



B E N E F I T

Better Effectiveness and Efficiency by Measuring and Modelling Interventional Therapies

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State of the art on Intra-interventional Imaging



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1 Introduction

1.1 Aim of activity

The goal of this document is to provide a state-of-the-art review on **intra-interventional imaging** that enables diagnosis and treatment selection during interventional procedures. This is limited to the time the patient is on the intervention table, so that adaptations to the treatment plan can be made if intervention results are sub-optimal. The objective is to identify how patient risk and intra-interventional imaging can be deployed to better treat patients with respect to the wide range of intervention tools and options.

The study is based on open literature and the knowledge provided by the technical and clinical partners of the project. Each of the imaging modalities is described in a standardized way in Chapter 5. In the first section, a short introduction is given that provides the background & context of the imaging technique. The second section describes the state of the art of the imaging technique. The last section provides the relation to the clinical usage.

1.2 Contributors

Several authors contributed to the production of this document. Each of those authors was responsible for one of the targeted procedures.

#	Section	Author
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2 Executive summary

This document provides the “State of the Art” for the imaging procedures that are targeted / used by the BENEFIT project. The goal of BENEFIT is to develop technologies that improve efficiency and effectiveness of minimally invasive interventional procedures based on improved quantification and modeling before, during and after interventions, whereby imaging is used as one of the major tools.

In total 4 imaging techniques are addressed:

- High Quality X-ray Imaging
- Intravascular Ultrasound and Optical Coherence Tomography
- MRI and Cone-beam CT
- Laparoscopic Imaging

From a clinical perspective 2 of these procedures are within the domain of endovascular interventions/PCI and two are in the domain of oncology. As such, the spectrum of selected imaging techniques covers a broad range of minimally invasive interventional procedures.

This deliverable D4.1.1 summarizes the state of the art for these imaging techniques which are used in the procedures on quantification and modeling to enable more personalized interventions.



3 Glossary

3DRA	3 Dimensional Rotational Angiography: 3D X-ray imaging of blood vessels
CABG	Coronary Artery Bypass Graft(ing): surgery to place a bypass vessel across an obstructed blood vessel of the heart
CBCT	Cone Beam CT: CT reconstruction made by an interventional X-ray system instead of a dedicated CT scanner
CT	Computer Tomography: method to mathematically reconstruct 3D images from a rotational sequence of 2D X-ray slices
CFR	Coronary Flow Reserve: measure for condition of vessels of the heart
CTA	Computer Tomography Angiography: 3D imaging of blood vessels with CT after injection of a contrast agent into a vessel.
CTO	Chronic Total Occlusion
DSA	Digital Subtraction Angiogram: 2D X-ray imaging of blood vessels after injection of a contrast agent
DWI	Diffusion Weighted Imaging: specific protocol of MRI
FFR	Fractional Flow Reserve: measure for condition of vessels of the heart
Fr	French, a catheter scale: 1 Fr = 0.33 mm
GUI	Graphical User Interface
IGIT	Image Guided Interventional Therapy
IVUS	Intravascular Ultrasound: imaging of a vessel wall from the inside with a US transducer mounted on the tip of a catheter
LGE-MRI	Late Gadolinium Enhancement MRI
LV	Left ventricle
MR	Mitral regurgitation: back flow of blood from left ventricle aorta into atrium due to leakage of mitral valve
MRI	Magnetic Resonance Imaging
MR-HIFU	MRI-guided High Intensity Focused Ultrasound
MS	Mitral stenosis: narrowing of mitral valve due to calcification
MW	MicroWave
OCT	Optical Coherence Tomography: imaging modality using laser pulses for high resolution imaging of a surface, for instance the vessel wall
OR	Operating Room
PCI	Percutaneous Coronary Intervention: minimally invasive treatment of an obstruction in the cardiac blood vessel through a catheter
PEI	Percutaneous Ethanol Injection
QCA	Quantitative Coronary Angiography
RF(A)	Radio Frequency (Ablation): removal of tissue by heat
SPECT	Single Photon Emission Computed Tomography: 3D imaging of molecular processes in the body after injection of a radio-isotope
SSS	Symptom Severity Score
TAVI	Trans-catheter Aortic Valve Implantation: implantation of artificial heart valve via a catheter (so no open surgery)
TEE	Transesophageal echocardiography: US imaging of the heart with a transducer mounted on a tube that is inserted in the esophagus
TTE	Transthoracic echocardiography: US imaging of the heart with a transducer on the chest in between of 2 ribs
US	UltraSound
VHD	Valvular heart disease

4 Imaging Procedures

In total 4 imaging techniques are addressed in this document:

- High Quality X-ray Imaging
- Intravascular Ultrasound and Optical Coherence Tomography
- MRI and Cone-beam CT
- Laparoscopic Imaging

This is by no means an exhaustive study of all imaging techniques used in and around intra-interventional imaging. The selection made here is focused on the imaging techniques used in BENEFIT, and especially in the Use Cases defined for the project.

All these techniques are described in a standard way. In the first section, a short introduction is given that provides the background & context of the imaging technique. The second section describes the state of the art of the imaging technique. The last section provides the relation to the clinical usage.

4.1 High Quality X-ray Imaging

Lead author: Philips Healthcare

4.1.1 Introduction

The dynamics of coronary atherosclerosis (progression and regression of coronary atherosclerotic lesions), the healing of lesions, and the development of new lesions, have intrigued cardiologists since the time that this process could be followed by repeated coronary X-ray Angiographic (XA) examinations [Oudkerk], [Bruschke], [Jukema].

Image guidance during the procedure is performed by mono- or biplane fluoroscopy (see Figure 1), which visualizes the guide wires and catheters (some of which have additional markers for improved visibility). The coronary arteries are visualized by injections of contrast agent, which result in a transient visualization of the vessels.

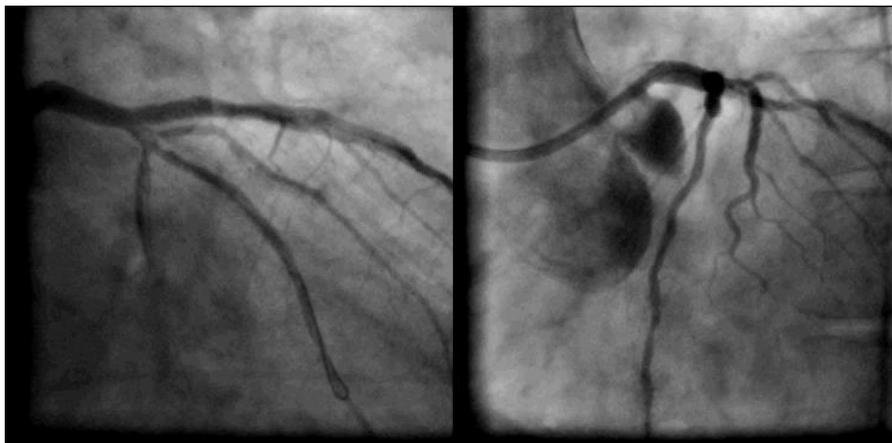


Figure 1: Biplane image of coronary intervention (Image courtesy Erasmus MC)

4.1.2 Technical State of the Art

The technology of XA imaging systems has progressed over the years (starting from conventional vacuum-tube image intensifier) and has resulted in completely digital flat-panel detectors. The advantages of these flat-panel detectors are obvious, the ability to preserve significantly more of the original signal (e.g. due to the large reduction of veiling glare (the scattering process within the image intensifier) and the absolute absence of spatial distortions (e.g. the magnetic field distortion and pincushion distortion, the last one being due to the curvature of the input screen of the image intensifier [van der Zwet], [Holmes], providing better image quality and enabling further image enhancement. In clinical practice, this means an improved visibility of vessels, lesions, and guide-wires, even at reduced X-ray dose levels [Geijer], [Tsapaki]. Typical matrix sizes for the flat panel systems nowadays are 1024x1024 pixels at 12.5 to 30 frames/s, using 8, 10 or 12 bits pixel depth for cardiac acquisitions.

4.1.3 Usage in intervention and treatment evaluation

Using XA imaging is the de facto gold standard for coronary interventions for decades. Both diagnostic and interventional procedures are guided by XA imaging. Treatment and device selection can be done both visually by clinicians as well as supported by quantitative methods like QCA [Reiber], [Lansky]. In interventional cardiology, QCA has been used for on-line vessel sizing for the selection of the interventional devices and the assessment of the efficacy of the individual procedures, for the on-line selection of patients to be included or excluded in clinical trials based on quantitative parameters (e.g. small vessel disease), and for training purposes. Further, it has been applied worldwide in core laboratories and clinical research sites to study the efficacy of these procedures and devices in smaller and larger patient populations [Reiber].

4.2 Intravascular Ultrasound and Optical Coherence Tomography

Lead author: LUMC

4.2.1 Introduction

Percutaneous coronary intervention (PCI) is one of the treatment options for patients with chronic stable angina (chest pain due to ischemia of the heart muscle). Whereas PCI is less invasive than other approaches, it is favorable for patients.

However, the preferred treatment depends on various issues, such as patient characteristics and classification of a lesion. The interventions do not cure the underlying cause of the atherosclerotic disease process but they are carried out to alleviate the symptoms and have a survival benefit for the patients.

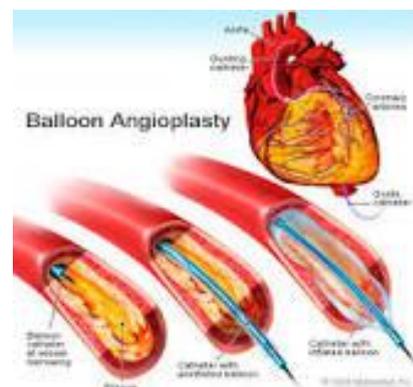


Figure 2: Illustration of balloon angioplasty

Coronary X-ray angiography currently is the standard modality for assessing coronary lesions, and a vessel diameter of 50% or less (75% area) is considered a significant lesion. However, the hemodynamic significance of a coronary lesion does not correlate well with stenosis measurements. Therefore other imaging techniques and quantitative measurements are nowadays investigated and employed during the intervention, to decide whether a lesion needs treatment. These modalities, Intravascular Ultrasound (IVUS), Optical Coherence Tomography (OCT) and Fractional Flow Reserve (FFR), provide additional information on the plaque burden and the plaque composition, and can indicate the hemodynamic significance of a coronary lesion.

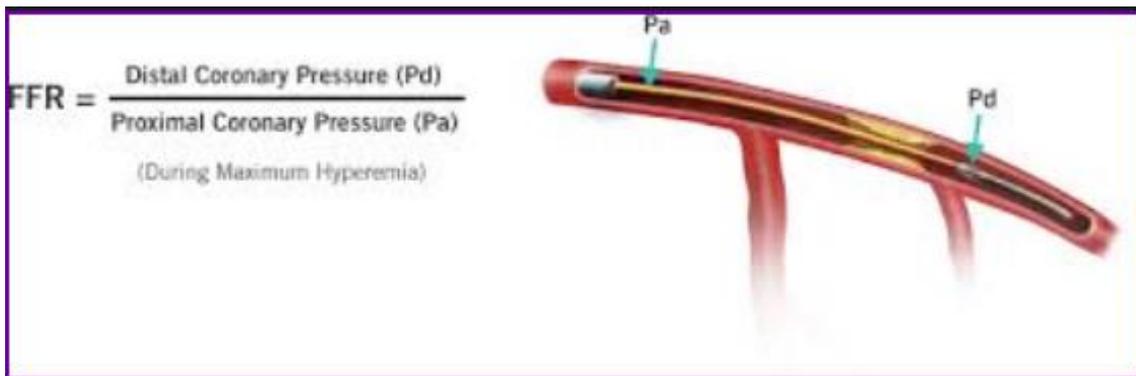


Figure 3: Illustration of the FFR measurement through a pressure wire

4.2.2 Technical State of the Art

Current IVUS systems can image a coronary with 45 Mhz, 30 frames per second, pullback speed of 0.5 mm/sec and a resolution of 100 micron. The quantification of images on-line is limited to single frame measurements by manual contouring. Some systems provide additional information by analyzing the RF signal and show tissue classification as overlay on the IVUS image.

Current OCT systems image the coronary artery with a speed of 180 frames per second and a pullback speed up to 36 mm/sec, Meaning that a segment of 100 mm can per visualized in 3 seconds. The resolution is about 10 micron. Some automatic processing is done on the console by automatic delineation of the lumen. No processing is available for stent detection or tissue classification on the console. For offline analysis, some software is available for lumen detection and stent strut detection. Tissue classification is still in its early stage.

4.2.3 Usage in intervention and treatment evaluation

The purpose of PCI is to restore the vascularization of the heart muscle by widening stenotic lesions in coronary arteries. To this end, a stent is placed in the coronary artery, possibly after prior dilation with a balloon. The procedure is performed minimally invasively, often via the femoral artery. First a guide catheter is introduced, to provide a safe access of the guide wires and catheters to the coronary arteries. Subsequently, a guide wire is inserted through this catheter, and advanced beyond the lesion. Through this, intravascular imaging (IVUS, OCT, FFR) can be performed.



Intra-arterial imaging with IVUS or OCT is used to assess the vessel wall condition and to characterize the obstructing tissue (plaque). An FFR measurement from a pressure wire is used to determine the hemodynamic significance of a lesion.

Furthermore, the landing zone of the stent can be selected, not only based upon the narrowing of the vessel, but also based upon the condition of the vessel wall proximal and distal. If necessary, it can be decided to place a longer stent to cover vulnerable plaque.

After stenting, it should be checked whether all the struts are positioned against the lumen wall and no struts are blocking an important side branch. If so, additional ballooning will be needed to improve the stent placement.

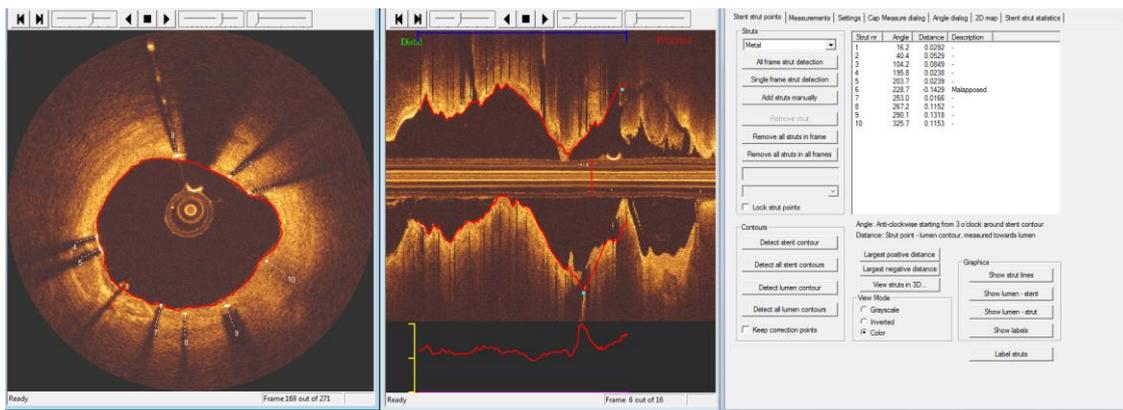


Figure 4: Example of OCT imaging (Image courtesy LUMC)

4.3 MR Imaging and Cone-beam CT

Lead authors: Elekta

4.3.1 Introduction

MR Imaging has become the standard imaging modality for soft tissue visualization of organs inside the human body. This enables distinction of different anatomical structures, i.e. in the brain, with a high degree of geometrical accuracy. Cone-beam CT has limited soft-tissue visualization capabilities but instead has a superior visualization of bony structures. To combine these imaging modalities in an intelligent way to enable accurate treatment of the brain with i.e. radiation has been the objective for some time.

4.3.2 Technical State of the Art

For brain surgery using the Leksell GammaKnife the preferred MR imaging uses at least a 1.5T MR scanner. Depending on the anatomical target, different sequences are used. Either T1, T1 contrast-enhanced or T2 are preferred. To optimally visualize glioblastoma as is the target in BENEFIT, the normally used MR sequences are T1, T1 contrast-enhanced, T2, and T2 FLAIR.

When additional resolution of the image set is needed, the option exists to use higher field strengths, like 3T machines.

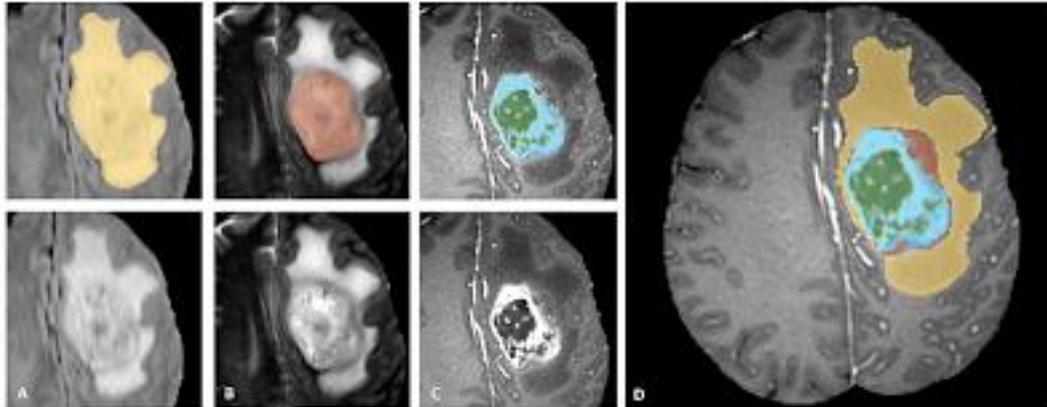


Figure 5: FLAIR imaging (image A), the tumor core in T2 (image B), the enhancing tumor structures in T1c (blue), surrounding the cystic/necrotic components of the core (green) (image C). The segmentations are combined to generate the tumor structures (image D). (Image courtesy <http://braintumorsegmentation.org/>)

CBCT is a common modality used to determine the position of the patient's head in radiotherapy. CBCT has recently been introduced as part of the Leksell GammaKnife Icon system. Due to the high geometrical precision required in radio surgery it is very important that the CBCT has a very high mechanical precision but also that the registration accuracy between the planning MR and the CBCT is highly accurate. The Icon system has an average mechanical accuracy of 0.2 mm and an average registration uncertainty of 0.3 mm.

4.3.3 Usage in intervention and treatment evaluation

The usage of CBCT during intervention has been standard procedure for about 10 years in traditional Radiation therapy. It has been used to verify the correct positioning of the patient on the treatment table, before initiating the treatment.

The intent of the introduction of CBCT in Radiosurgery using the Leksell GammaKnife has been to verify the correct positioning of the patients' head, independently, before initiating the single-session or multi session treatments. As experience is gained it has become clear that the CBCT functionality greatly facilitates the introduction of fractionation therapy into the Leksell GammaKnife way of treating patients. This is probably (has to be validated) of great importance when treating Glioblastomas.

4.4 Laparoscopic Imaging

Lead author: Barco

4.4.1 Introduction

As illustrated in the figure below, in an operating room multiple unrelated visualization devices are present, mostly cameras linked to displays, mostly provided by different manufacturers. Those manufacturers typically do not report tolerance and variability of these devices. It is known that the characteristics of those devices are changing over time, like the light bulb.

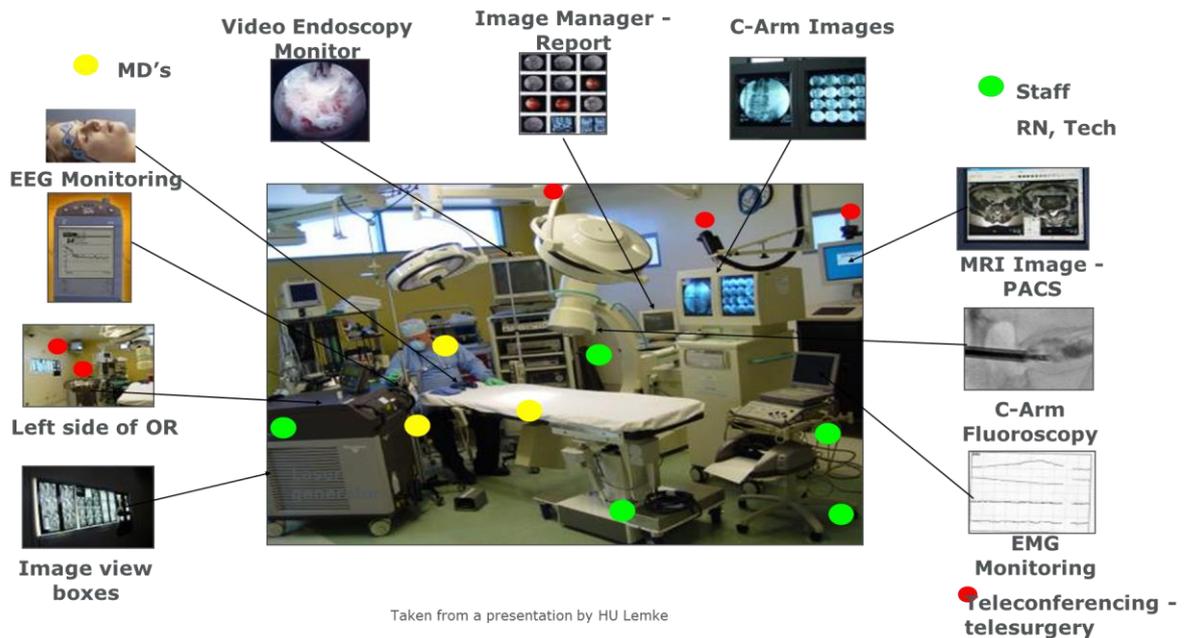


Figure 6: Typical devices in an operating room

To the best of our knowledge, no studies have been done to quantify and qualify the variability and / or the degradation of those devices over time. And it is not known however how large these changes are and what the causes and the main driving factors are. As independent devices are used in such system, the end-to-end variability of the total system will only increase.

Some practitioners are advising to replace a camera after 6 years or after 1500 to 2000 examinations [Systchenko]. This is a rough estimate taking into account various parameters (maintenance cost, security, reliability etc.). These estimates are also limited to the device itself.

4.4.2 Technical State of the Art

In endoscopy as for every medical imaging modality, color rendering plays an important role. Endoscopic images provide color images from inside the body. Following the observed region or organ of interest, colors can be very different: the stomach contains pinkish colors, the small intestine pinkish-yellowish colors [Systchenko Yasushi] etc.

When looking for abnormalities, colors play an important role: for instance white colors will be typical of scars and ulcerations; black for necrotic aspect; red for hemorrhagic; blue for a bruise [Vahedi].

Also, artificial colors can be extremely useful to highlight abnormalities:

- Fluorescence lighting can be used [Tajiri] to highlight tumors, as illustrated below.

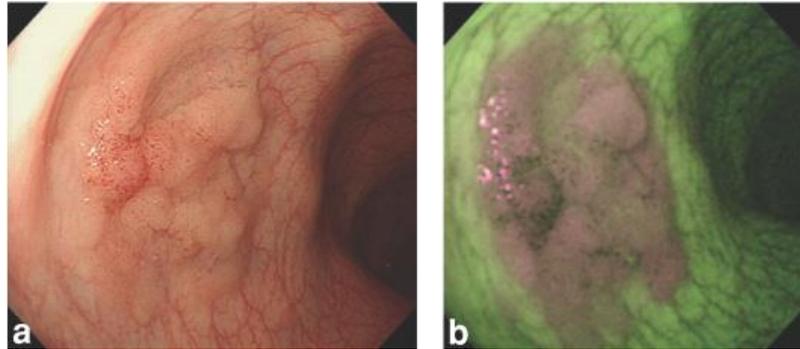


Figure 7: Example of the highlight of a tumor thanks to fluorescent lighting (left: normal lighting; right: fluorescent lighting). Source: [Tajiri]

- Artificial colorations, by means of dyes for instance, can be used to improve the detection of lesions [Dray] [Vahedi]. For instance Indigocarmin is typically used to highlight the surface relief, as illustrated below.



Figure 8: Example of artificial colors with Indigocarmin. Source: [Vahedi]

For clinical practice, it is crucial to ensure true color rendering for the acquired images, ensuring a consistent color rendering over time, whatever are the acquisition and display devices used. This is important to compare examination over time [Delmotte], segmenting efficiently the images and increasing the reliability of the diagnostic.

4.4.3 Usage in intervention and treatment evaluation

The need for a calibration standard for endoscopic images

To the best of our knowledge, there is currently no calibration standard for endoscopic images to ensure true and consistent color rendering of inside the body, although the literature demonstrated the need for it [Haneishi] [Hiroyuki] [Yokoi] [Yamaguchi2013] [Heki] [Billmann] [Constantinou2013] [Yamaguchi2001].

Color rendering will be influenced by the display used in combination with the camera; by the type of lamp; their aging etc. Focusing on the results of the presentation of [Yokoi], the general conclusion from the questioned people is clear regarding the image rendering in endoscopy: each monitor renders colors differently, and in the case of laparoscopy, this can have an influence on the diagnosis.

Another conclusion of this study demonstrates the clear need to have a standardized color representation and that there is a need to have color management for endoscopy. The study in [Ref Miyake], conducted with 2 skilled physicians, shows the importance of colors for endoscopic images. [Billmann] conducted a study



demonstrating that a color deterioration of laparoscopic images result in an increase of the time needed to achieve the task.

[Neofytou2007b] [Constantinou2009] [Neofytou2007] demonstrated that gamma color correction is a necessary pre-processing for CAD to differentiate normal and abnormal endometrial tissue in the early stage of gynecological cancer. The AAPM TG196 [Flynn] points out that a color standardization should be introduced in endoscopy. [Yokoi2006] proposed color standardization for endoscopy examinations.

The work presented in [Haneishi] details a post-process image adjustment to do color correction on endoscopic images, but this process is specific to the review of mucous membrane, and is a 3*3 matrix correction. And as far as we know, only limited research have been made so far to standardize the color rendering of input medical device to ensure true color rendering [Li2006] [Yamaguchi2011] [Grana] [Wee] [Haeghen2000] [Haeghen2006]. And none of them are taking into account the display used to visualize the acquired images. However, it is worth noticing that some work has been done to reduce endoscopic images distortions [Rdf2013a] [Wurzbacher] [Barreto] [Zhang2000] [Wengert] [Wu] [Shahidi], but this does not take into account color fidelity.

White-balancing calibration procedure

Currently, the only calibration-step performed [Cotton] [Saxena] is a white-balancing, performed by pointing the camera to a white-paper. Then the user is manually adjusting the parameters of the display to tune the colors according to its own preferences. He will typically modify the following parameters on the display: luminance, contrast, display function, white point by changing individual red green and blue, gamma. This is done prior to each examination.

Conclusion

Some manufacturers [Oev261h] are advising to use their camera with their display, but here as well, it is only claimed that the display is calibrated to ensure a good color rendering, but no calibration procedure is described to redo it. And if the display is changed, there is a high chance that the colors will not be rendered the same way (different gamut etc.).

Finally, no studies have been done to describe the use-cases, the requirements and the workflow to perform a reliable calibration of those devices, while having the possibility for the surgeon to use its own preferences. Also, those individual preferences have not been studied yet.



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