Endoscopy by Interferenceless Coded Aperture Correlation Holography Device with Annular Optical Aperture (EI-COACH)

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ABSTRACT
In this article we present results of imaging through an annular aperture, which can resolve small details of the observed scene similarly to the full disk aperture with the same diameter. However, unlike the full aperture, the annular aperture enables using the inner area of the ring for other applications. We consider the implementation of this special aperture in medical imaging instruments, such as endoscopes, for imaging internal cavities of the human body. By use of this annular aperture, it is possible to transfer through the internal open circle of the ring elements such as surgical tools and illumination devices.

Keywords: Imaging systems; Three-dimensional imaging; Digital image processing; Digital holographic imaging.

1. INTRODUCTION

Endoscopy is an important medical diagnosis and treatment tool for many body cavities such as the colon, esophagus, abdomen, uterus, lungs and stomach. In various medical areas, endoscopy provides an alternative for open surgery, for faster recovery and less post-operative pain and discomfort. In the minimal invasive surgery like laser lithotripsy, an endoscopic system is used as a high-resolution imaging setup which helps surgeons to operate delicate organs with high precision. However, with all the advantages, endoscopy also faces some considerable limitations, mainly because of the limited size of the lateral cross-section of the observed cavity. The use of surgical tools in parallel with the vision system adds several limitations on optical performances of the endoscope.

Endoscopes with high resolution imaging capabilities are of great importance for optimized interactions in medical procedures. The surgical part of the system, may consist of a fibre delivering laser radiation, a high-intensity focused ultrasound surgical applicator, a radio-frequency device or a mechanical tool. Each of them can be used for tumor ablation or resection. In addition, there is an illumination component. Since the internal size of an organ under treatment is limited, additional instruments force engineers to decrease the aperture diameter of the imaging system, and hence the image resolution and the field of view are reduced. Alternatively, if the imaging system has an annular aperture with the maximal diameter for a given organ, the maximal resolution is guaranteed, and the space surrounded by the annular aperture is free

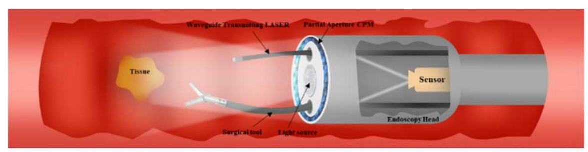

Fig. 1. Schematic of the proposed EI-COACH system.

to be used for the other required instruments. A scheme of the new imaging concept is shown in Fig. 1, where the annular imaging aperture is implemented on the periphery of the distal tip of the endoscope. The internal area of the ring is utilized by a light source, illuminating fibre and surgical tools. The image sensor is positioned behind the annular aperture. Fig. 1 is a conceptual representation of our new imaging idea and depending upon this application, more tools can be introduced into the system. The main goal of this study is to develop a new applicator, with superior features, by integrating optical and digital image processing tools. To a large extent, this is now possible thanks to currently available computers and state-of-the-art electro-optical devices, including spatial light modulators (SLMs) and digital cameras.

In this article, we present the preliminary investigation of implementing the annular aperture in medical imaging instruments, such as endoscopes for imaging of internal cavities of the human body (i.e. gastrointestinal tracts, colon, uterus and stomach). The investigated system is termed endoscopic interferenceless coded aperture correlation holography (EI-COACH). The annular aperture of EI-COACH with the outer radius of R gives a resolution performance similar to a full disk aperture with the same outer radius R. This high-resolution feature is achieved due to the unique modulation transfer function (MTF) with relatively high transparency in the non-zero frequencies.

2. STATE OF THE ART

The new imaging concept belongs to a family of systems dubbed interferenceless coded aperture correlation holography (I-COACH) [1-3]. In I-COACH, a one-time calibration procedure is required, in which a library of pattern responses to a point object positioned at various axial locations are created. Each complex-valued response function is termed point spread hologram (PSH). Following the calibration stage, the intensity response of a 3D object, placed within the axial boundaries of the library, is recorded. The object response, termed object hologram (OH), is a collection of the PSHs, distributed according to the shape of the object. Once the complex hologram of the object is recorded into the computer, any axial plane of the observed object space is finally reconstructed by a digital two-dimensional cross-correlation between the OH and the corresponding PSH from the library. Following the initial I-COACH, other versions [2,4] have been developed in order to improve various features of imaging. Among the advanced I-COACH systems published in 2017 there is one [4] that can image 3D scene with only annular aperture. More importantly, the imaging through the annular aperture resolves small details of the observed scene similarly to the full disk aperture. Annular aperture is a special case of a more general partial aperture and hence the system has been termed as partial aperture imaging system (PAIS). The PAIS system [4] and the proposed EI-COACH both use annular aperture, but PAIS is developed for far-field imaging and EI-COACH is developed for near-field imaging. Another major difference between PAIS and EI-COACH is the nature of the PSH. The PSH of PAIS is continuous chaotic pattern, whereas the PSH of EI-COACH is a sparse collection of randomly distributed dots. This advanced PSH makes EI-COACH more power efficient system with higher signal-to-noise ratio than PAIS.

3. BREAKTHROUGH CHARACTER OF THE PROJECT

The EI-COACH system is, to the best of our knowledge, the first attempt to design a practical endoscope with a partial aperture, but with performance as close as possible to that of a full aperture system with the same external diameter. The main benefit of this system is that part of the aperture originally used for imaging can be now used for other purposes and can be occupied by other devices. The proposed method in this project can improve dramatically a single incision laparoscopic surgery [5] and can be applied also to robotic surgery [6]. The breakthrough of this system is the ability to provide simple, 3D, real-time imaging with image resolution higher than can be achieved by current technologies. The amount of the resolution improvement is actually the ratio between the maximal aperture diameters of the proposed and the current endoscopes. Our proposed system provides also the abilty to work in a much more optimized way since we create a space along the axis that is open for surgical instruments (forceps, cutters, suction, irrigators energy delivery instruments such as RF applicators and fibers transmitting lasers).

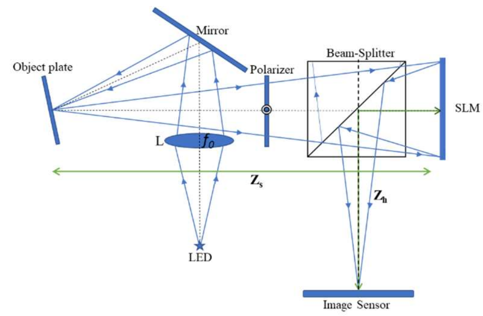

Fig. 2. Experimental setup of the EI-COACH system.

Annular aperture imaging is a new technology to image objects through part of the aperture area with resolution capabilities as close as possible to the full aperture. By using our new imaging method, the area of any optical aperture can be reduced by about one order of magnitude without any reduction of the imaging resolution, as long as the reduced aperture is in a shape of a ring along the border of the original aperture. This statement has practical and theoretical importance. In the practical aspect, the proposed method offers much more efficient imaging in the sense of weight and aperture utilization. In the theoretical aspect, we show that reducing the aperture still enables to transfer of the same amount of information transmitted by the original large aperture. In other words, this project opens a new route of research which possibly could be termed “reduced-aperture imaging” and as a pioneer of a novel field this project is expected to be an important breakthrough, much beyond robotic surgical devices, endoscopes and other medical imaging tools. We believe that the demonstrated idea of EI-COACH with annular aperture can be adapted for implementation in biomedical optical devices as well as in space-based and ground-based telescopes. The preliminary results shown herein using a laboratory model are highly promising and might be a significant contribution to the field of imaging in general and to medical imaging in particular.

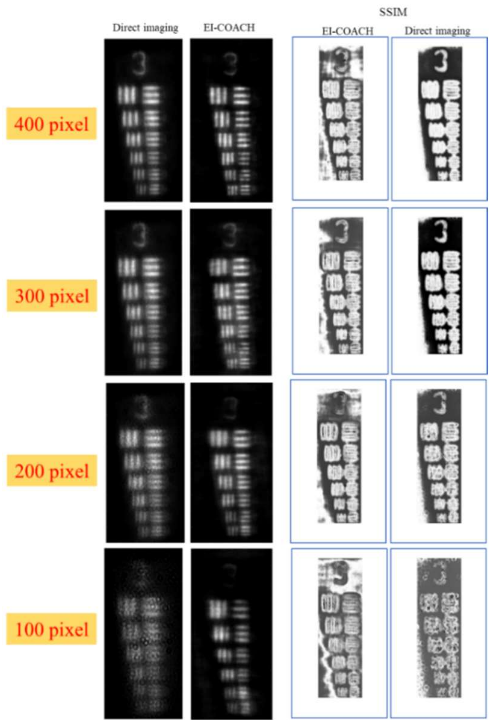

Fig. 3. Reconstruction results of EI-COACH and direct imaging with structural similarity index measure (SSIM) map [7].

4. PROJECT RESULTS

The experimental study of EI-COACH was carried out using the setup shown schematically in Fig. 2 [7]. For recording the intensity response of a point object, a 15μm pinhole was illuminated by a HeNe laser. Light diffracted from the pinhole was polarized to the active orientation of the SLM. The phase pattern displayed on the SLM was obtained by phase addition of the coded phase masks (CPM) with the diffractive lens of f =15*cm* focal length. Since only 1080×1080 pixels of the SLM are used to display the CPM, the maximum CPM diameter is 1080×8μm=8.64*mm*. A beamsplitter was used to reflect back the modulated light coming from the SLM toward a digital camera. The camera was at 29*cm* away from the center of the beamsplitter and the gap between the center of the beamsplitter and the SLM was 3*cm*. Therefore, the distance between the SLM and the camera was z_h=32*cm*.

For the OH, the optical setup was the same as for the PSH, but the object was illuminated by a LED in order to maintain the spatially incoherence needed for appropriate operation of EI-COACH. The LED was mounted at a distance of 11*cm* from the lens L (focal length, f_o=7*cm*) and critically illuminated the object. Unlike previous experiments of PAIS [4], the targets in these experiments are light reflective and hence the illumination mode is similar to the case of typical endoscopes. 3rd group of USAF resolution chart was used as an object in this study. Bipolar OH was recorded by following the same procedure of recoding the bipolar PSH. The diffractive lens was displayed on the SLM along with the CPM and the target was at a distance of z_s=28*cm* from the SLM.

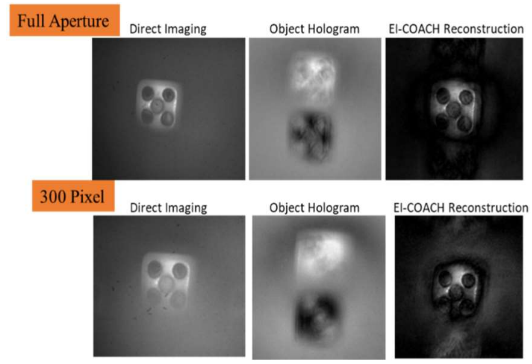

Fig. 4. Images of a dice with full aperture and with 300-pixel annular aperture by direct and EI-COACH system.

We started the experiment by looking for the optimal number of dots in the intensity response I_{PSF}, where the visibility of the reconstructed images of a full aperture I-COACH system has been used as the figure of merit. The number of dots from each CPM was varying between 5 to 20 dots in the interval of 5 dots and between 20 to 70 dots in the interval of 10 dots. Note that the number of total dots of each bipolar PSH is double the number of dots created from each CPM. Visibility of the 6th element of the 3rd group was used as the figure of merit for choosing the optimal number of dots. Apparently, the reconstruction results with 10 dots gives the best visibility over other reconstruction results. Therefore, a 10-dot pattern is chosen for the rest of the experiments with the EI-COACH systems. Annular ring CPMs with width of 100-400 pixels, in a step of 100 pixels were synthesized by the iterative algorithm and tested. The reconstruction results of EI-COACH in comparison to direct imaging are shown in Fig. 3. MTF plots of EI-COACH system with various ring size were calculated and compared with the MTF of the direct imaging system with the same annular apertures. The MTF plots demonstrate that with the same annular aperture on average, EI-COACH suppresses the signals in the higher-than-zero spatial frequencies less than the direct imaging. To demostrate the capability of EI-COACH to image everyday objects, we compare in Fig. 4 direct images of a dice with EI-COACH images, with a full aperture and with annular aperture of 300 pixels. Non-linear adaptive reconstruction technique [8] was used for the EI-COACH images. Based on Fig. 4, EI-COACH images have better contrast than the direct images and when the aperture is reduced to 300 pixels the reduction in the contrast is more considerable in direct imaging than in EI-COACH. Our latest lab experiments indicate that the 3D capabilities of EI-COACH have been reached.

5. FUTURE PROJECT VISION

The EI-COACH is a sophisticated optical component for 3-D visualization within body cavities. Its advantage is threefold: First, for better imaging for detection of abnormalities, second, real-time imaging of surgical procedure whether; Laser; RF, Ultrasound (HIFU) or mechanical. The hollow core of the optical setup is a third very important characteristic of this component that enable the insertion of all types of applicators for the optimization of the visualization and surgical procedure. Our device is designed to be integrated in endoscopes (flexible and rigid); surgical robots and other image guided surgical instruments.

5.1 Technology Scaling

The optical laboratory setup and experiments achieved this far satisfy TRL 1 to 4. We have advanced from the principles, through formulation, design, proof of concept in the lab and validation on tissue like phantom imaging and controlling laser tissue interaction procedure.

We plan to achieve TRL 5 to 7 in the next phase should our proposal be approved. We plan to integrate our device with an endoscopy system (TRL 5). Specifically, we will integrate it with a laparoscope which uses 2-3 entrance ports in tissue (e.g. the abdomen for an endometriosis procedure to fulfil TRL 6). We will demonstrate the ability to repeat this procedure through one port only taking advantage of our enabling technology of hollow core optical system. We aim to demonstrate it on animal model in an operation room in the university animal facility (TRL 7).

5.2 Project Synergies and Outreach

The integration of our system in an endoscopy system will require us, of course, to reach out to companies within the European community that manufacture this type of devices. Luckily, there are some excellent companies operating in this field in Europe. We can mention Covidien (Medtronic) Ireland who operates as a stand-alone company in the endoscopy market. Karl Stortz from Tuttlingen, Richard wolf from Knittlingen, both in Germany. Additional Potential collaborators will be surgical robot companies. This may include Avatera from Germany and Zimmer Biomet Robotics from Montpellier, France. Siemens the German giant has purchased about a year ago Corindus for $1.1B and became also an important plyer in this field. The integration of our device into instruments made by those companies is important in order to be able to achieve TRL 7 for sure and important for TRL 5 and 6.

We will work together with one or maybe even two of the companies (one endoscopy and one surgical robot). We intend to integrate the device into their system. The integration will include physical, electronical, and software. The full system will be used to carry out the experiments to fulfil the requirements till TRL 7 and make a new much more powerful device ready to move to the next development stage.

5.3 Technology application and demonstration cases

The field we are operating in is healthcare. Specifically, we are working in minimal invasive procedures. This includes rigid and flexible endoscopy, Surgical robotics and image guided procedures. We claim that our device will become a game changer in the corresponding fields. It will allow real time 3D visualization of a medical procedure within body cavities with better control thus better outcome.

The global endoscopy device market is estimated at almost $51.7B in 2022 with CAGR of 6.9%. Out of those rigid endoscopes will be about $7B in 2022. If we analyse the market by region, we can find that the European market is estimated at about $684.3M at 2020, only second to the North America market, estimated at $1.13B. The global field of Medical Robotics and Computer-assisted Surgery size is estimated at $6.483B in 2021 with a CAGR of 11.3% since 2015. The surgical robot section is $5.403B with CAGR of 11.4%. Our system can play also an important role in two other sections of this field: Surgical navigation systems and surgical simulators and planners. Looking at the geographical areas in this field; we can find that the European region market size is $829.7M (9.5% CAGR) only second to the North American market of $4.372B. Naturally share of the North American Market is European manufactured systems. (The analysis was done on combination of a few sources).

The availability of these instruments in the European market will increase the number of minimal invasive procedures in Europe. This type of procedures can be done in outpatient clinics, they do not require hospitalization and the patients can go back home at the end of the day. It causes much less pain and discomfort to the patient and the recovery time is much faster than in open surgeries. This reduces the cost of the procedures (no need for hospital beds) and much faster returns to work, thus fewer working days are lost and the economy is less hurt.

5.4 Technology commercialization

Commercialization steps will start in the next phase together with the companies that we will work with in the phase 2 of the project. This step can be done only after completing clinical trials. We already had some preliminary discussions with potential collaborators for the next stages of the development. There was much interest in our device. We will of course need to work with surgeons, especially opinion leaders in the field that will participate in the second phase of this research and design with us the clinical studies and participate in them. Additional mandatory steps will be passing regulatory procedures of the EU with the new guidelines taking place now. We will of course need to pass FDA clearing if we want the new instruments to be sold and used in the US markets. This also applies of course other geographical regions and their corresponding regulatory agencies (China is an important rising market with it CFDA which has very strict requirements that are not less and sometimes even more demanding than the US FDA). To be clear, any change/improvement done in an instrument which already has regulatory clearance still need to get new approval. Another important issue to solve is the reimbursement code for covering the cost of the procedures by the medical insurance companies, HMOs and other clinical organizations.

5.5 Envisioned risks

In any new device, especially with our device which we believe is a game changer in minimal invasive surgery, there is always an issue of educating the users with the new way the process is done. This is the reason we plan to get in touch with key opinion leaders in the corresponding fields to be involved with the development of this device. We intend also to work with leading hospitals in Europe as beta sites for clinical studies.

5.6 Liaison with Student Teams and Socio-Economic Study

During the phase one of this research we have already students, pursuing their PhD or M.Sc. degree, involved in the project. As next phase will include much more research and development, we will have more Master level as well as doctorate level students. This will include students pursuing degrees in Biomedical Engineering, Electrical Engineering and computer science. As regularly in our labs, PhD students and post-doctoral fellows are taking part in the research and help mentoring the other students. We also incorporate in the studies, undergrad students doing their senior design projects in our labs. In phase 2 we will also include physicians studying towards specialization in surgery (gastroenterological, gynaecology, orthopaedics and ENT). These will be mentored by the senior physicians who are opinion leaders in the field.

This type of research is multidisciplinary. It requires expertise in different fields of science. A main theme of the PIs of this project is team science [9]. We apply principles of team science approach in building a synergetic group of researchers that will not only have different expertise but also will complement each other in a way that will be for the benefit of each individual. The next phase will include partners from different countries in Europe. Individuals with cultural differences will work together on one project. Some of them may come also from countries outside of Europe (even in this phase there are two post-doctoral fellows from India in each of the PIs' labs). An important part will be to have a good supportive work ethics that will respect this diversity. We will also follow principles of ethically aligned design of the instrument, software and procedures [10].

6. ACKNOWLEDGEMENT

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