Head-worn 3D-Visualization of the Invisible for Surgical Intra-Operative Augmented Reality (H3D-VISIOnAiR)

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ABSTRACT

During surgery, surgeons must identify vital anatomical structures (nerves and lymph nodes) to prevent damage. Correct identification remains enormously challenging and surgeons require high-tech intra-operative imaging. Our team worked on developing a demonstrator of H3D-VISIOnAiR that enables visualizing the invisible by combining a commercial spectral + RGB camera, advanced image analytics and near eye display. Tests were performed with a simulated surgical task consisting of positioning beads in a nailbed with very low contrast. The results show proof of concept by real-time 2D high-resolution image acquisition, processing of hyperspectral images and displaying augmented reality overlay of processed hyperspectral images.

Keywords: near eye display; hyperspectral imaging; automated tissue classification; human tissue; surgery

1. INTRODUCTION

When cutting away sick tissue, surgeons meantime must correctly identify vital anatomical structures such as nerves, lymphatic tissue and blood vessels to prevent accidental damage to these structures. Identifying these to prevent damage remains enormously challenging, especially due to natural differences between individual human bodies. High tech imaging techniques are truly a break through aid for surgeons in addition to their anatomical knowledge for reliable high-resolution visual discrimination of critical anatomical structures.

The targeted breakthrough and disruptive system offers head-worn augmented reality (AR) for surgical use. It consists of two multi-spectral cameras (combining visual range with near infrared visualization), a belt computer with data processing, and a high-end stereoscopic near-eye display with wireless connection to the operating room digital display and archive infrastructure. The spectral signature of specific pre-defined tissues will be used to develop machine-learning models to segment vital anatomical structures. These models will be used to generate the AR-overlays on top of the current clinical field of view.

The main result is a demonstrator prototype that consists of the following hardware: a commercial spectral+RGB camera in a head mounted display with a dedicated near infrared LED ring that intermittently illuminates the scene for improved spectral image acquisition. The accompanying software enables the entire chain of high-resolution images acquisition, pre-processing for correct RGB display, processing of spectral images with filters, creating an AR overlay based on spectral image filtering displayed on top of the correct RGB display (Fig. 2). Due to limitations of the commercial camera, we developed a surgical simulated scene with low contrast (black background and black beads to be placed over black nails). Surgeons executed this task with and without the spectral image enhancement to show proof of concept visualizing the invisible. Parallel to this, we developed a complete new dissection protocol to recruit porcine samples containing nerve in fatty tissue; and recruited 50 samples for fast training of the advanced machine algorithms.

2. STATE OF THE ART

Originating from the late 1980s, spectral imaging applications are relatively well known in ind Whereas the human eye senses the colour of visible light by three types of cells red, green, and blue, spectral imaging adds additional spectral content, which can be extended beyond the visible range (Fig. 1). Various intra-operative optical imaging techniques have been proposed to identify

critical tissues (1-3) including ultrasonography (1), optical coherence tomography (4), optoacoustic imaging (4) and collimated polarized light imaging (5). Furthermore, the use of optical contrast agents (e.g. saline, indocyanine green dye, methylene blue or 5-aminolevulinic acid) in combination with infrared, fluorescence or near-infrared imaging allows the identification of various critical tissues and can be combined with normal imaging for straightforward interpretation (1, 3, 4). Although (near-infrared) fluorescence imaging has been most widely implemented, the injection of exogenous contrast agents can lead to anaphylactic reactions, and contrast agents only allow visualization of a subset of critical tissues.

In contrast to (near-infrared) fluorescence imaging, spectral imaging requires no foreign substances to be administered. This imaging technique identifies natural reflectance signatures of tissues based on their chemical composition (Fig. 1). This is similar to the perception of colors by our own eyes, but with the added benefit that many more spectral bands can be used (6). So, **one can literally see beyond human vision** by adding useful information from the abundant spectral bands (Fig. 1).

Positive results have been found for differentiating between normal and tumor tissue in thyroid and parathyroid glands (7), and differentiating nerve tissue from surrounding tissue (8).

Recently, we have shown (4, 9-11) the feasibility of fibre optic spectral analysis to identify tissue-specific optical reflectance signatures. We showed the different spectral signatures between nerve, lymph, muscle, ureter, fatty, thyroid and parathyroid human tissues (Fig. 1). As these results were achieved with single-spot measurements in full contact-mode between the tissue and the optic fiber, intra-operative application is laborious.

3. BREAKTHROUGH CHARACTER OF THE PROJECT

So, our attention was redirected to the feasibility 3D optical imaging and non-contact spectral imaging (12-14). Further development of this inherent elegant imaging technique has been slow due to the large dimensions and cumbersome handling of spectral camera systems, and the lack of optimal spectral, spatial and time resolution for surgery (15).

The H3D-VISIOnAiR project aims to solve the cumbersome limitations by miniaturized front-end sensor technology (imec & Ximea multi spectral cameras) with unsurpassed compact full-HD resolution back-end technology (i-MedTech HD near-eye stereoscopic displays); AND clinical expertise on spectral tissue discrimination (Maastricht UMC) combined with real time innovative augmented reality image processing and (Fig. 2 Top). The latter generates unique unprecedented datasets of spectral signatures of critical human tissues that feed dedicated spectral chip design.

The intended H3D-VISIOnAiR product weighs 250 gram and the belt-worn computer 800 gram. The present benchmark device (Leica ARveo surgical microscope) weighs 350 kg and takes up a considerable amount of valuable space around the patient: A thousand-fold reduction in weight and size for a fraction of the price. Finally, intended H3D-VISIOnAiR product offers ergonomic ease-of-use of surgical magnifying glasses to support optimal eye-hand coordination and unrestricted freedom to move around for the surgeon (Fig. 3).

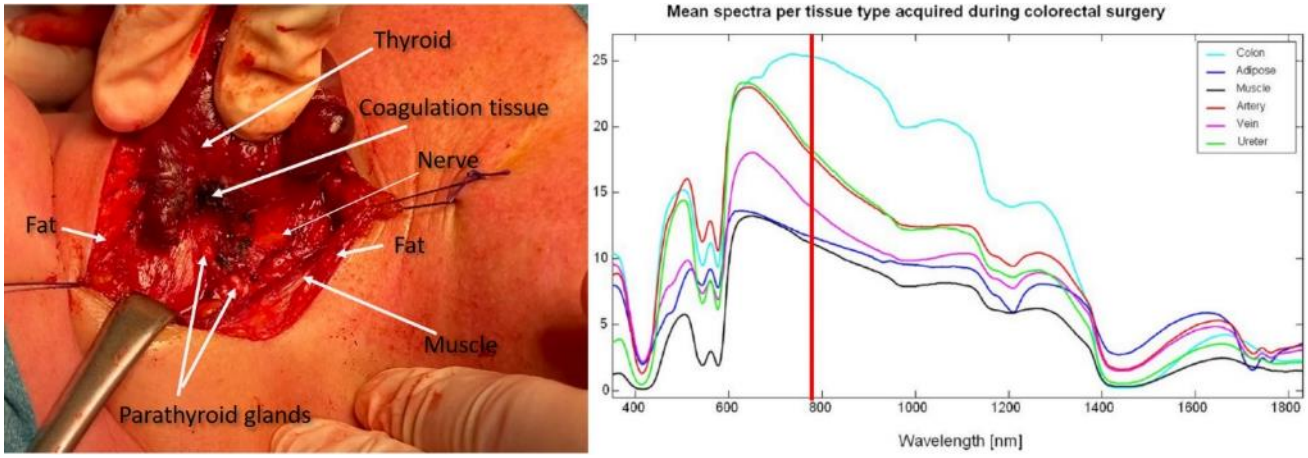

Fig. 1. Left: Typical view when performing thyroid surgery. It illustrates the difficulty in identification of critical tissues such as arteries and nerves, because they have similar colours as surrounding tissue. Right: Mean spectra per tissue type acquired during colorectal surgery. Average tissue spectra for ureter (green), mesenteric adipose tissue (dark blue), artery (red), colon (light blue), muscle (black), and vein (purple) (9). The visible range ends at 780nm, marked by red vertical line.

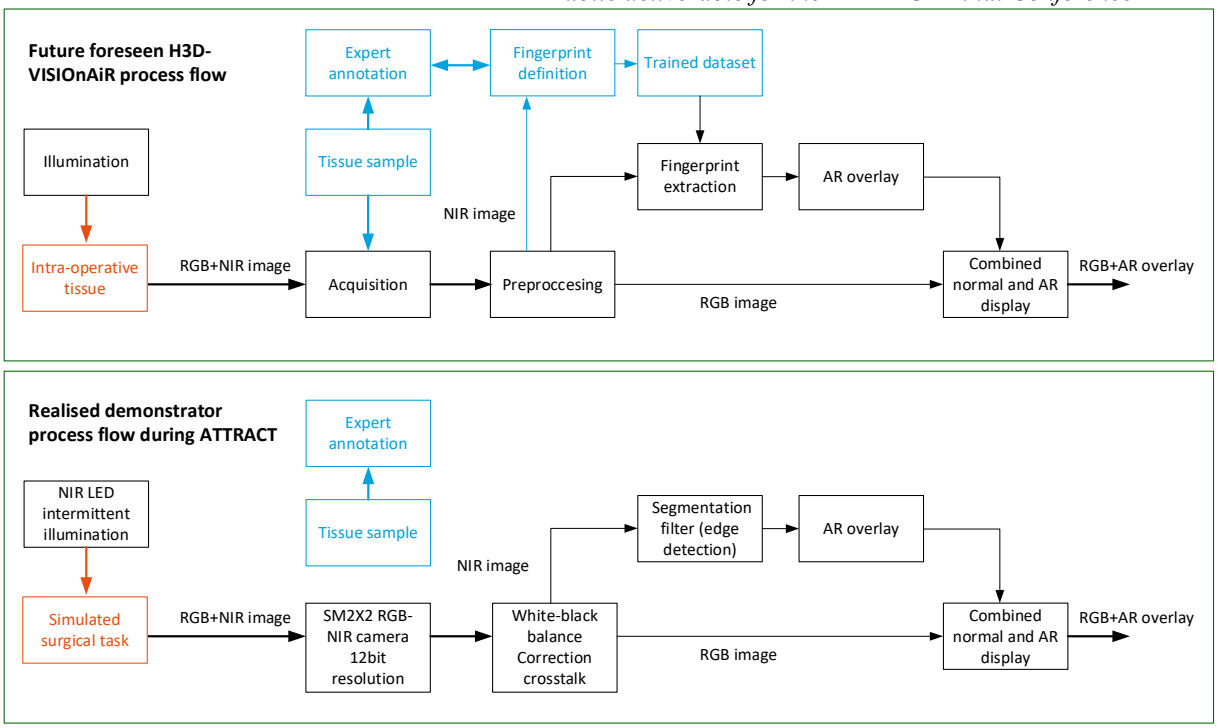

Fig. 2. Top: Scheme depicting the future H3D-VISIOnAiR product performance in the operating room. The blue boxes is off-line a priori information on spectral fingerprints of tissues that serve as input to the AI algorithms that perform real-time fingerprint extraction. Bottom: Scheme depicting the demonstrator prototype in combination with a simulate surgical task and tissue sample recruitment that was achieved within this year's ATTRACT period.

4. PROJECT RESULTS

Over the past year, our team worked on developing a demonstrator prototype of the H3D-VISIOnAiR as elucidated below and in Fig 2 (Bottom).

4.1 Recruitment of tissue samples

As no intraoperative solution exists, we focused on discriminating nerve in fatty tissue during for example thyroid surgery (Fig. 1). Subsequently, we recruited porcine tissue samples from both surgical training courses and slaughterhouse as they mimic human tissue, are easily available and allow fast off-line training of the AI algorithms to be developed (Fig. 2 Bottom blue boxes). A dedicated dissection protocol was developed and applied to recruit 50 porcine samples containing nerve in fatty tissue from the neck area. Identification of the tissues was performed in the golden standard manner by eyesight, palpation and careful dissection. Annotation was performed with conventional surgical markers, which are also applicable in the operating room for validation. Currently, we are scientifically validating the spectral resemblance between porcine and human tissue.

4.2 Experimental set up

To start the development of the H3D-VISIOnAiR, an ex vivo experimental setup was built with a commercial spectral (NIR) + RGB 2D camera (SM2X2RGBNIR, Ximea GmbH, Münster, Germany) and 4 halogen lamps (mimicking operating room light) to quickly collect spectral tissue information (Fig. 3 Left). Unfortunately, the spectral + RGB camera offered a disappointing performance due to presence of cross talk, lack of software processing capacities and improper white balancing of RGB images.

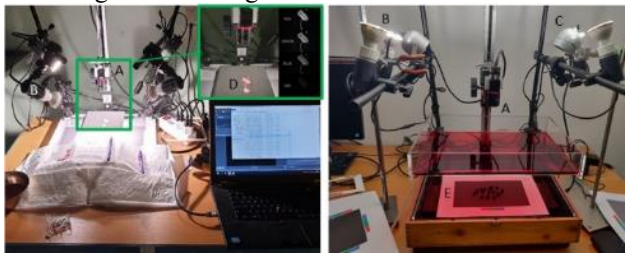

Fig. 3. Left: Experimental set up with porcine tissue sample without optimizations. Right: Adjusted experimental set up with optimal illumination for the simulated surgical task. A: RGB+NIR camera. B: normal illumination. C: 800 nm NIR illumination. D: tissue sample. E: Simulated surgical task development.

Furthermore, the single bandwidth (around 800 nm) was not suitable to actually discriminate between fat and nerve tissue. So, we focused on demonstrating the feasibility of a lightweight head mounted display using the spectral + RGB camera; and on developing accompanying software that offers the entire workflow as presented in Fig. 2 Bottom. The experimental set up was used to optimize the illumination by adding an 800 nm infrared light source and to develop a simulated surgical task that was adapted to the capabilities of the camera (Fig 3 right).

4.3 Simulated surgical task

From literature, we selected a commonly used simulated surgical task for skills training, which consisted of picking of beads with a tweezer placing them over a bed of nails in a certain pattern (Fig. 3 and 5). We adapted the task such that with normal eyesight it would be difficult to perform and that by adding information from the spectral image as augmented reality overlay it would become easy to perform. Thereto, a black environment was created with a black nailbed that gave a low contrast. Also, 2 sets of beads were painted: one set with normal black and one set with black without carbon. The latter set appears light grey in the spectral image and with this offers the ingredient to discern the black beads from their black surrounding.

4.4 Demonstrator prototype

With all information from previous steps we built a demonstrator. For the hardware, we integrated the commercial spectral+RGB camera in one of our head mounted displays (i-Med Technology BV) (Fig. 4). To minimize cross talk, RGB and spectral images were acquired intermittently at double speed to allow real-time image display. Also a dedicated near infrared (800 nm) LED ring was built that in synchronization with the spectral image acquisition illuminated the scene. We developed custom software algorithms using Python code, which allowed high resolution 12 bit image acquisition (RGB and spectral intermittently), proper white balancing of the RGB images, real-time spectral images segmentation and augmented reality display of the spectral information on top of the normal RGB image (Fig. 5).

Surgeons in our team performed tests with and without the added spectral information when performing the simulated surgical task (Fig. 5). They confirmed the added value of the additional spectral information. The information was experienced as real-time display and the demonstrator was light enough to wear, although the weight of the camera created an undesired moment. The tests indicate proof of concept of visualizing the invisible; and the feasibility of a head worn advanced intraoperative imaging system.

Fig. 4. Demonstrator of H3D-VISIOnAiR. Spectral+RGB camera, head mounted display, dedicated infrared LED ring.

5. FUTURE PROJECT VISION

5.1 Technology Scaling

In parallel the 'Digital Surgical Loupe' (main product of i-Med Technology) has been developed and allows real-time 3D full HD display. So, the most logic approach is to follow the roadmap of this product as it already solved some of the issues that are also applicable for H3D-VISIOnAiR product (currently TRL 3). Furthermore, a key step is actual spectral fingerprint determination, for which we have set up the foundation, but requires a spectral camera with many spectral bandwidths. With this crucial information, dedicated spectral filters can be developed and the AI algorithms can be trained. Additionally, a camera driver board with no cross talk needs to be developed. From than on the conventional trajectory of design for manufacturing is followed by maximizing the use of standard components and team up with experienced production partners in our network. Validation and CE marking is performed within our network of surgeons who also will be the launching customers H3D-VISIOnAiR product (reaching TRL 7 when all steps are executed).

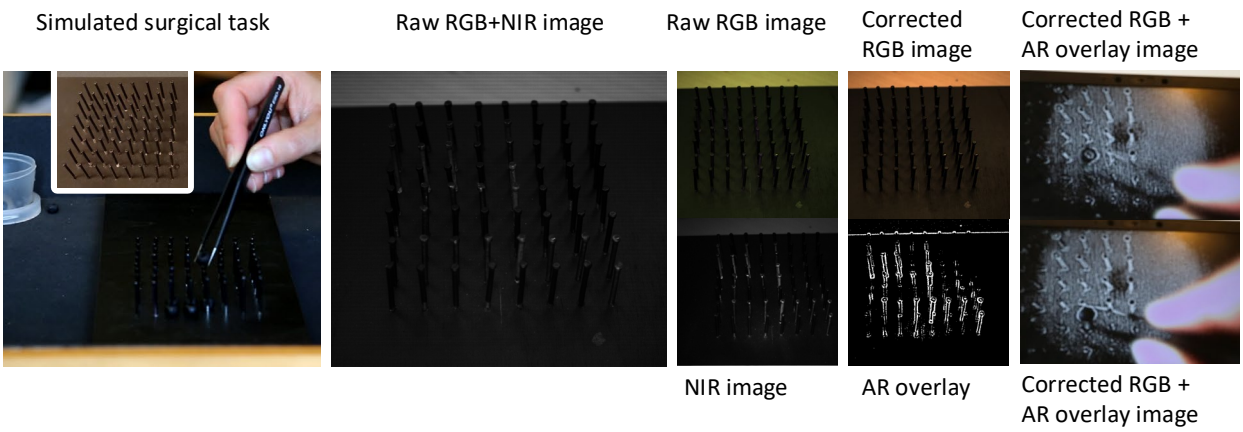

Fig. 5. From left to right: Photo of the simulated surgical task taken with a conventional photocamera, Combined spectral+RGB image, separation in RGB and spectral with RGB corrected and spectral filtered by conventional color based an edge detection segmentation, combined into RGB with augmented reality overlay image

5.2 Project Synergies and Outreach

Our current consortium of i-Med Technology BV, imec, Maastricht UMC+, Twente University, CIN-ergy BV, and Azilpix covers spectral filter design, embed software development, AI algorithms development, 3D-imaging and end-users. We would highly benefit by extending the knowledge and expertise to AR display, FPGA design, high-end camera chip design as well as accessories. ATTRACT I drew our attention to related projects that seem to have strong commonality or could reinforce: 1. FUSCLEAN (Spain), 2. HERALD (Belgium), 3. Mixed Reality For Brain Functional and Structural Navigation During Neuro Surgery (Italy).

Following dissemination deliverables as set in this ATTRACT consortium we continue to give demonstrations at exhibitions and conferences, publish new results in engineering and medical peer-reviewed journals, and give presentations at conferences by the professors in our team.

5.3 Technology application and demonstration cases

Within ATTRACT II, we would develop the actual H3D-VISIOnAiR product. This will contribute scientifically to contactless identification of spectral fingerprints for all critical tissues (nerve, vessels, lymph nodes, tumours) embedded in different tissue types (fat, muscle) and would generate datasets for fast off-line training of AI algorithms. This will also contribute to the industry by allowing the design of dedicated spectral hardware filters (initially for tissues) but the method can be applied to many more substances, dedicated FPGA programming to allow real-time data processing, miniaturized back-end technology and software building blocks for high-end fast processing of big data.

Finally, society would benefit greatly from the result of the project, by first and foremost allowing safe surgery for all, which also radically changes the way residents are trained. The technology will also be applicable for other domains such as professional telepresence, remote observation vessels, airborne drones, telemanipulators in hazardous environments, agriculture applications by analysing soil and leaves, food quality and safety, pharmaceutical monitoring and forensic analysis.

5.4 Technology commercialization

When the product in the third year of ATTRATC II is at TRL7 level, clinical trials will be performed at the MUMC+ to acquire medical European MDR certification Class IIa. In parallel, MUMC+ has indicated to buy a minimum 5 VISIOnAiR systems. They will use this to perform surgical precision procedures, but also to perform studies to develop new medical applications (like oncology). Several interviews with surgeons and hospitals show huge interest in this new head worn technology with the claimed safe and high precision surgery a breakthrough advantage to radically improve quality of surgery. Through the imec network, partner for the RGB-NIR and hardware filter development, also other new customers will be found in medical and other application domains as mentioned in Section 5.3.

In the third year, the sales of normal RGB Head Mounted Systems is predicted in Europe at €10 mio. The price of a H3D-VISIOnAiR will be 60% higher than a standard system, and will already generate additional €1 mio in the first year of introduction. In the 5th year, the percentage will be grown to 20% of the total TO with €4 mio. Main market will be Europe until FDA certification been given in the 3rd year for the VISIOnAiR. At the CES (US) in January 2020, clear interest was expressed from US and Europe investors provided a higher TRL

level can be demonstrated. With ATTRACT II, we can achieve this.

5.5 Envisioned risks

It could be the case that the sensitivity of the camera required at working distance of 40 cm is not sufficient. This would cause a delay as a re-design of the camera chip and chosen filters must be done with partner imec. In parallel, more effort should be made to improve the algorithms. Another solution improve sensitivity is to optimize ambient illumination by small powerful pulsating NIR LEDs of specific wavelengths.

Another risk is the processing power of the wearable PC to calculate the overlay information in almost real-time (<32ms). This could lead to a lower frame rate from 60 to 30fps. In the launching customer phase, this might be acceptable. To mitigate this risk, a straightforward back up is to use a powerful desktop computer with wired connection. We also develop the AI algorithms such that training can be performed off-line, and increase processing speed by adding FPGA.

Finally, the development could require more money and time to develop than the estimated €1,5mio. With proof of concept, we are confident that we can invite new investors. We expect this to be successful as a 3D HD demonstration system will be available for sure.

5.6 Liaison with Student Teams and Socio-Economic Study

In summer 2019, a MSc team of the TU-Delft investigated new applications for the H3D-VISIOnAiR, and advised to focus on security in ATTRACT II a. More teams will be invited to address other application areas and investigate common interests of related ATTRACT I projects (section 5.2)

During the ATTRACT II project, two PhD students will work on AI algorithm development (lead by University Twente) and tissue fingerprint analysis (lead by Maastricht University.

A relevant socioeconomic study is to analyse the overall impact when unnecessary surgical errors are prevented using H3D-VISIOnAiR on patients but also on their family. This is highly linked to Health Technology Assessment, which should be performed anyway and is part of the development strategy.

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7. REFERENCES

[1] de Boer E, Harlaar NJ, Taruttis A, Nagengast WB, Rosenthal EL, Ntziachristos V, et al. Optical innovations in surgery. Br J Surg. 2015;102(2):e56-72.
[2] Schols RM, Bouvy ND, van Dam RM, Stassen LP. Advanced intraoperative imaging methods for laparoscopic anatomy navigation: an overview. Surg Endosc. 2013;27(6):1851-9.
[3] Al-Taher M, Hsien S, Schols RM, Hanegem NV, Bouvy ND, Dunselman GAJ, et al. Intraoperative enhanced imaging for detection of endometriosis: A systematic review of the literature. Eur J Obstet Gynecol Reprod Biol. 2018;224:108-16.
[4] Schols RM, Bouvy ND, van Dam RM, Masclee AA, Dejong CH, Stassen LP. Combined vascular and biliary fluorescence imaging in laparoscopic cholecystectomy. Surg Endosc. 2013;27(12):4511-7.
[5] Chin K, Engelsman AF, Chin PTK, Meijer SL, Strackee SD, Oostra RJ, et al. Evaluation of collimated polarized light imaging for real-time intraoperative selective nerve identification in the human hand. Biomed Opt Express. 2017;8(9):4122-34.
[6] Lu G, Fei B. Medical hyperspectral imaging: a review. J Biomed Opt. 2014;19(1):10901.
[7] Lu G, Little JV, Wang X, Zhang H, Patel MR, Griffith CC, et al. Detection of Head and Neck Cancer in Surgical Specimens Using Quantitative Hyperspectral Imaging. Clin Cancer Res. 2017;23(18):5426-36.
[8] Stelzle F, Adler W, Zam A, Tangermann-Gerk K, Knipfer C, Douplik A, et al. In vivo optical tissue differentiation by diffuse reflectance spectroscopy: preliminary results for tissue-specific laser surgery. Surg Innov. 2012;19(4):385-93.
[9] Schols RM, Alic L, Beets GL, Breukink SO, Wieringa FP, Stassen LP. Automated Spectroscopic Tissue Classification in Colorectal Surgery. Surg Innov. 2015;22(6):557-67.
[10] Schols RM, Alic L, Wieringa FP, Bouvy ND, Stassen LP. Towards automated spectroscopic tissue classification in thyroid and parathyroid surgery. Int J Med Robot. 2017;13(1).
[11] Schols RM, ter Laan M, Stassen LP, Bouvy ND, Amelink A, Wieringa FP, et al. Differentiation between nerve and adipose tissue using wide-band (350-1,830 nm) in vivo diffuse reflectance spectroscopy. Lasers Surg Med. 2014;46(7):538-45.
[12] Bauer JR, Beekum Kv, Klaessens J, Noordmans HJ, Boer C, Hardeberg JY, et al. Towards real-time non contact spatial resolved oxygenation monitoring using a multi spectral filter array camera in various light conditions: SPIE; 2018.
[13] den Blanken MvdB, S;Liberton, M;Grimbergen, M;Hofman, MBM;Verdaasdonk, RM. Quantification of cutaneous allergic reactions using 3D optical imaging: a feasibility study. Skin Research and Technology. 2019.
[14] Klaessens JHGM, Nelisse M, Verdaasdonk RM, Noordmans HJ. Multimodal tissue perfusion imaging using multi-spectral and thermographic imaging systems applied on clinical data: SPIE; 2013.
[15] Schols RM, Dunias P, Wieringa FP, Stassen LP. Multispectral characterization of tissues encountered during laparoscopic colorectal surgery. Med Eng Phys. 2013;35(7):1044-50.