がんの早期発見・早期治療-大腸・食道・胃がん-, 基調講演1、市民公開講座 がんを予防して幸せに生きる! がんがあっても前向きに生きる! 2013/8/17 北本市文化センター、埼玉県北本市。

21. 齋藤豊: 大腸、教育講演、JDDW2013、2013/10/12 グランドプリンスホテル新高輪 国際館パミール 第1会場「北辰」、東京都。

22. 齋藤豊: 早期大腸がん-内視鏡診断と治療の最前線-, 教育講演3、第39回日本消化器内視鏡学会埼玉部会学術講演会、2013/11/9 大宮ソニックシティ 4階 国際会議場、さいたま市

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2. 学会発表
1. Saito Y.: ESD for Colon. Panelist at SAGES/JSES Panel: Endoscopic Submucosal Dissection (ESD) - When Will We catch Up With Our Japanese Colleagues? Oral Presentation and discussion. SAGES 2014, 4th Apr, 2014, The Salt Palace Convention Center, Salt Lake City, UT, USA.
2. Saito Y.: ASGE World Cup of

- Endoscopy. Chair at the Video Forum (5365).Moderator (Judge). DDW 2014, 6th May,2014, McCormick Place, Chicago, Illinois, USA.
3. Saito Y: Consensus conference Early rectal cancer. Panelist at Scientific session. Oral Presentation and discussion,WCES-PARIS 2014, 26th June,2014, Palais de Congrès, Paris, France.
  4. Saito Y: 1) Lower gastrointestinal bleeding. 2) Colorectal ESD. 3) ESD Live demos. 1) Lecture at Session 4 for Internists and General Practitioners. 2) Lecture at Session 1 for Gastroenterologists and Gastrointestinal Surgeons. 3) Hands on (Session I and Session II) .1) and 2) Oral Presentations at the symposium on July 5, 2014. 3) Transmission from Metropolitan Hospital at the Athens Endoscopy Live 2014 on July 4, 2014. 2nd Athens International Symposium, 5th July, 2014, 1)&2) Athens Hilton Hotel, 3) Metropolitan Hospital, Athens, Greece.
  5. Saito Y: 2) & 3) Saito Y and Ikezawa N as ESD Live assistant. 1) ESD on Lower GI tract. 2) Live endoscopy: Diagnosis. 3) Live endoscopy: Treatment. 1) Lecture. 2) & 3) Live demonstrations. 1) Oral Presentation. 2) and 3) Live demos. **Endoscopic Workshop, 10th Oct, 2014, Xijing Hospital, Xi'an, China.**
  6. Saito Y: 1) Resection approach for colonic LST. 2) Live demonstration of ESD in a Tissue model. 3) Hands on ESD stations. 4) Coffee & Discussion about ESD Knives. 1) Lecture. 2) Live demo. 3) Hands on. 4) Lecture and discussion, 1) and 4) Oral Presentations. 2) and 3) Live demos. **ESD (Endoscopic Submucosal Dissection) Workshop,16th ~17th Oct,2014, VIMAS Education Centre at Quad, Queen Alexandra Hospital, Portsmouth, UK.**
  7. Saito Y: Efficiency and clinical case presentation of BLI in colon. Lecture and Discussion. Oral Presentation, **FUJIFILM's UEG Week 2014 Satellite Symposium, 20th Oct,2014, ACV Vienna, Hall I/K, Vienna, Austria.**
  8. Saito Y: EFFICACY AND SAFETY OF ENDOSCOPIC SUBMUCOSAL DISSECTION FOR EARLY STAGE COLORECTAL NEOPLASIA; RESULTS FROM A NATIONWIDE REGISTRY THROUGHOUT JAPAN. Lecture at the Symposium "Endoscopic management of early colorectal neoplasia." Oral Presentation. **UEGW 2014, 21st**

- Oct,2014, ACV Vienna, Hall G/H, Vienna, Austria.
9. Oka S. and Saito Y: 1) Video recorded clinical cases of colorectal tumor and Quiz. 2) Video recorded clinical cases in esophagus carcinoma and quiz. 1) Lecture at the Scientific Program: WEO/A-PSDE/JGES ADEC, Session: Lower GI, Practice of narrow-band imaging (NBI) diagnosis. 2) Lecture at the Scientific Program: WEO/A-PSDE/JGES ADEC, Session 2: Upper GI. 1) & 2) Oral Presentations. APDW 2014, 24th Nov, 2014, Bali Nusa Dua Convention Centre, Room7, Bali, Indonesia.
  10. Saito Y. 1) Difficult Gastric ESD. 2) Endoscopic Submucosal Dissection a safe alternative to Laparoscopic Colectomy? 3) ESD with IT knife. 4) Flat lesions of right colon. 5) Videos Championship. 6) Difficult Mucosal Resection. 1) Lecture at the Symposium "Surgical treatment of early gastric cancer." 2) Lecture at the Symposium "Gastrointestinal Cancer." 3) Exhibitor at the Inaugural Conference "ESD with IT knife." 4) Lecture at the Symposium "New Concepts in Cancer Colo-rectal." 5) Arbiter at the Videos Championship. 6) Lecture at the Symposium "Complex Therapeutic Endoscopy." Oral Presentations. VII Uruguayan Congress of Digestive Endoscopy, IV National Meeting of Assistant Digestive Endoscopy, 1st National Conference for Young endoscopists, 1st International Workshop on Endoscopic Training in Simulated Models and 1st Latin American Forum of Digestive Neoplasm. 1st -3rd Dec,2014, Conrad Resort & Casino Punta del Este, Montevideo, Uruguay.
  11. Saito Y. 1) Colorectal ESD for masters: beyond the current limitations. 2) Lateral resection margin involvement by cancer: what's your plan? 1) Lecture at the Session III. ESD for Treatment of Early Colorectal Cancer. 2) Lecture at the Session IV. Lessons from Experts: How to Troubleshoot? Oral Presentations. 7th Asan International Digestive Disease Symposium (AIDDS 2014). 13th Dec,2014, Asan Hall, Asan Institute for Life Sciences 15F, ASAN Medical Center, Seoul, Korea.
  12. Saito Y. 1) Critics to ESD in Japan and in the West: facts & fictions. 2) Related perforations: prognostic factors and management. 3) ESD indications & results: today and tomorrow. 4) my difficult ESD commented by "Experts". 5) Colorectal ESD Live. 1) 2) 3)

Lectures for Introduction, ESD Technique, Early Colorectal Cancer. 4) Retraining. 5) Live demonstrations. 1) 2) 3) Oral Presentations. 4) Moderator. 5th Italian-Japanese Meeting "Curative Endoscopic Resection of Superficial Neoplastic Lesions" and "Colorectal ESD Live". 12th - 13th Jan, 2015, Circolo delle Forze Armate D'Italia and Ospedale San Giuseppe, Rome, Italy.

13. Saito Y. Presentations, Demonstrations, and Intensive hands-on as faculty for the ASGE

course, "ASGE JGES Masters' Course in ESD with Optional POEM Add-on". Feb. 27 - Mar.1, 2015, ASGE Institute for Training and Technology, Downers Grove, IL, USA

G. 知的所有権の取得状況

1. 特許取得  
なし。
2. 実用新案登録  
なし。
3. その他  
なし

厚生労働科学研究費補助金(医療機器開発推進研究事業)  
総合研究報告書

レーザー消化管内視鏡治療装置の開発に関する研究

研究分担者 貝瀬 満 虎の門病院 消化器内科

研究要旨

(株)モリタ製作所、大阪大学、神戸大学で開発してきた試作機に対し、生体ブタを用いた前臨床試験を神戸医療機器開発センター(MEDDEC)において行った。改良試作機はESDの操作に必要なパワーが十分得られた。本炭酸ガスレーザーシステムはin vivo 生体ブタにおいて、胃粘膜層を切開するが、粘膜層通過後粘膜下層注入材によってレーザー光が吸収され、血管や筋層を傷付けずに、安全に粘膜及び粘膜下層のみを選択的に切除することが出来、より安全な消化管内視鏡治療が実現された。また、止血においても、レーザーパワーを5Wに落として照射することにより、止血が十分可能であった。試作機改良を重ね、ほぼ最終のものと判断した。本事業年度内に3度PMDA薬事戦略事前相談を受けることが出来た。

A. 研究目的

内視鏡的粘膜下層剥離術(ESD)のハイポリュームセンターにおける経験を下に、生体ブタを用いた前臨床試験により、試作機を評価する。

B. 研究方法

(株)モリタ製作所、大阪大学、神戸大学で開発してきた改良試作機に対し、生体ブタを用いた前臨床試験をMEDDECにおいて行った。レーザーシステムの効果を次の点で評価した。

- ・炭酸ガスレーザー装置の効能
- ・導光ファイバーの効能
- ・ガイド光の効能

(倫理面への配慮)

本課題で行う、生体ブタを用いる前臨床試験に対しては、動物実験委員会で審議、

承認の上、実験動物に対する動物愛護に対して十分配慮した。

C. 研究結果

レーザー装置は、スコープの最大屈曲時にガイド光がやや弱いことが認められたが、十分なレーザーのパワーも有し、操作上に何ら支障が認められなかった。また、止血においても、レーザーパワーを5Wに落として照射することにより、止血が十分可能であった。試作機はほぼ最終のものと判断できた。

D. 考察

今後は、最終システム構成を決定し、in vitro、in vivo 安全性の検証実験を実施し、データを整理した上で、PMDAの対面相談を受け、臨床試験を実施する必要がある。

## E. 結論

開発の改良試作機が完成した。今後、in vitro、in vivo 安全性の検証資料を整理した上で、PMDA の対面相談を受け、臨床試験の規模を決定し、臨床試験を実施するとともに、薬事承認申請へと進める。

## F. 研究発表

### 1. 論文発表

(H24)

#### 1. 論文発表

- 1) Kato M, Kaise M, Obata T, Yonezawa J, Goda K, Toyozumi H, Yoshimura N, Yoshida Y, Kawamura M, Tajiri H. Bacteremia and Endotoxemia after Endoscopic Submucosal Dissection for Gastric Neoplasia - Pilot study- Gastric Cancer. 15:15-20, 2012
- 2) Iizuka T, Kikuchi D, Hoteya S, Takeda H, Kaise M. A new technique for pharyngeal endoscopic submucosal dissection: peroral countertraction (with video). Gastrointest Endosc. 76 (5) :1034-8, 2012
- 3) Kikuchi D, Iizuka T, Hashimoto M, Hoteya S, Yamashita S, Nakamura M, Yamada A, Mitani T, Fujimoto A, Matsui A, Arase Y, Kaise M. Safety measures for gastrointestinal endoscopy in patients receiving antithrombotic therapy. Dig Endosc. 24:16-20, 2012

- 4) Kaise M, Miwa J, Fujimoto A, Tashiro J, Tagami D, Sano H, Ohmoto Y. Influence of Helicobacter pylori status and eradication on the serum levels of trefoil factors and pepsinogen test: serum trefoil factor 3 is a stable biomarker. Gastric Cancer. 2012 Aug 21. [Epub ahead of print]
- 5) Kikuchi D, Iizuka T, Hoteya S, Yamada A, Furuhashi T, Yamashita S, Domon K, Nakamura M, Matsui A, Mitani T, Ogawa O, Watanabe S, Yahagi N, Kaise M. Safety and efficacy of secondary endoscopic submucosal dissection for residual gastric carcinoma after primary endoscopic submucosal dissection. Digestion. 86 (4) :288-93, 2012
- 6) Hoteya S, Matsui A, Iizuka T, Kikuchi D, Yamada A, Yamashita S, Furuhashi T, Domon K, Nakamura M, Mitani T, Ogawa O, Kaise M. Comparison of the clinicopathological characteristics and results of endoscopic submucosal dissection for esophagogastric junction and non-junctional cancers. Digestion 87 (1) :29-33, 2013

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1. Hoteya S, Matsui A, Iizuka T, Kikuchi D, Yamada A, Yamashita S, Furuhashi T, Domon K, Nakamura M, Mitani T, Ogawa O, Kaise M: Comparison of the Clinicopathological Characteristics and Results of Endoscopic Submucosal Dissection for Esophagogastric Junction and Non-Junctional Cancers. *Digestion*, 87(1):29-33, 2013.1. Epub Jan 21, 2013.
2. Kikuchi D, Iizuka T, Hoteya S, Yamada A, Furuhashi T, Yamashita S, Domon K, Nakamura M, Matsui A, Mitani T, Ogawa O, Kaise M. Prospective Study about the Utility of Endoscopic Ultrasound for Predicting the Safety of Endoscopic Submucosal Dissection in Early Gastric Cancer (T-HOPE 0801). *Gastroenterol Res Pract*. Doi: 10.1155/2013/329385, Epub Mar 28, 2013.
3. Kaise M, *Miwa J*, Fujimoto A, *Tashiro J*, *Tagami D*, *Sano H*, *Ohmoto Y*. Influence of *Helicobacter pylori* status and eradication on the serum levels of trefoil factors and pepsinogen test: serum trefoil factor 3 is a stable biomarker. *Gastric Cancer*. 16(3):329-337, 2013.
4. Hoteya S, Haruta S, Shinohara H,

Yamada A, Furuhashi T, Yamashita S, Kikuchi D, Mitani T, Ogawa O, Matsui A, Iizuka T, Udagawa H, Kaise M: Feasibility and safety of laparoscopic and endoscopic cooperative surgery for gastric submucosal tumors, including esophagogastric junction tumors. *Dig. Endoc.* Nov.2013. (DOI: 10.1111/den.12215)

5. Hoteya S, Iizuka T, Kikuchi D, Mitani T, Matsui A, Ogawa O, Furuhashi T, Yamashita S, Yamada A, Kaise M, Yahagi N : Secondary endoscopic submucosal dissection for residual or recurrent tumors after gastric endoscopic submucosal dissection. *Gastric cancer*, Dec.6.2013.(DOI 10.1007/s10120-013-032

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- 1 Kaise M, Kimura R, Nomura K, Kuribayashi Y, Kikuchi D, Iizuka T, Ohkura Y: Accuracy and concordance of endocytoscopic atypia in the diagnosis of gastric cancer. *Endoscopy*. *Endoscopy*. 46(10); 827-832, 2014.
- 2 . Kikuchi D, Yamada A, Iizuka T, Nomura K, Kuribayashi Y, Kimura R, Yamashita S, Furuhashi T, Matsui A, Mitani T, Ogawa O, Hoteya S, Yahagi N, Kaise M : A new device for

simultaneous manipulation of an endoscope and a treatment device during procedures: an ex vivo animal study. Endoscopy. 46 : 977-980, Aug 1, 2014 [Epub ahead of print]

during procedures: an ex vivo animal study.

3 . Hoteya S, Kaise M, Iizuka T, Ogawa O, Mitani T, Matsui A, Kikuchi D, Furuhashi T, Yamashita S, Yamada A, Kimura R, Nomura K, Kuribayashi Y, Miyata Y, Yahagi N : Delayed bleeding after endoscopic submucosal dissection for non-ampullary superficial duodenal neoplasias might be prevented by prophylactic endoscopic closure: analysis of risk factors. Dig Endosc. 2015;27:323-330 Sep 3, 2014 doi: 10.1111/den.12377. [Epub ahead of print]

2. 学会発表  
なし。

4 . Iizuka T, Kikuchi D, Yamada A, Hoteya S, Kajiyama Y, Kaise M : Polyglycolic acid sheet application to prevent esophageal stricture after endoscopic submucosal dissection for esophageal squamous cell carcinoma. Endoscopy. Nov 20, 2014 [Epub ahead of print]

5 . Kikuchi D, Yamada A, Iizuka T, Nomura K, Kuribayashi Y, Kimura R, Yamashita S, Furuhashi T, Matsui A, Mitani T, Ogawa O, Hoteya S, Yahagi N, Kaise M. A new device for simultaneous manipulation of an endoscope and a treatment device

G. 知的所有権の取得状況

1. 特許取得  
なし。  
2. 実用新案登録  
なし。  
3.その他  
なし。

厚生労働科学研究費補助金(医療機器開発推進研究事業)  
総合研究報告書

レーザー消化管内視鏡治療装置の開発に関する研究

研究分担者 上堂 文也 地方独立行政法人大阪府立病院機構大阪府立成人病センター  
消化管内科

研究要旨

(株)モリタ製作所、大阪大学、神戸大学で開発してきた試作機に対し、生体ブタを用いた前臨床試験を神戸医療機器開発センター(MEDDEC)において行った。改良試作機はESDの操作に必要なパワーが十分得られた。本炭酸ガスレーザーシステムはin vivo 生体ブタにおいて、胃粘膜層を切開するが、粘膜層通過後粘膜下層注入材によってレーザー光が吸収され、血管や筋層を傷付けずに、安全に粘膜及び粘膜下層のみを選択的に切除することが出来、より安全な消化器内視鏡治療が実現された。また、止血においても、レーザーパワーを5Wに落として照射することにより、止血が十分可能であった。試作機改良を重ね、ほぼ最終のものと判断した。本事業年度内に3度PMDA薬事戦略事前相談を受けることが出来た。

A. 研究目的

内視鏡的粘膜下層剥離術(ESD)のハイボリュームセンターにおける経験を下に、生体ブタを用いた前臨床試験により、試作機を評価する。

B. 研究方法

(株)モリタ製作所、大阪大学、神戸大学で開発してきた改良試作機に対し、生体ブタを用いた前臨床試験をMEDDECにおいて行った。レーザーシステムの効果を次の点で評価した。

- ・炭酸ガスレーザー装置の効能
- ・導光ファイバーの効能
- ・ガイド光の効能

(倫理面への配慮)

本課題で行う、生体ブタを用いる前臨床試験に対しては、動物実験委員会で審議、承認の上、実験動物に対する動物愛護に対して十分配慮した。

C. 研究結果

レーザー装置は、スコープの最大屈曲時にガイド光がやや弱いことが認められたが、十分なレーザーのパワーも有し、操作上に何ら支障が認められなかった。また、止血においても、レーザーパワーを5Wに落として照射することにより、止血が十分可能であった。試作機はほぼ最終のものと判断できた。

D. 考察

今後は、最終システム構成を決定し、in

vitro, in vivo 安全性の検証実験を実施し、  
データを整理した上で、PMDA の対面相  
談を受け、臨床試験を実施する必要がある。

#### E. 結論

開発の改良試作機が完成した。今後、in  
vitro, in vivo 安全性の検証資料を整理し  
た上で、PMDA の対面相談を受け、臨床試  
験の規模を決定し、臨床試験を実施すると  
ともに、薬事承認申請へと進める。

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