Max-Planck-Innovation

Technology Offer

Soft Capsule Endoscope - “B-MASCE”

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Im Zuge der stetigen Weiterentwicklung und Nachfrage auf dem Gebiet der minimal invasiven Chirugie wurde am Max-Planck-Institut für intelligente Systeme in Stuttgart im Team von Herrn Prof Sitti für patientenfreundliche Magen-Darm-Untersuchungen ein kabelloses kapselförmiges Endoskop in Pillengröße, das sogenannte "B-MASCE" entwickelt. Die aus einem Elastomer bestehende Kapsel dient hierbei sowohl als Gehäuse als auch als Federelement für die Nadel. Über in der Kapsel eingebaute Magnete wird das Endoskop über ein externes Magnetfeld gezielt an die gewünschte Stelle bewegt, wo es nicht nur betroffenes Gewebe identifizieren sondern gleichzeitig über die "Fine Needle Capillary Biopsy Technique" (FNCB) Biopsie-Proben aus tiefer gelegenen Gewebe entnimmt. Letztgenannter Punkt führt zu deutlich besseren präziseren Diagnosraten. Zudem spart man mit diesem neuartigen Endoskop einen Eingriff, was sich insgesamt nicht nur positiv auf den Patienten auswirkt sondern auch Kosten spart.

Background

At present the major medical technologies are converging to minimally invasive diagnosis and therapy. In regard to gastrointestinal (GI) diseases the development of capsule endoscopes to reduce patient discomfort is already established. Especially tiny wireless capsule endoscopes in the size of a pill are well accepted by patients and are currently used to take images and videos for the identification of suspicious lesions. Unfortunately, besides the identification these kinds of endoscopes are not able to take a biopsy sample, so that an additional endoscopic procedure is still required.

In 1967, the first swallowable electromagnetic biopsy device designed for GI diseases was presented by Driller and Neumann. A couple of years later, several biopsy capsule endoscope designs were presented by Kong *et al.*, Swain *et al.,* Simi *et al.,* Park *et al.,* Chen *et al.* and Yim *et al.*. Most of those capsules used razor blade inside the capsule to cut off the GI tract sample or forceps to grap sample tissues. Whereby Yim *et al.* presented the first magnetically capsule endoscope called “MASCE”.

However one of the main limitations of all prior designs is that they can only take superficial biopsy samples. Those are useful to retract the tissues on the mucosal layer of the GI tract, however, it is difficult to reach deep masses inside a lesion in a GI tract. Thus, they can miss submucosal tumors (SMTs), which can lower the diagnostic accuracy.

To overcome the aforementioned problems, we developed a new enhanced pill-sized all-in-one capsule endoscope which is designed to identify suspicious lesion and to take a biopsy sample in the subsurfaces of the tissue in an easy, gentle and precise way, using the Fine Needle Capillary Biopsy (FNCB) technique.

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Technology

The proposed soft capsule endoscope is magnetically actuated and uses fine needle aspiration capillary biopsy suitable for the upper gastrointestinal tract.

The so called „B-MASCE“ is controlled by multiple custom-designed electromagnets while its position and orientation is tracked by a magnetic sensor array.

The endoscope composed of a soft elastomer capsule with an attached needle, a camera and custom-designed permanent magnets whereby the soft elastomer capsule works not only as housing but also as spring element for the needle.

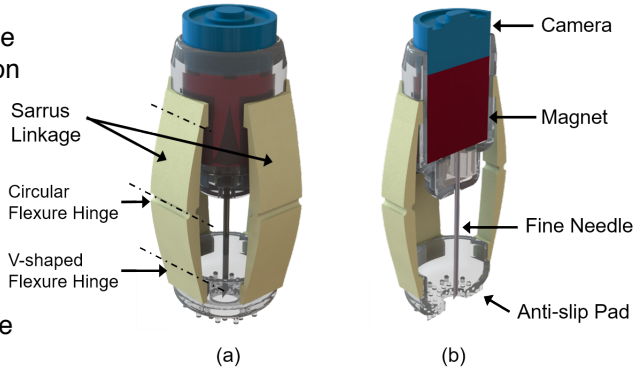

Fig. 1: B-MASCE. **a)** The Sarrus linkage constraints the axial collapsing movement. **b)** Section view: Magnetic forces induce the axial movement of the fine-needle along the Sarrus linkage.

The capsule is protected by a shell which is configured to dissolve in a liquid in a pre-defined time from 10 sec to 10 min as the endoscope is inserted and therefore coming into contact with the human or animal body. Due to an external magnetic field control that induces a magnetic force and a torque on the magnets inside the capsule, the capsule rolls in a controlled manner towards the desired location. Once it reaches the target, the needle is contructed to carry out 5 to 10 axial jabbing motions penetrating the tumor tissue deeply obtaining subsurface biopsy samples on demand.

Tab. 1: Parameters of the capsule endoscope

Overall dimension	ø12 mm × 30 mm
Fine-needle	24 G, 15 mm (length)
Penetration depth	10 mm
Magnet	NdFeB 42 G, ø8 × 8 mm^3
Sarrus linkage:	
-Young's modulus	2.07 MPa
-Leg dimension	14 mm (H) × 6 mm (W) × 1.5 mm (D)
-Flexure hinges dimension	Circular: 0.275 mm (D), 0.4 mm (radius) V-Shaped: 0.275 mm (D), 135° groove

The computer controlled external electromagnetic system and magnetic sensor arrays that are arranged at different locations in a 2D plane are employed to control the external magnetic field precisely. Such sensors are generally able to produce a 3D vector field map in 2D of the movement of the endoscope capsule within a target region by sensing the changes in the magnetic field. In addition the aforementioned apparatus may further comprises a display device, wherein the captured images or videos from the camera of the endoscope can be displayed in real-time.

Until now „B-MASCE“ could be demonstrated regarding rolling locomotions and biopsy in *in vitro* trials on a plastic stomach model containing a swine adipose tissue model. Biopsy samples could be successfully captured by retaining a tissue sample in the needle (A video demonstration can be provided).

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Advantages

- All-in-one capsule endoscope: tool for identification of suspicious lesion and biopsy
- easy handling combined with precise control techniques
- improved accuracy
- comfortable biopsy, tiny capsule
- cheap method to produce the capsule:
  - 3D printing
  - molding techniques

Patent Information

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