Needs analysis and construction of a simulation mannequin for diagnosing head and neck cancer

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Abstract— *Besides imaging, the central step in diagnostics of head and neck cancer is biopsy and rigid triple endoscopy, a routine procedure for over 50 years. However, the assessment of this procedure in terms of comparative studies has so far been unfeasible for ethical and practical reasons. The goal set was to construct a simulation mannequin of lifelike synthetic tissue for the evaluation and training of triple endoscopy. Paired up as a tandem, mechanical engineering and medicine postgraduates captured the work environment and gross steps of the procedure by means of observations in the surgery room, creation of a workflow and brainstorming in a multidisciplinary team. The further specifications, derived from in-depth interviews with eight ENT senior physicians, were as well incorporated into a quality function deployment (QFD), that resulted in focus on realistic, computed tomography (CT) scan based anatomy, lifelike haptics and optics of mucous membrane surfaces. These priorities lead to the decision to construct a modular triple endoscopy simulator which was integrated into a suitable mannequin already available on the market. As triple endoscopy was consistently judged by 100% of the interviewed ENT senior physicians as a challenging procedure the project was considered to be meaningful. The first consideration was to assess the procedure, which is now possible, but during the project time we decided to alter the weighting in the direction of simulator based training.*

***Keywords—* Quality Function Deployment, high-fidelity simulator, head and neck cancer, training, triple endoscopy, multi disciplinary engineering, difficult airway management.**

I. INTRODUCTION

Approximately 50 out of 100.000 people in Germany develop head and neck cancer per annum (1). Among the diverse entities, ENT (Ear-Nose-Throath) oncologists most frequently deal with larynx- and hypopharynx carcinoma. According to EUROCARE-4 and -5 analysis the overall cure rate totals 42%, noted that carcinomas of the hypopharynx have a very poor prognosis with a cure rate of only 26% (2), (3). Besides imaging, the central step in diagnostics is rigid triple endoscopy and biopsy. In the course of the examination, a secondary malignancy can be detected in the upper airways and esophagus in approximately 2 to 7% of the cases (4), (5), and of same importance, the endoscopy allows accurate inspection and palpation. The tumor data that is collected during endoscopic examination is needed for a precise therapeutic decision in the tumorboard. Although this approach is valid for more than 50 years, it has never been assessed so far (6). Firstly, for ethical reasons it is problematic to repeat the same triple endoscopy under general anesthesia in one and the same patient during comparative studies. Secondly, the tumor undergoes instant alterations in the very moment of the examination. Therefore simulation mannequins of lifelike tissue are needed for such assessment studies.

Furthermore and despite of being a standard procedure, triple endoscopy can yet be considered as challenging and risky examination even for experienced surgeons. “Learning by doing” is no longer feasible against the background of patient safety and no longer viable given the fast-paced daily routine in the wards (7), (8), (9). A rising number of skills labs and offers of simulator training for medical students and residents evidences the need for a simulation-based education (10), (11), (12), (13).

There is a growing number of simulators on the market for teaching, learning and assessing surgical knowledge and skills. There are task trainers, part-task trainers in low- or high-fidelity versions as well as mannequins and software-based simulation systems. However, the majority of simulators have been developed for use in laparoscopic surgery, endoscopic procedures and trauma care. For head and neck surgery there is only a very limited number of simulators available so far, mostly addressing temporal bone surgery (14), (15), (16), (17). Furthermore, there are some simulators for sinus surgery, one simulator for neck dissection, a three-dimensional virtual reality myringotomy simulator using haptic feedback, and a simulator for surgical planning of anterior and lateral skull base surgery (18), (19), (20), (21), (22), (23), (24).

In order to evaluate triple endoscopy and for the purpose of improving ENT training, we intended to construct a simulation mannequin with lifelike haptic and optic properties (i.e. anatomical structures) based on synthetic materials. The systematic, multidisciplinary approach to this endeavour is presented in this paper, considering the given circumstances of limited time and financial resources in particular.

II. METHODS

2.1 Project team

The construction of a realistic simulation mannequin for the diagnostics of head and neck cancer was part of a large-scale project undertaken by the Leipzig University of Applied Sciences, the Leipzig Medical University and the ENT Department of the University Hospital of Leipzig.

Engineering and medicine postgraduates closely worked together in tandems in a multidisciplinary setting with the aim of constructing patient simulation systems for surgical training (PascAL) (see figure 1).

2.2 On-site visits and workflow diagram

Several rigid triple endoscopies conducted on patients with head and neck cancer were observed by both tandem partners at the cooperating ENT department. Each team member took notes in the surgery room and wrote the minutes for every observed procedure. Possible influencing factors were named, utilized instruments specified and finally a workflow diagram was generated based on the details of the engineer's and the physician's independent observations. Furthermore, the student's skills lab was visited in order to inspect training mannequins of basic life support and airway management. In addition to that, the realistic jaw mobility of the simulators used there was examined in the skills lab of the department of odontology, also investigating how such a mobility was technically achieved.

2.3 In-depth interviews

A guideline for in-depth interviews was developed consisting of three areas concerning triple endoscopy: (1) surgical approach (including personal experience, preparation, challenges and complications and analysis of the surgical workflow), (2) decision making in presence of a larynx carcinoma in an advanced stage and (3) training of triple endoscopy (including conception of the training and properties of a suited simulation system). Furthermore, during interviews we showed samples of silicones varying in elasticity, consistency and thickness for the mucous membranes and the areas of the tongue, tonsils, epiglottis and esophagus to obtain a first impression of the properties of the needed materials for simulator construction.

Eight ENT senior physicians from seven different clinics in Central Germany were interviewed. Each interview lasted about one hour, the conversation was recorded, transcribed and anonymized. For the qualitative analysis MaxQDA software was used (MAXQDA, Software für qualitative Datenanalyse, 1989 – 2014, VERBI Software. Consult. Sozialforschung GmbH, Berlin, Germany).

2.4 Brainstorming and Mind Mappin

A brainstorming session in a multidisciplinary setting was conducted first. Besides both tandem partners, a designer, an industrial engineer and the advisor of the cooperating ENT department attended the session. The technique of brainstorming without moderation was applied, which allowed us to collect many ideas after a short introduction of the task within the time span of only 20 minutes (25). According to the general rules it was permitted to pick up ideas of other participants and to develop them further, but not to rate or judge any of the propositions made. The principle behind this approach is to generate quantity not quality, which keeps thoughts in a good flow and at the same time it promotes concise formulations of ideas. Subsequently, mind maps were drafted by the engineer (see figure 2, as one example) and the physician separately, each of which seizing the numerous fragments of thoughts that remained after brainstorming and developing own aspects (26).

2.5 Quality Function Deployment (QFD) and the House of Quality

QFD is a quality management tool for conception, realization and selling of products and service widely used in industry and economy since the 1970ies (27), (28), (29). The method indicates the "Voice of the Customer", thus making his requests transparent, allowing for structuring and weighting and at the same time correlating them to the necessary specific functions and parameters of the desired product. First, the customer (in our case represented by the physician) decided on his ten most important requests and rated them from 1 (little important) to 5 (very important). Subsequently, the engineer assigned the functions of the product necessary to meet the requests and classified the relation (1=weak, 3=moderate, 9=strong) to the request. Now the precise parameters were discussed and defined, as well as the technical difficulty to accomplish them (0=easy to 10=extremely difficult). The prior to this drawn mind map proved helpful for the client and the engineer. The QFD matrix (QFD Online, http://www.qfdonline.com/) used in our project automatically calculated column and line values based on the ratings of the project partners, resulting in an overall weight and a ranking of priorities. Additionally, it was possible to rate the correlations of the various technical parameters amongst each other, detecting positive and negative interactions. The matrix itself is called "House of Quality", interactions are represented by "the roof of the house" (28).

2.6 Rapid Prototyping

Cartilagenous structures and the moulds for the soft tissue structures were manufactured via rapid prototyping technology with an Objet30 Pro printer (Stratasys, Edina, USA) The printer can build objects with a maximum dimension of 300 x 200 x 150 mm and an accuracy of 0.1 mm. One layer has thereby a thickness of 28 micrometer (30). To realize complex geometries and to secure overhanging elements, supporting material has been used, which was removed with a water jet device after the printing process. For manufacturing of the training model, the materials FullCure835 VeroWhithe Plus and FullCure705 Support have been used.

III. RESULTS

3.1 On-site visits and workflow diagram

By nature, the engineer and the physician had different approaches, different ways of thinking and foci. During the on-site visits in the ENT operation room, the engineer observed the importance of communication in the team, the setting in the surgery room, the instruments and their alignment, and the environmental factors such as illumination and noise. Meanwhile, the physician was busy with scrutinizing the movements of the surgeons, the positioning of the patient, anatomic patient details like shape of the jaw, weight and the details of documentation. Only after comparing the notes that were taken, it was possible to see the procedure as a whole and to depict it as a workflow diagram (see figure 1).

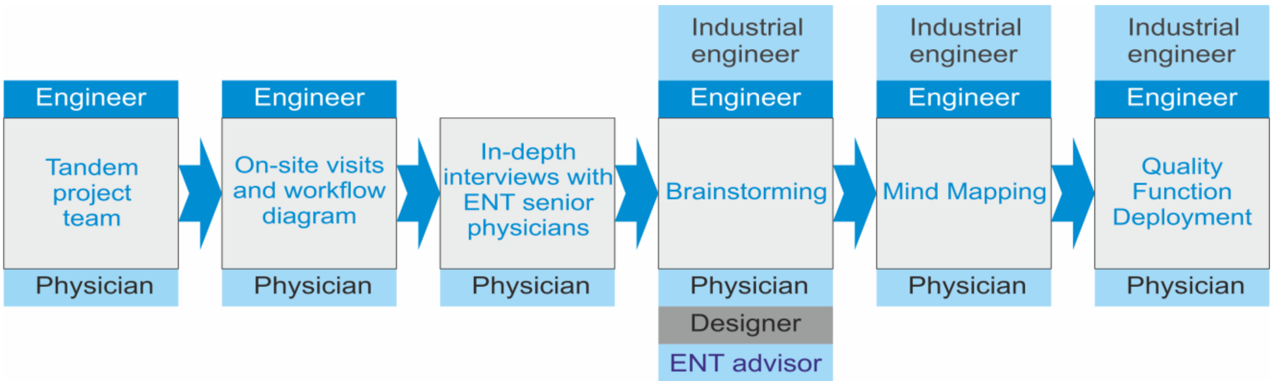

FIGURE 1 1ILLUSTRATES THE MEMBERS OF THE MULTIDISCIPLINARY TEAM AND THE METHODS USED TO IDENTIFY THE REQUIREMENTS OF A REALISTIC SIMULATOR BASED ON SYNTHETICS TO BE USED FOR EVALUATION AND TRAINING OF TRIPLE ENDOSCOPY.

3.2 Brainstorming and Mind Mapping

Mind maps generated after the brainstorming phase proved to be an important preparatory work for the QFD. The mind map of the physician showed the client requests, the mind map of the engineer the necessary functions. Both mind maps (see figure 2) were the basis for our QFD.

New aspects concerning the materials that popped up during brainstorming included, amongst others, the adhesives, pigments and lubricants that needed to be tested. The durability of the materials especially under examining conditions and the desirable longevity of the simulator in relation to the artificial materials of the simulator turned out to be of key importance. Another aspect for consideration is the possibility of integrating sensor mechanisms. The limit values for the mobility of the jaw and the cervical spine were further important input parameters for the construction of the model.

Talking about the use of the simulator, a variance of tumors at different locations of the head and neck region were asked for in order to avoid habituation and being able to present different challenges for different training levels of the trainees. Very wide-spread tumors, as well as extremely tiny tumors at easy-to be overseen spots like the bottom of the piriform sinuses as well as in the submucosa located tumors were thought of.

3.3 In-depth interviews

In-depth interviews with ENT senior physicians were conducted and revealed that all involved physicians considered triple endoscopy as a challenging procedure. Especially when encountering patients with cervical spine syndromes (n=2) and patients with large tumors, rigid tracheobronchoscopy and esophagoscopy were often difficult to perform, even for an experienced examiner (n=2) - the same was stated for intubation (n=2). Also the interpretation of imaging scans, in particular MRT scans, can put great demands on the examiner (n=3) (see figure 3). Perforations of the esophagus or piriform sinuses (n=5), severe bleedings of a large tumor (n=2), either possibly following biopsy (n=3) or spontaneously were cited amongst the dreaded complications (see figure 3). Also bleeding of esophageal varices caused by rigid esophagoscopy or severe life-threatening bleeding owed to tumor arrosion of the carotid could be provoked by the examination.

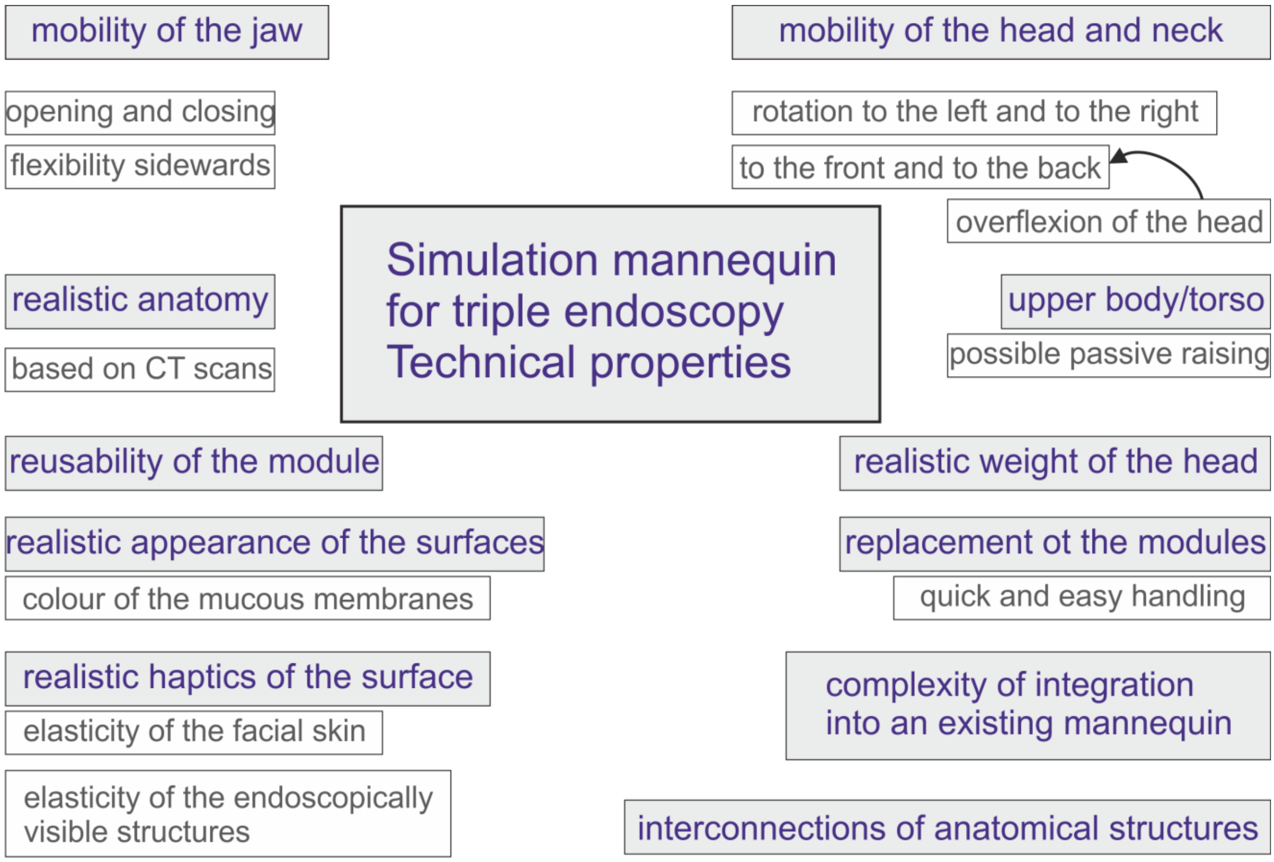

FIGURE 2 MIND MAP OF THE ENGINEER SHOWING RELEVANT FUNCTIONS THAT NEED TO BE CONSIDERED AND INTEGRATED INTO THE QUALITY FUNCTION DEPLOYMENT.

When being asked, whether or not the construction of a simulator of the upper airways and esophagus would be valuable, all of the interview partners agreed - but they also pointed out that the anatomy as well as the haptical and optical properties have to be true-to-life. The simulator was rated as a useful tool to equip the trainees with knowledge and competences for palpation, handling of instruments, and the mere course of action. A standardized procedure was seen as an important factor. The majority voted for an optional training in the first year of specialization (n=5) because of the emergency intubations that could occur during on-call duty. Two senior physicians regarded the second year and the third year, respectively, as a more adequate point in time. There was only one ENT specialist who did not see any need for a simulator training at all.

There was, however, a common view that the best training still is the training on real patients, as the complexity of the sum of all influencing factors could in any case never be represented by a simulation mannequin. There was absolute agreement on the importance of low costs for the training (up to a maximum of 300 Euro).

3.4 Quality function deployment

The medical postgraduate representing the "Voice of the Customer" defined the nine most important features of the desired product, i.e. the simulator, and ranked them based on the brainstorming diagram. Without the general overview obtained by the in-depth interviews, the on-site visits, and the consultations with the cooperating ENT department, it would have been hardly possible to create this ranking.

	SP 1	SP 2	SP 3	SP 4	SP 5	SP 6	SP 7	SP 8
challenges for the expierienced examiner	●	■		●			●	●
endoscopical orientation								■
presence of cervical spine syndromes						■		■
intubation			■		■			
CT/MRT scan reading		■				●		●
exposition of the larynx		●				■		
rigid tracheobronchoscopy		■	■					
rigid esophagoscopy in presence of a large tumor		■	●					

FIGURE 3 ALL OF THE EIGHT ENT SENIOR PHYSICIANS (SP) REGARDED TRIPLE ENDOSCOPY AS A CHALLENGING PROCEDURE. THE RED SQUARES SHOW THAT THIS CHALLENGE WAS MENTIONED SEVERAL TIMES IN THE INTERVIEW, THE SMALL BLUE CIRCLES INDICATES THAT THIS TOPIC WAS ONLY MENTIONED ONCE.

The requests with the highest priority, resembled by 5.0 in column 4 "weight/importance", turned out to be the possibility of life-close performance of triple endoscopy, the realistic anatomy, optics and haptics as well as the reproduction of different head and neck tumors and a raisable torso. A reasonable selling price and the mobility of the head and neck were graded as little less important (resembled by 4.0 in column 4). The realistic mouth opening and the quick and easy replacement of the endoscopy module were of medium importance. In this proceeding the guidance by the industrial engineer, who was experienced in the method, was indispensable. Especially when the client does the ranking, every request was initially of equally high importance. Here, critical inquiries were needed to really prioritize and to determine exact values. While completing the QFD matrix cooperatively, many of the requests and technical aspects were discussed over again - in case of doubt, a third team member with more experience in the respective area was consulted. Finally, the “House of Quality” showed the relationships between the requests and functions, interdependencies of the functions and their importance to the customer. The highest importance score was shown for the realistic anatomy (359 points), that had to be CT scan based. As a consequence, a software for segmentation and the suitable patient CT scans had to be arranged. Realistic haptics and optics is on second place (both reaching 346.2 points), for which a continuous medical validation was deemed necessary. The replaceability of the module was placed third (284.6 points). Comparison of the ranking of particular functionalities and the technical difficulty required to accomplish them helped to identify specifications that would imply a lot of time and cost-intensive development on the one hand, but at the same time being not crucial for achieving customer satisfaction. In the given case, such a mismatch would show up for the complex mobility of the head (rank 4, difficulty 7) and jaw (rank 5 and 7, difficulties 7 and 8) as well as for the construction of the upper body (rank 6, difficulty 5). Details can be seen in figure 4.

In order to accomplish the required task with limited ressources, the simulator had to be designed in a way that it could be integrated into a preexisting mannequin. Such a suitable mannequin should already provide.

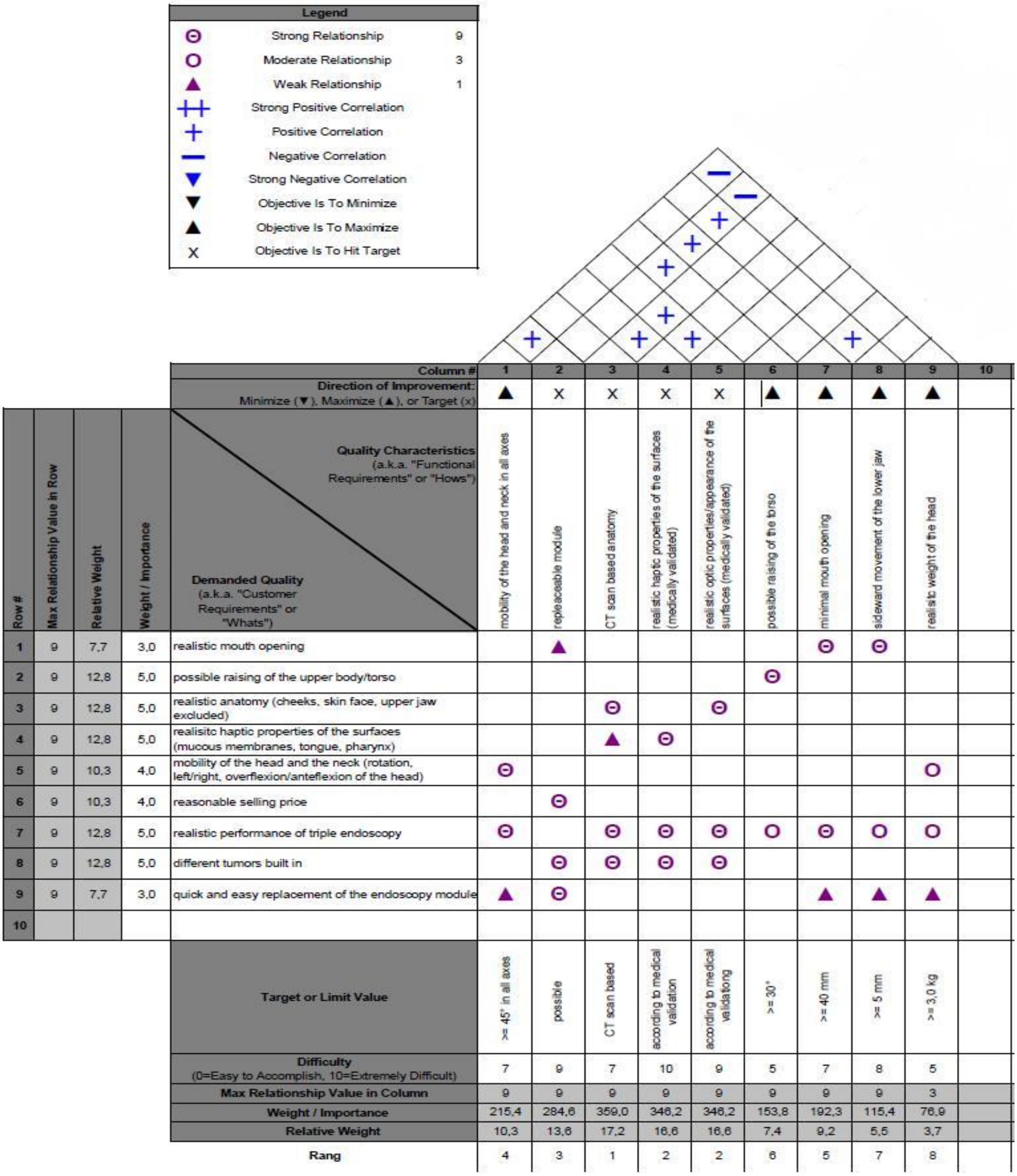

FIGURE 4: QUALITY FUNCTION DEPLOYMENT RESULTED THAT THE FOCUS OF THE DEVELOPMENT PROCESS HAS TO BE SET ON CLOSE-TO-LIFE ANATOMY, HAPTICAL AND OPTICAL PROPERTIES AS WELL AS ON THE REPLACEABILITY OF THE MODULE.

A mobility of the head and neck of 45° in all axes, a mouth opening of at least 3cm combined with a sideward flexibility of approximately 5mm, and a head weight of around three kilogramms. To meet these requirements, a field survey of airway mannequins has been conducted in order to find a suitable mannequin which can serve as a carrier system for the endoscopy module to be fitted in.

The original idea of having a number of different exchangeable tumor modules in one standard endoscopy simulator turned out to be not technically feasible. It would rather be necessary to construct different endoscopy simulators with a tumor entity - each to be replaced as one whole piece. Considering the project time, it was decided to focus on one standard anatomy model and one selected tumor only.

3.5 Construction of the prototype

Cervical CT scan data of a patient with supraglottic larynxcarcinoma was selected and segmented by the medical postgraduate and controlled by the advisor of the cooperating ENT department (author AB) using the Dornheim Segmenter Software (Dornheim Medical, Magdeburg, Germany). The segmented structures included tongue, hyoid bone, the cartilages and the soft tissue of the larynx, trachea, esophagus, the scull, upper jaw, and the mandible. The jaw and the skull data was needed for planning of the modelling process. Fine soft tissue structures are by nature not sufficiently depicted in a CT scan, so we had to create data for fine structures according to anatomical drawings.

The segmented data was then imported into the Geomagic Freeform Modelling 2013 (Geomagic Solutions, Morrisville, USA) as .stl files. Geomagic Freeform Modelling is based on voxels, which makes a conversion from .stl data into clay modells possible and therefore allowed reworking and refinement of all of the anatomic strucutres As a next step the clay structures representing the cartilageneous structures were reconverted into .stl format and created on the rapid prototyping 3D printer Objet 30 Pro (Stratasys, Edina, USA).

Soft tissue structures have been realized with addition-crosslinking silicone. The moulds of the structures were again planned using the Geomagic Freeform Modelling Software 2013 and then 3D-printed. Because of the complex anatomy, some of the moulds consisted of several parts, for example the mould for the trachea and the larynx.

For identification of the most suitable matieral, several silicones were blended and realized in seven 1mm to 4mm thick bars. As results of these tests, performed during the in-depth interview, materials for the tongue, larnyx, trachea, and esophagus were chosen and poured into the respective moulds. For particular models, auxiliary material, such as cotton flakes to obtain a core structure of higher consistency, have been added. The single anatomical silicon-based components finally have been fixed together at predefined splices. Combination of rapid-prototyping parts with silicon-based components is realised with commercially available superglue. The pharynx of the chosen airway mannequin was newly casted and served as a „container“ for the panendoscopy module. It is fixed to the mannequin by four screws - two of them fixing it to the lawer jaw and two other screws fixing it to the upper jaw. Finally, the panendoscopy module was glued into the pharynx. The hard palate, the jaw, and the teeth of the mannequin did not need any further modification and could be used in its original form. The final prototype of the triple endoscopy mannequin is shown in figure 5.

IV. DISCUSSION

As a result of the project it became clear that even though mannequin based assessment is important, the simulation based training is even more relevant in daily practice. The construction of a life-like tissue mannequin with the given properties (see QFD) is possible with the current technology.

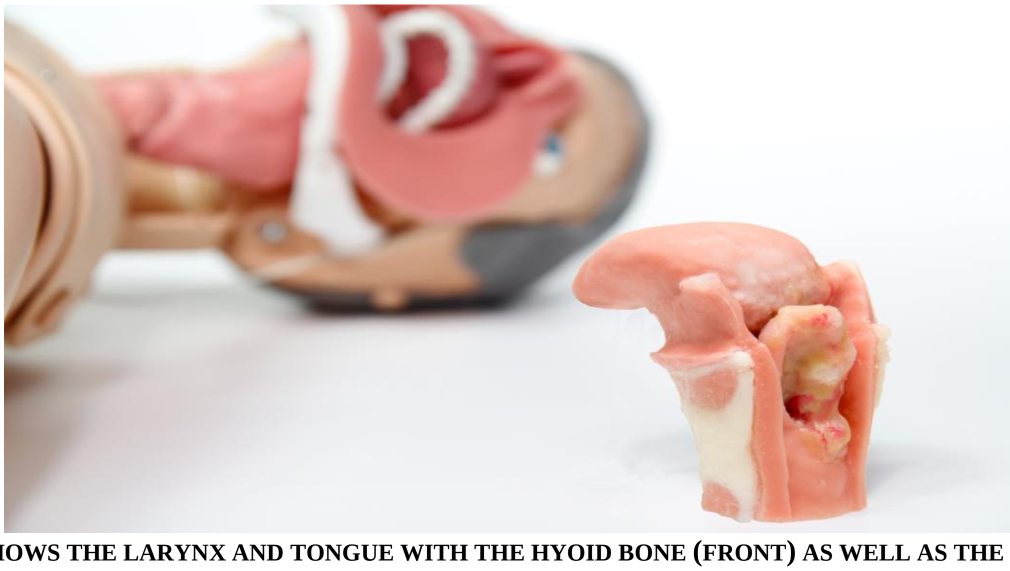

FIGURE 5 SHOWS THE LARYNX AND TONGUE WITH THE HYOID BONE (FRONT) AS WELL AS THE SIMULATION MANNEQUIN WITH THE ADAPTED PHARYNX (BACK).

Looking at available virtual reality simulators (i.e. for gastroesophagoscopy or bronchoscopy, (10), (11)) it became clear that they were not suitable for our project as the anatomy is simplified and, moreover, a haptic feedback is not given. As palpation is an essential part of the endoscopic examination in the evaluation of head and neck cancer this feature, however, is substantial. This also counts for the many mannequins for airway management training, where missing haptics and inadequate anatomy are once again major deficits (12), (13).

At the beginning of the project we encountered difficulties in our own communication – mainly due to different terminology, and thus the main focus of attention often differed. After creation of a common view and with introduction of "tandems", consiting of an engineering and a medicine postgraduate, these tandem partners could more appropriately explain the specific problems to other colleagues in "their language". Working in tandems turned out to be beneficial as it expands one's view and supports permanent checkup of the working steps, which finally prevents development going in the wrong direction. Further, working in a multidisciplinary team of engineers, psychologists, educationalists, designers and industrial engineers - all of them working in the area of simulation technologies - had the advantage of constant exchange of ideas and led to early detection of important aspects in the various depending areas. The psychologists, for example, gave us valuable hints for the development of the in-depth interview guideline and already had their concept for a training with our simulator roughly in mind. The designers in the team brought in a lot of experience with synthetic materials and processing of plastics gathered during a previous simulator project for lumbar discectomy (34), (35).

The industrial engineer suggested to perform a QFD and was informed about the situation of the simulation market. Different publications (31) (32) (33) (27) present the QFD as a tool to integrate the costumer needs in the design process of medical products in a structured way. Regarding the development of medical products, the QFD is an effective system thinking approach, which allows to better understand the customers' needs and wants, to identify opportunities for process improvement, supports communication and a more transparent process (33). Some concrete results of the QFD application in this area show a significant reduction of faults, compared to products developed without this tool (31). However, studies reporting the use of QFD for the development of mannequin-based simulation systems could not be found in literature.

In addition to its application for ENT purposes, the simulator could be of use for training of difficult airway management - for instance when presenting the possibility of bleeding of the tumor, which is a very stressful situation for both the anesthesiologist and the ENT surgeon. The communication between the two medical specialists in the stressful setting of an operating room could be analyzed.

V. CONCLUSION

Summing up, our methodical approach resulted in a streamlined development for a simulation mannequin for diagnosis of head and neck cancer. This simulator will support further assessment of triple endoscopy. Simulator based training is prerequisite for the improvement of patient safety.

For the construction of a simulator mannequin, work in "tandems" – consisting of a medical and construction engineer postgraduate - has turned out to be very valuable in the conception process. On-site visits and strong involvement of a clinical cooperation partner were indispensable for getting a detailed view on the task in its actual context. In-depth interviews and QFD were helpful tools to capture, analyze and at the same time to prioritize complex needs.

The further integration of sensors into our mannequin will improve the feedback for surgical training. Besides surgical training, the application of the simulator in difficult airway management and other applications is intented.

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