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Technological contributions to endoscopic submucosal dissection

Dipl.-Ing. (Univ.) Andreas B. Brehm

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Abstract

The introduction of the endoscopic submucosal dissection technique was a milestone in dissecting large tissue defects minimal-invasively in one single piece. This technique is less invasive than surgery and offers better histological examination of the specimen, due to the en-bloc resection compared with other endoscopic resection therapies. Yet this promising technique is associated with long procedure durations due to the technical complexity of this intervention and high complication rates, especially related to unintended heat defects caused by high-frequency currents used for cutting.

Consequently the influence of the electrode design – with regard to material, wire design and surface topography – on the thermal tissue impact is experimentally assessed. It could be shown that specific design characteristics, such as thin wires with low heat capacities promote and other characteristics such as irregular wire designs deteriorate good high-frequency cutting behavior. Suggestions for improved electrode designs with lower thermal tissue impact for high-frequency cutting applications are presented.

To overcome the limitation of long and complex endoscopic submucosal dissection interventions, a novel and innovative treatment device is designed and implemented. The multi-functional asymmetrical snare electrode enables the endoscopist to intuitively adapt the electrodes size and shape to the manifold interventionally related requirements. In addition with a series of implemented features, time consuming intraoperative change of instruments can be eliminated. The electrode design is furthermore adapted to the results obtained from the experimental electrode assessment.

The validation of the implemented design includes a preliminary in-vivo animal study and a first clinical evaluation. The safety and efficacy, as well as a drastically expedited intervention can be confirmed. In conclusion, a new treatment opportunity for the endoscopic submucosal dissection technique can be presented.

Überblick

Die Einführung der Endoskopischen Submukosa Dissektion (ESD) war ein Meilenstein in der Entwicklung von Therapien mit flexiblen Endoskopen, da erstmals auch großflächige Gewebedefekte im Ganzen abgetragen werden konnten. Die ESD ist weniger invasiv als operative Eingriffe und ermöglicht eine bessere histologische Beurteilung des Resektats, im Vergleich zu konventionellen endoskopischen Abtragungsmethoden. Die Nachteile der technisch aufwändigen Intervention sind lange Interventionsdauern und erhöhte Komplikationsraten, die primär auf thermische Schädigungen der Muskelschicht durch Hochfrequenzstrom zurückzuführen sind.

Infolgedessen wird der Einfluss des Designs der Elektrode – insbesondere deren Werkstoff, Drahtdesign und Oberflächengestaltung – auf thermische Gewebeschädigung experimentell untersucht. Es konnte gezeigt werden, dass Anpassung von Elektrodencharakteristiken, beispielsweise dünne Drähte mit niedriger Wärmekapazität, zu deutlichen Verbesserungen, und andere Charakteristiken wie beispielsweise unregelmäßige Drahtkonstruktionen zu deutlichen Verschlechterungen des hochfrequenzinduzierten Schneidens führen. Aus dieser Untersuchung werden Empfehlungen zur Elektrodengestaltung zum Schneiden mit Hochfrequenzstrom abgeleitet.

Des Weiteren wird ein neues, innovatives Instrument konzipiert, welches es ermöglicht, die langen und technisch aufwendigen Interventionen zu vereinfachen. Die Vielseitigkeit des Instruments ermöglicht es dem Endoskopiker, die asymmetrische Schlingenelektrode intuitiv auf die sich ständig ändernden interventionellen Anforderungen anzupassen. Das vorgestellte Instrument ermöglicht es, die ESD ohne zeitaufwändige Instrumentenwechsel durchzuführen. Die aus der experimentellen Untersuchung erhaltenen Kenntnisse wurden in der Elektrodengestaltung umgesetzt.

Abschließend wird das neu konzipierte Instrument durch eine in-vivo Tierstudie am Schwein und eine klinische Bewertung validiert. Hiermit konnte die Sicherheit und Wirksamkeit bei deutlich verkürzter Interventionsdauer bestätigt werden.

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Munich, Mai 20th, 2015 Andreas B. Brehm

Nomenclature

Abbreviations

[1], [2], [n]	continuous notation of literature
[A. A1], [A. B1], [A. B2]	continuous notation of appendices
Ag	silver
Al	aluminium
DIN	Deutsches Institut für Normung
EMR	endoscopic mucosal resection
EN	Europäische Norm
ESD	endoscopic submucosal dissection
ESU	electrosurgical unit
FDA	Food and Drug Administration
GI	gastrointestinal
GmbH	Gesellschaft mit beschränkter Haftung
IEC	Int. Electrotechnical Commission
IRC	infrared camera
ISO	Int. Standardization Organization
NiTi	Nitinol (Nickel-titanium alloy)
NTC	negative temperature coefficient
POM-C	Polyoxymethylen-Copolymer
SD	standard deviation
Ti	titanium
USP	United States Pharmacopeia
V	vanadium
W	tungsten

Variables and units

a	thermal diffusivity	[m^2/s]
A	area	[m^2]
c	specific heat capacity	[J/(kg K)]
C	heat capacity	[J/K]
d	diameter	[mm]
f	frequency	[Hz]
F	force	[N]
h_{HF}	power density applied by high-frequency application	[W/m^3]
h_{met}	heat basal metabolism	[W/m^3]
I	current	[A]
j	current density	[A/mm^2]
k	thermal conductivity	[W/(K m)]
L	length	[mm]
n	amount/number	[-]
p	pressure	[Pa]
P	power	[W]
Q	heat	[J]
r	distance from active electrode	[mm]
R	electrical resistance	[Ω]
R^2	coefficient of determination	[%]
R_a	roughness average	[µm]
r_e	electrical resistivity	[Ω m]
RH	relative humidity	[%]
RPc	peak count	[-]
T	temperature	[°C], [K]
t	time	[s]
U	voltage	[V]
V	volume	[m^3]
w	blood perfusion	[$kg_b/(kg\ s)$]
x	coordinate	[mm]
Δ	difference	[-]
ε	emission coefficient	[-]
η	dynamic viscosity	[kg/(m s)]
ρ	density	[kg/m^3]
Φ	volumetric flow rate	[m^3/s]

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