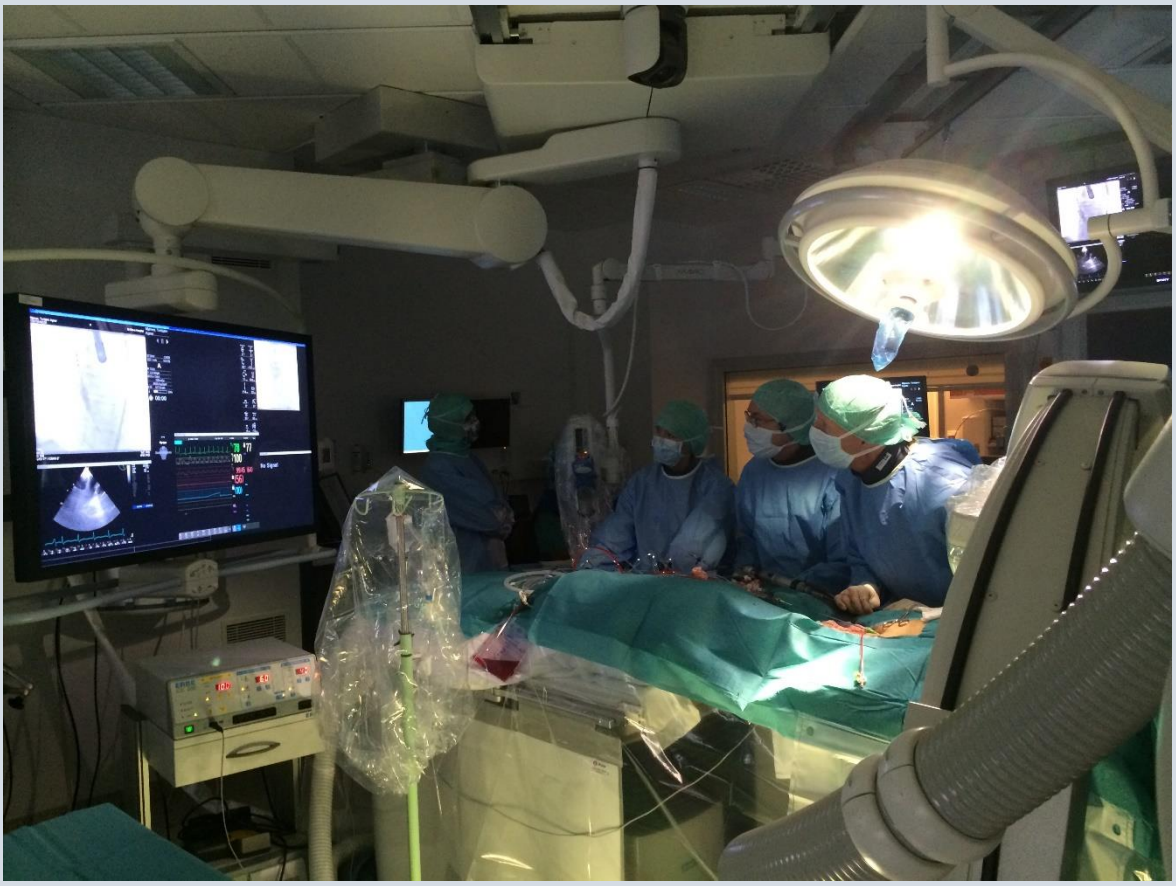
Operating Room of the Future
Annual report 2022



St. Olavs hospital FOR – NorMIT Infrastructure

Operating Room of the Future

ST. OLAVS HOSPITAL
TRONDHEIM UNIVERSITY HOSPITAL

NTNU

ST. OLAVS HOSPITAL
UNIVERSITETSSYKEHUSET I TRONDHEIM

NTNU | Norwegian University of Science and Technology

Frontpage photo: Liv- Inger Stenstad, FOR

Preface

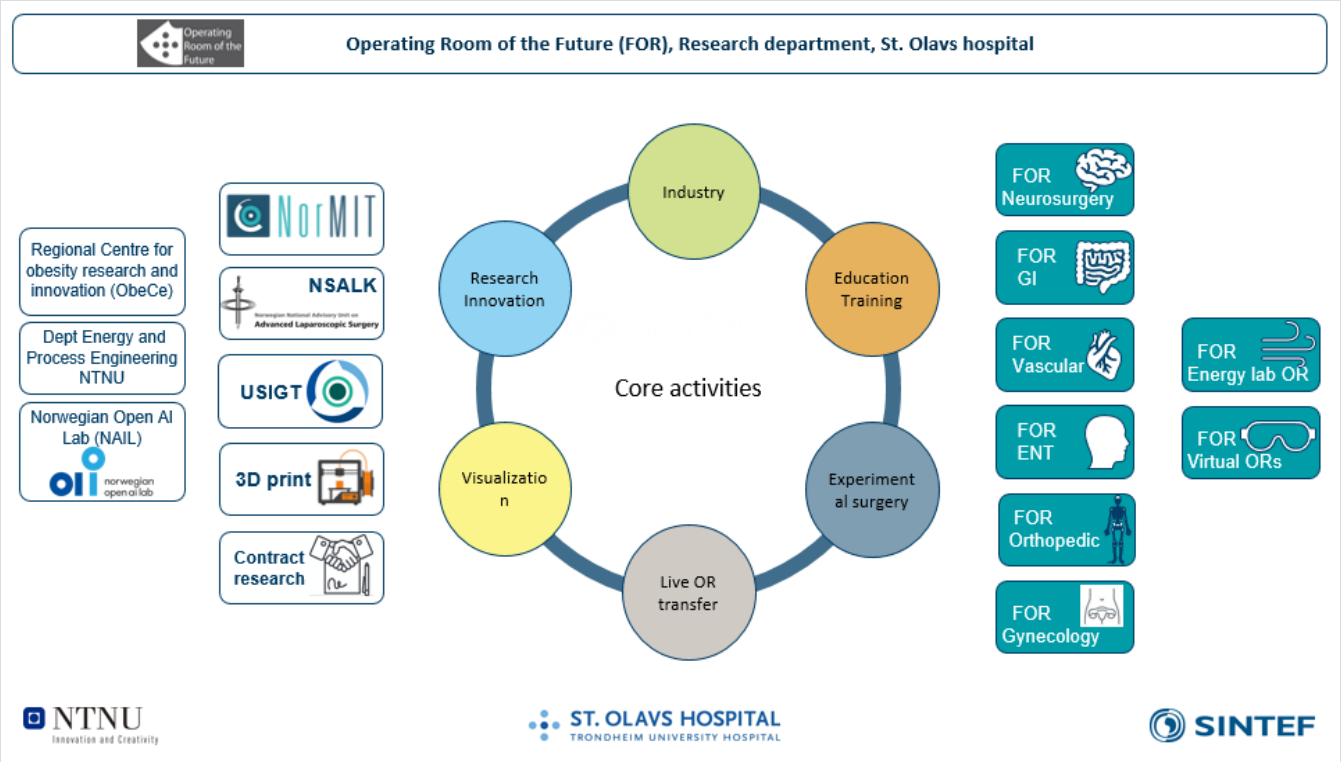
The year 2022 has been more or less a normal year, where we see that activity has increased after 2 years of pandemic.
During the year, we followed up and arranged for PhD scholars, master's students and bachelor's students who all carried out their tasks using the FOR infrastructure. We also pleased to a see an increase in activity.
Several different research-initiated or industry-initiated projects have been carried out during the year.

NorTrial's center for Medical Equipment was established - New partnership for research on patient treatment commissioned by the HOD.
Clinical studies are central to the development of new medicines and medical equipment. It gives patients access to new forms of treatment, it gives physicians and researchers new knowledge, and it gives the pharmaceutical industry the opportunity to test the effects of medicines and equipment. NorTrial's center for medical equipment has been added to St. Olav's hospital, the Research Department at FOR.

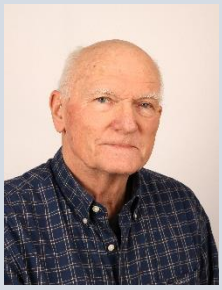
In this edition of the annual report, we will show what FOR and NorMIT's infrastructure consists of and at the same time give you an insight into our activity during 2022.
We wish you a good reading of our annual report for 2022!

Jan Gunnar Skogås
Head of department
Managing director
Photo: St. Olavs Hospital

Organization of the Operating Room of the Future



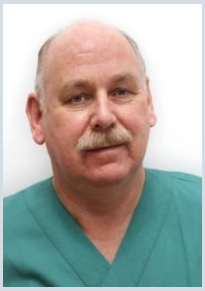
Staff



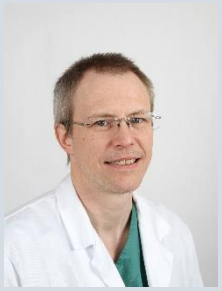
Hans Olav Myhre
Emeritus professor
of surgery

Jan Gunnar Skogås
Managing Director

Ivar Rossvoll
Associate Professor



Ronald Mårvik
Associate Professor



Frode Manstad-Hulaas
Associate Professor

Liv-Inger Stenstad
R&D coordinator

Jan- Magne Gjerde
R&D coordinator

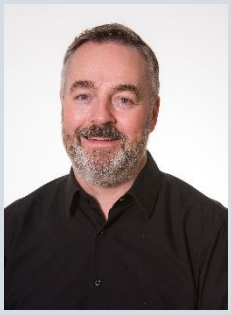
Gabriel Kiss
Scientist, R&D coordinator

Ingrid Granbo
R&D coordinator

Marianne Haugvold
Advisor R&D

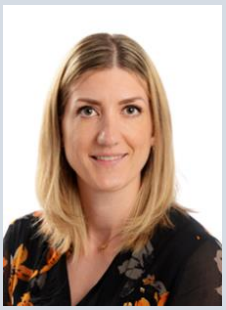
Vigdis Schnell Husby
R&D coordinator

Guangyu Cao
Professor NTNU



Thomas Langø
Chief Scientist

Gunnar Gjeldnes
R&D coordinator



Trine Selbekk Øvstebø
Economic adviser

Sara Edvardsen
Scientist, R&D coordinator

Photo: St. Olavs Hospital

Scientific advisory board

An important task for FOR is to improve the quality and quantity of clinical research. Therefore the scientific advisory board is going through all research protocols, giving advice to those who are doing projects under the direction of FOR. FOR has special guidelines for projects, including the tasks of the scientific advisory board as well as a description how to make research protocols (Professor Per Farup). These documents are forming the basis for the collaboration between FOR and those who are conducting research projects there. In addition we are making separate agreements between FOR and the project leaders.
FOR additionally contributes a great deal to students at the research line at The faculty of Medicine (NTNU), an offer for medical students who are interested in research and a possible future research career possibly parallel to clinical activities.

The scientific advisory board has the following members:

Associate Professor Ivar Rossvoll (leader)

Emeritus professor Hans Olav Myhre

Professor Per Farup

Professor Olav Haraldseth

Professor Ståle Nordgård

Associate Professor Frode Manstad-Hulaas

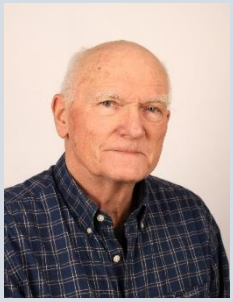
Associate Professor Knut Haakon Stensæth

Research director Thomas Langø

Associate Professor Wenche Moe Thorstensen

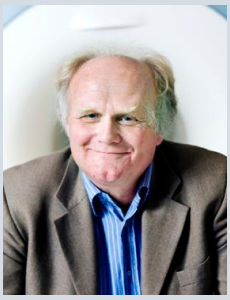
Specialist in clinical pharmacy Trond Oskar Aamo

Ivar Rossvoll
Scientific adviser
Associate professor



Hans Olav Myhre
Emeritus professor
in surgery

Per G. Farup
Professor



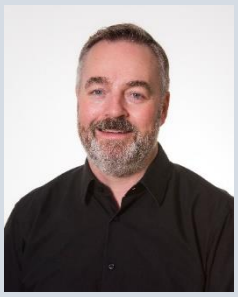
Olav Haraldseth
Professor

Wenche Moe
Thorstensen
Associate Professor

Ståle Nordgård
Professor

Frode Manstad-Hulaas
Associate Professor

Knut Haakon Stensæth
Assistant professor



Thomas Langø
Chief Scientist

Trond Oskar Aamo
Specialist in clinical
pharmacology

Photos: St. Olavs Hospital, NTNU, SINTEF and private

Activity in 2022

FOR – NorMIT 3D-printlab

2022 was another busy year at the 3D-print lab. The total number of incoming orders increased by 22% compared to 2021.

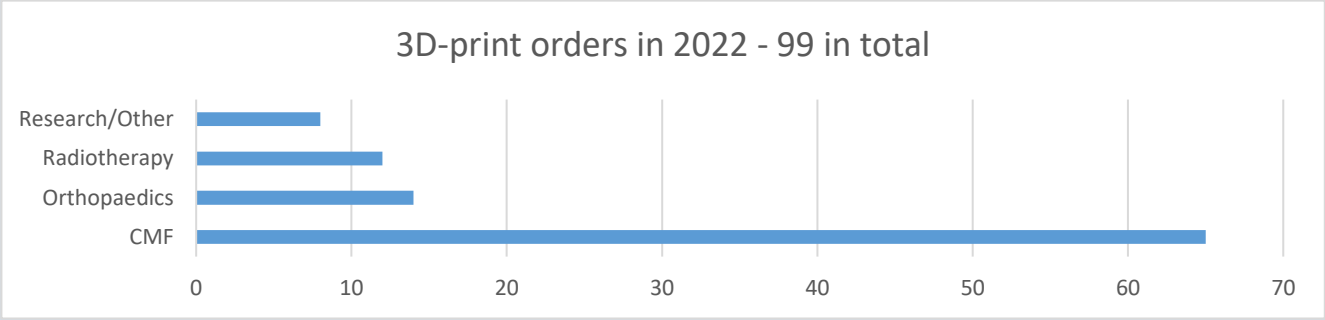
More than half of the cases in 2022 came from the cranio-maxillofacial department where virtual planning and 3D-printing were used as standard tools for orthognathic surgery, temporomandibular joint replacement, and mandibular reconstructions, in addition to anatomical models for better understanding other complex cases.

The rest of the orders came from the Radiotherapy- and Orthopedic department, and research activities from both NTNU and St Olavs Hospital.

In December 2022 the first SLS printer was installed at the lab which now consists of 7 running printers using 4 different print technologies. The new SLS-printer from FormLabs prints in a material that is currently considered the best choice for custom-made surgical cutting and drilling guides. Having this print-option in-house can make a huge difference when performing advanced corrective osteotomies.

The increasing use of 3D-printing at hospitals has led to the establishment of a national network for 3D-printing in Hospitals. The intention is to exchange knowledge, and to collaborate on issues that are common for all the different labs. The network will establish a forum for communication and plan to arrange digital and physical meetings on a regular basis.

Another consequence of the increasing use of 3D-printing in the hospitals is that 3D-printing has been introduces as a topic in the radiography-educations. Radiography students at NTNU will now learn how 3D-printing is used in patient treatment, and how the quality of medical imaging is influencing 3D-printing. The lectures on this topic is given by the 3D-print lab.



Activity at St. Olavs hospital FOR - Research and Contracts

St. Olavs Hospital FOR Research and Contracts is managing externally financed clinical trials at St. Olavs Hospital, Levanger Hospital and Namsos Hospital. On behalf of these hospitals, we are responsible for study contracts and budgetting, as well as the financial control from the start until completion of the study.
St. Olavs hospital FOR Research and Contracts handle:
- Contract and financial negotiations with the companies, based on the study protocol and associated resource requirements for implementation of the study
- Contact with the various service departments, such as laboratory and radiology service, collecting price estimates and setting up the study budget
- Finalizing and signing of main contract together with the external company
- Sub-contracts with internal departments at the hospital
- Financial control and follow-up during the study; including invoicing, project accounting and reporting
- Filing essential documents for completed studies (15 years according to GCP)

In 2022, **16 new studies were registered** - of which **12 are industry sponsored studies** (the Clinical study is initiated by an external party covering all study costs) and **4 are partly fundes studies**. Partly fundes studies are investigator initiated clinical studies which receive financial contribution covering parts of the study costs. The investigator/hospital is the sponsor (responsible for the study and owner of the data). St. Olavs hospital FOR Research and Contracts has a portfolio and administers are present approximately 90 active studies.

Collaboration with DRIV NTNU

How can we achieve innovation in healthcare? First, we need to define a problem. This means we need input from healthcare personnel that faces challenges on a daily basis. Second, we need problem solvers which could be the engineers. They are known for their interest in finding solutions to complex problems. Once you combine these with each other, you have a good platform where innovation can take place. This is what DRIV NTNU represents, a Health Innovation Arena, driven by students.


Photo: DRIV NTNU

Together with FOR, DRIV NTNU arranged Health Tech Challenge in March 2022. This is a challenge where students in technology and students in medicine are cooperating to solve real needs brought forward by the hospital. The challenge encourages the students to come up with new ways to perform diagnostics, surgery and therapy. This years competition involved problems or needs from two clinics; Ear, Nose & Throat (ENH) and Diagnostic Imaging – Radiology.

Regulatory Guidance for Medical Devices

Medical devices has a huge potential to improve healthcare. It gives opportunities to practice medicine in new and better ways than before. When developing such devices, it is important not to neglect the work required to obtain a CE mark. In order to legally sell a medical device in Europe, the device must have a CE mark. This is accomplished by showing that the device complies with the Medical Device Regulation (MDR).

Since May 2021 all medical devices must comply with the new Medical Device Regulation (MDR) 2017/745, which has replaced the previous Medical Device Directive (MDD) 93/42/EC. The new regulation is to ensuring patient safety by focusing on clinical evidence, transparency, traceability and post-market surveillance. The process towards regulatory compliance therefore requires time, money and knowledge. The sooner the regulatory pathway is started, the smoother the route is to market access.

The Operating Room of the Future (FOR) now has its own specialist in regulatory affairs, who offers guidance in understanding what is required when developing a medical device. Medical devices differ in technologies and associated risks. Accordingly, they all require their own path towards regulatory compliance. Our specialist is assisting in the regulatory process required for your medical device. Does the definition of a medical device, defined in the Norwegian legislation on medical devices, cover your device? If so, which risk class does the device belong to? All important questions to be answered when developing such devices.

The most important task when developing a medical device is to define the intended use of the device. This is where the regulatory pathway begins. What will the device be used for, who will use it, and for which purpose? This needs to be defined clearly, as soon as possible, considering that the regulatory steps towards approval are directly linked to the intended purpose of the medical device.

For assistanceregarding the Medical Device Regulation and regulatory affairs, please contact our team member Sara Edvardsen.
sara.edvardsen@stolav.no

FOR-NorMIT infrastructure

An overview of all equipment that can be ordered from FOR-NorMIT is available at www.normit.no

Department of Circulation and Imaging (ISB)
Thomas Grønli, senior engineer, ISB

The ultrasound laboratory at NTNU, Department of Circulation and Medical Imaging hosts two Verasonics Vantage systems which are used in various projects related to cardiovascular imaging, contrast agent development and imaging, and for the development and use of dual-frequency ultrasound transducers, used for instance to enhance image quality and cancer treatment. The laboratory also hosts the Onda Acoustic Intensity Measurement System (AIMS III) which is used for determining acoustic safety in clinical trials using both NorMIT Verasonics systems and research scanners owned by the laboratory.

At ISB we use these systems to develop high frame rate imaging applications, such as vector-Doppler imaging which may shed light on the development of plaques in the carotid artery, as well as new high frame rate cardiac imaging setups to improve quantification of cardiac function. These efforts use extensive imaging setup enabled by the powerful Verasonics systems in NorMIT and has resulted in international collaboration.

Another project connected to Center for Innovative Ultrasound Solutions (CIUS) focuses on optimizing the performance of Doppler ultrasound using single element transducers for flow estimation through cracks/fissures in industrial construction and resulted in one journal paper in 2022[1].

In a project funded by The Liaison Committee for Education, Research and Innovation in Central Norway, SINTEF is working in collaboration with ISB and pulmonologists at St. Olavs Hospital and Levanger Hospital to improve characterization of mediastinal lymph nodes in lung cancer patients. The Verasonics Vantage system is used for implementation of shear wave imaging applications with clinical linear transducers. Implementation for nonlinear tissue characterization with a dual frequency transducer is also ongoing. The dual frequency transducer was ready for use Q3 2022.
In a project funded by The Liaison Committee for Education, Research and Innovation in Central Norway, NTNU is working together with St Olav's Hospital and SINTEF to enhance tumor uptake of chemotherapeutics in patients with pancreatic cancer by therapeutic ultrasound and microbubbles. A custom-made, dual-frequency probe for combined imaging and therapy is integrated with the Verasonics Vantage system. Publications are expected in 2023.

Several other groups are using the systems, including the Dept. of Physics and Prof. Catharina Davies, SINTEF Digital, and SURF imaging, a spin-off company from ISB led by Prof. Bjørn Angelsen.

NorMIT has been very important in conducting both experimental, preclinical, and clinical investigations of new ultrasound methods for better detection of cancer in the early stages, and also ultrasound efficacy of chemotheraphy.

1)Optimization of pulsed-wave Doppler ultrasound for estimation of influx/efflux in oil and gas boreholes while drilling using conventional LWD transducers. Shivanandan Indimath, Stefano Fiorentini, Bjarne Rosvoll Bøklepp, Jørgen Avdal, Svein-Erik Måsøy. Journal of Petroleum Science and Engineering Volume 218, November 2022, 111000

SINTEF Digital, Department of Health Research, uses the NorMIT infrastructure in several ongoing research projects. The Verasonics Vantage systems are instrumental in our effort to develop novel ultrasound imaging algorithms, and the Onda Acoustic Intensity Measurement System (AIMS III) is of critical importance when doing acoustic safety tests before preclinical and clinical trials.

Sigrid Berg, Research Manager (PhD),Medical Technology Group Dept. of Health ResearchSINTEF Digital

Projects

Fatty liver disease characterization by Sonography

In the project "Fatty liver disease characterization by Sonography (2022-2023)" financed by The Liaison Committee for Education, Research and Innovation in Central Norway, researchers at SINTEF collaborate with the Regional Centre of Obesity Research and Innovation (ObeCE) at St. Olavs Hospital and engineers from SURF Technology AS to implement and test a novel ultrasound method for quantitative measurements of fat content in tissue. The technique is based on non-linear acoustics and estimation of an elastic tissue parameter called nonlinear compressibility. The research ultrasound platform Verasonics Vantage system has been used together with a custom-made ultrasound transducer that is capable of transmitting two distinct frequencies simultaneously. The goal of the project is to test and validate an ultrasound method for diagnosis of fatty liver disease. The disease is characterized by the accumulation of fat in the liver, and in patients with untreated fatty liver disease, the condition can eventually lead to inflammation, the formation of scar tissue and a significantly increased risk of chronic liver disease or liver cancer.

During 2022, the method has been tested in tissue mimicking materials (in vitro) with various amounts of added fat, and in a preclinical study (in vivo) where rats were fed a high-fat diet to develop fatty liver disease. The results from experiments show very promising result, and the next step is to test the method in patients with suspected fatty liver disease. A publication describing the in vitro experiments was submitted in 2022 (due to be published in Q1 2023) and a publication on the in vivo experiment is in preparation.

Lymph node characterization with quantitative ultrasound methods.

In a project funded by The Liaison Committee for Education, Research and Innovation in Central Norway, SINTEF is working in collaboration with ISB and pulmonologists at St. Olavs Hospital and Levanger Hospital to improve characterization of mediastinal lymph nodes in lung cancer patients. The Verasonics Vantage system is used to quantify the stiffness of the tissue by using an implementation of shear wave imaging. Both clinical linear transducers and a custom-made dual frequency transducer have been used. The latter transducer is also used for assessing the nonlinear compressibility, similar to what is done in the characterization of liver fat. We hypothesize that both tissue stiffness and the nonlinear compressibility can be of diagnostic value when differentiating between benign and malignant lymph nodes.

Improved ultrasound-guided resection of brain tumors

In a qualification project financed by the Research Council of Norway, researchers at SINTEF have developed a method for improved ultrasound imaging of brain tumors. The method is implemented on the Verasonics Vantage platform and the clinical transducer L8-18i from GE Healthcare is used. The method has been tested on tissue-mimicking materials in the lab, and together with neurosurgeons at St. Olavs hospital the method will be tested on patients who are scheduled for surgical removal of brain tumors.

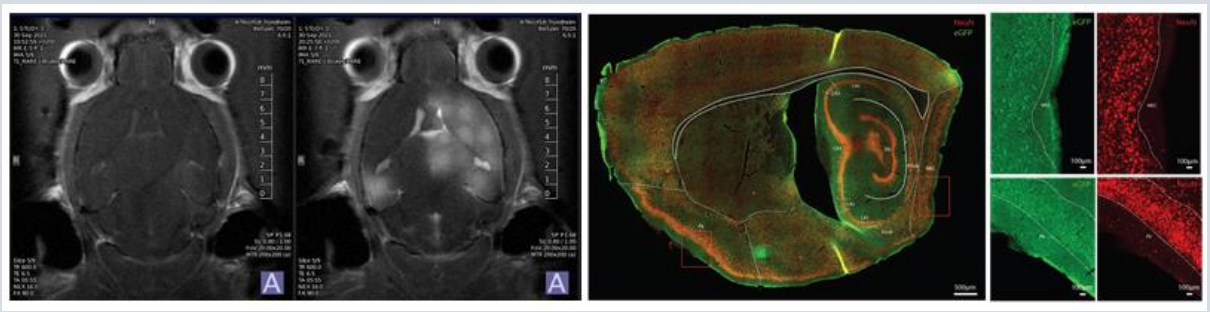
Few cancers have proven to be as difficult to treat as malignant brain tumors, and the prognosis remain dismal for the most common types. Maximal surgical resection of the tumor has been shown to be very important in increasing survival. However, it is often difficult for the surgeon to distinguish between tumor and healthy tissue. This is especially true towards the end of the surgery when the neurosurgeon is approaching the outer border of the tumor. Both before and during the surgery it is advantageous to use ultrasound to image the tumor and the surrounding area. As tumor tissue is removed it often becomes increasingly difficult to interpret the images and find the boundary between the tumor and healthy brain tissue. By improving the image quality of the ultrasound images, especially towards the last phase of the operation, the surgeon can get a tool that makes it easier to remove the last important millimeters of the tumor.

Department of Physics at NTNU uses the FOR-NorMIT infrastrucure for characterization of transducers Preclinical research

Catharina de Lange Davies, professor

Water tank-hydrophone system (Onda AIMS III Scanning Tank)
The water tank-hydrophone system is used regularly to characterize the acoustic field from various ultrasound (US) transducers. In 2022, we have particularly used the system to characterize a new 1 MHz transducer from Precision Acoustics and a custom-made dual frequency transducer at 0.5 MHz and the 5th harmonic.

Magnetic Resonance imaging (MRI) guided ultrasound (FUS Instruments RK-100)
The MRI guided ultrasound system from FUS Instruments, has been used in a pilot project to open the blood-brain barrier locally at predefined brain areas to deliver genes to brain areas affected by Alzheimer's disease.



Pre and post MRI images of mouse brain showing localized enhanced intensity in US treated areas (bright spots), and an example of a brain tissue section stained to image transgene expression by neurons (red and green) in specific brain regions.

Experimental surgery

All FOR operating rooms are authorized for experimental surgery including animal research. Such experimental procedures can be ordered at FOR who will then organize them. This arrangement is well established among clinicians and scientists. We have a "package" where FOR is organizing and planning the animal experiments in collaboration with Department of Comparative Medicine (AKM). FOR has trained and authorized personnel assisting during the whole process. Personnel who is planning or taking part in animal experiments must go through courses in animal experiments approved by the Norwegian Food Safety Authority. An important part of this course is to understand laws and regulations connected with the use of animals in medical experiments. The regulation regarding animal experiments assumes that all persons planning or performing such experiments should have passed the courses and be registered in the electronic system (FOTS) of the board for animal research. Both the responsible scientist and his co-workers involved in the practical performance of the experiments, including those who are taking care of the animals, should be included in the registration and have documentation that they have passed the course in animal experiments, category C.

We had 16 experimental surgeries in 2022

Research Collaborations - National and international partners

Together with the Intervention Center (IVS) at Oslo University Hospital, FOR has since 2014 run the national research infrastructure, NorMIT; Norwegian center for minimally invasive image-guided therapy and medical technology, an infrastructure in both Oslo and Trondheim, with several ongoing projects. The NorMIT infrastructure is available both nationally and internationally.
In 2022, we have run several projects in collaboration with partners in our own health region; Helse Midt-Norge RHF, the health register HUNT and Møre og Romsdal at Kristiansund hospital.
SINTEF is one of FOR's most important partners. The collaboration is, among other things, built around the "National Competence Center for Ultrasound and Image-Guided Therapy". FOR also has a very good collaboration with NTNU through the MH faculty, at the Department of Circulation and Medical Imaging, Department of Energy and Process Engineering, Department of Design, Department of Mathematics, Department of Electronic Systems and Department of Technical Cybernetics and AI laboratory .
The students at the Faculty of Health Sciences at NTNU use the FOR infrastructure for projects related to the bachelor's and master's degrees in collaboration with FOR. Various competence centers such as the "National center of competence for ultrasound and imaging" and the "National center for advanced laparoscopic surgery", NTNU Technology Transfer (TTO), Center for interdisciplinary research in space (CIriS) are important partners, and it is important to maintain the synergy effect of this collaboration.
An important infrastructure on the way forward will be the six National NorTrials centres, especially NorTrials Medical Devices, where we, together with all hospitals in Norway, will become an important infrastructure in collaboration with national and international industry. This will be a unique arena for increased clinical research.
Furthermore, FOR has good cooperation with a number of industrial partners, for example: GE, Sony, Medtronic, Brainlab, Intuitive, Siemens, Stryker, Karl Storz, IBM, Apple, Olympus, Ortomedic, Smith & Nephew, Infiniwell, Aviant, ZimmerBiomet and Telenor . This is to name a few. Good practice and guidelines for cooperation with industrial partners have been developed together with experts in this area.
FOR has established joint research projects with several international partners, where we examine the effect of new treatment methods on technological solutions and decisions made in the operating room. We want to collaborate on the effective use of ICT in the operating rooms to optimize workflow and patient flow.
Cooperation with several other international partners has been established over the years. FOR also collaborates with organizations such as the European Association for Endoscopic Surgery (EAES), Society for Minimally Invasive Therapy (SMIT), Norway Health Tech, Nordic Proof, Norwegian Smart Care Cluster and Technoport in Trondheim.

Research and development in collaboration with SINTEF

The Operating Room of the Future (FOR) is the arena and infrastructure provider for several ongoing research projects, including many projects in collaboration with SINTEF and NTNU. At SINTEF, FOR collaborates closely with Research Group for Medical Technology, at the SINTEF Digital institute, Department for Health Research. The Medical Technology group at SINTEF constitutes approximately 15 research scientist, most of them are working on or in relation to projects at FOR and MIDT (The reesently established National Research Center for Minimally Invasive and Image-Guided Diagnostics and Therapy, at St. Olavs hospital, FOR). The 15 researchers at SINTEF all have PhDs in related fields to medical imaging (ultrasound), medical image analysis and/or image-guided interventions (diagnostics and therapy). Some of them have collaborated with St. Olavs Hospital since 1995, at the time of establishing the previous National Advisory Unit for Ultrasound and Image-Guided Therapy (www.USIGT.org).

SINTEF is a key research partner in the new MIDT center and in FOR. Thomas Langø at SINTEF/St. Olavs hospital was leading the former USIGT-part of MIDT and was also previously the coordinator for USIGT. The new MIDT is a merging of three previous national advisory units. In addition to USIGT, fMRI (National Advisory Unit for Functional MR Imaging) and NSALK (the National Advisory Unit for Advanced Laparoscopic Surgery) are part of the new center, from 2023 organized under FOR at St. Olavs hospital.

SINTEF carries out many projects in collaboration with FOR, i.e., using it as an arena for a number of clinical and technological research projects, development and innovation projects, ranging from technology development, prototyping and clinical trials / studies of new solutions to improve patient care. In 2022 there were more than ten PhD projects in progress at different clinics and at SINTEF/NTNU. About half of these have a workplace at SINTEF, having a shared position

between SINTEF and NTNU. Often, a technologist and a clinician are working together on PhD projects related to the same clinical application, investigating the problem from both a clinical and a technological perspective. There were published about 20 scientific papers with peer review were published at USIGT (now MIDT) in 2022, and some from projects were conducted at FOR, St. Olavs hospital.

Through several user-driven projects supported by the Research Council and EU, the collaborative group at SINTEF / St. Olavs hospital / NTNU unit has been an important competence environment for innovation and industrial cooperation in the field of medical technology. The center has a broad national and international network and extensive activity related to the development and dissemination of expertise and knowledge, one of the core tasks of the center. Through participation in several EU projects like the previous (finished) VECTOR, IIIOS, FUSIMO, MISTELA, RASIMAS, TRANS-FUSIMO, HiPerNav, and currently on-going projects like IDEAR, MIREIA, and MEDITATE, important expertise from international academic environments has been "imported", while at the same time generating and contributing to the spread of local expertise both nationally and internationally.

The new MIDT research center focuses on competence fields built up in the previous national advisory units. In the description from the Ministry of Health and Care Services in Norway, the fields of focus for the new MIDT center are:

- minimally invasive therapy and allied technologies
- medical imaging, focus on ultrasound and MRI
- image analysis, including artifical intelligence
- image-guided diagnostics, therapy, intervention, including robotics
- technology enhanced learning (simulator based training)

The clinical areas of focus are vascular surgery, endovascular treatment, neurosurgery, laparoscopic and flexible endoscopic surgery, pulmonary medicine and radiology/urology. In addition to the use of ultrasound, navigation, visualization, image analysis using deep learning techniques (artificial intelligence) and decision support are also important fields of research in the center and carried out in collaboration with SINTEF / NTNU.

Software research platforms like CustusX and FAST, developed and maintained by SINTEF/NTNU, are available as open-source software packages (at: www.CustusX.org and fast.eriksmistad.no) to the research community. Through collaboration in NorMIT with the Interventional Centre at the National hospital in Oslo, these platforms are expanded with the planning and intraoperative guidance software platform of NorMIT (www.normit.no). The purpose is to make the diagnosis better and the treatment safer and more targeted. These platforms are disseminated nationally through the NorMIT infrastructure and internationally as open-source software in the form of customized versions for clinical applications. An example of the latter is Fraxinus (based on CustusX), a project that will create and distribute a free software package for bronchoscopy guidance (particularly the planning phase) and thus making the diagnosis of lung lesions more robust with the ambition of a higher success rate in sampling suspicious lesions in the peripheral parts of the lungs.

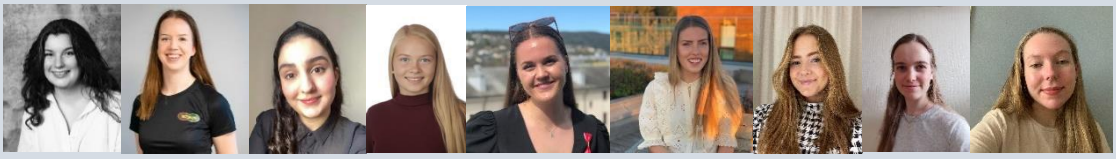
The activity of the national research center is a good example of how FOR can support research, development and testing of new medical technology and methods, while strengthening national and international cooperation, including industry. In addition, FOR contributes with expertise related to courses and publishing popular science articles in close cooperation with SINTEF. SINTEF also brings considerable expertise into the collaboration and utilizes its basic funding for strategic efforts to develop new technology for minimally invasive surgery / therapy.

Thomas Langø
Chief Scientist, Medical Technology
Dept. Health Research, SINTEF
and Future OR, St. Olavs hospital
Photo: SINTEF

Bachelor degrees completed in 2022

NTNU Faculty of Medicine and health sciences, Bachelor`s degree program Nursing

Oda Strand Aasberg og Mette Felde Nordby	**Nurses' attitudes to self-mutilation**
Leila Abduljalil og Karoline Bakke Kjerstad	**How can nurses look after and communicate better about the sexual health of patients who have been diagnosed with gynecological cancer?**
Kristine Hansen,Mathilde Iversen Ramm, Siri Mathilde Nåvik Schanke	**What differences are there in communication from nurse to patient in order to look after the patient's psychological needs when it comes to spontaneous abortion and induced abortion?** **Do nurses want more tools in the form of transparency, routines and measures to deal with patients' psychological needs after miscarriage? What do nurses emphasize when interacting with patients who have experienced miscarriage?** **Do the nurses feel that the measures (e.g. the brochure) which have been put in place to attend to the patient's psychological needs after a miscarriage, is it sufficient?**
Julie Brennsæther og Julia Kvam	**The impact of the Covid-19 pandemic on the everyday working life of operating room nurses at the surgical operation department**



From left: Oda S Aasberg, Mette F Nordby, Leila Abduljalil, Karoline B Kjerstad, Kristine Hansen, Mathilde I Ramm, Sir Mathilde N Schanke, Julie Bennsæther, Julia Kvam

Master degrees - finished in 2022

Positioning of sterile tables under laminar airflow and the effect on postoperative infections
The main goal of this master's thesis is to investigate the effect on bacterial contamination on surgical instruments based on different placement of sterile surgical table under vertical laminar airflow ventilation. Operating rooms with vertical laminar flow have a limited operating area within the laminar airflow. This can result in surgical tables being placed in the boundary area of the laminar airflow, an area where the laminar airflow can be unstable with a higher proportion of turbulence. This can theoretically lead to a higher proportion of bacteria landing on the sterile surgical tables, compared to the surgical tables being placed inside the laminar flow. This can ultimately result in patients developing surgical site infections due to the bacteria being transported to the patients surgical wound via instruments placed on the sterile surgical tables. The goal is therefore to understand the effect of placing the sterile surgical inside, in the border area and outside the vertical laminar airflow.

Runar Lundøy
Photo: private

PhD degrees - Ongoing

Kent Are Jamtøy
Project title: Botulinum toxin type A blocking of sphenopalatin ganglion in chronic pain and inflammatory conditions of the craniofacial region.

Innomet is a research group based at St. Olavs hospital and the Norwegian University of Science and Technology (NTNU) in Trondheim. A new method of blocking ganglion sphenopalatinum (SPG) with botulinum toxin type A (BTA) has been developed. This is done using a navigation-based instrument (MultiGuide) to ensure accurate deposition of BTA. The method has been usedin 10 patients with headache pains using transnasal access under the anesthesia.Endoscopic block of the sphenpalatine ganglion is investigated in intractable cluster headache. A pilot study on chronic migraine has also been published, where the injection is done with lateral access (through the cheek). This study also shows acceptable side effects and good potential for effect. In addition, there is also a pilot study on the injection of botulinum toxin against SPG in patients with trigeminus neuralgia. In this PhD project, Jamtøy will inject botulinum toxin against SPG from chronic rhinosinusitis with nasal polyps and atypical facial pain. Jamtøy plans to complete his research with a 50% position over 6 years

Kent Are Jamtøy
Photo: NTNU

Javier Pérez de Frutos, PhD candidate SINTEF/NTNU

Javier is working on a PhD project with the title: “Intraoperative registration techniques for improved ultrasound-based navigation in laparoscopic soft tissue surgery.” It is a technological PhD linked to the HiPerNav EU project (an ITN project under the MSCA program). Oslo University Hospital is coordinating the project and among the partners are SINTEF and NTNU. In Trondheim the project overlaps and is linked to the Laparoscopy project at the new MiDT research center at St. Olavs hospital where he is using one of the Future ORs. Javier plans to finish his PhD and defend it in 2023.

Javier Pérez de Frutos
Photo: SINTEF

Yang Bi

“Energy efficient airflow distribution methods for surgical microenvironment control in operating rooms”.

The design of indoor air distribution system of operating rooms (OR) is a complex task due to the strict requirements of indoor environment parameters on which there is no global consensus.The purpose of this PhD project is to explore energy efficient indoor environment control and airflow distribution methods enabling safe surgical microenvironment in ORs.

To achieve this goal, many tasks should be accomplished. Firstly, an evaluation system should be established to help designers directly evaluate the comprehensive effect of air distribution systems in ORs. Secondly, a well-performed air distribution system in ORs should be developed, optimized, and validated. Finally, a new model/tool of virtual reality should be developed to visualize the indoor environment together with St. Olavs Hospital.

Yang Bi
Photo: Private

The main method of the research is the combination of simulation and experiments. The experiments will be carried out in the laboratory of NTNU and a real OR of St Olavs Hospital. CFD simulations will be performed for validation and optimization of the air distribution system.
The results of this study will provide a solid scientific basis for ventilation design in ORs. Visualization tools will help designers better analyze CFD results.
Supervisor: Prof. Guangyu Cao

Erik Nypan

Three-Dimensional Visualization and Navigation in Endovascular Procedures

Erik Nypan
Photo: Private

Abdominal aortic aneurysm (AAA) can be treated minimally invasive by stent graft insertion endovascularly. Endovascular treatment is not possible for all aneurysms depending on anatomy, but in complex cases more advanced stent grafts allowing fenestrations or branches deployed through the graft are now available. Image fusion, which allows high-definition pre-operative imaging to be used intraoperatively, is introduced in the resent years. The aim of this project is to facilitate better and easier endovascular navigation in endovascular aortic procedures, potentially leading to more patients being treated by endovascular methods as well as a reduction in x-ray radiation and use of contrast media, which can be toxic to the kidnes. The project has several sub studies, and consists of studies conducted on phantoms, animal models and in patients. An integral part of the project is to study the feasibility of combining preoperative imaging to the patient on the operating table. With the help of position sensors integrated into instruments, it is possible to record position data inside the patient. The position data may then be registered to the preoperative imaging and can be used for navigation. Together with medical student Håvard Ulsaker and with help from FOR, we have in 2020-21 utilized 3D printed models to try to correct for tissue deformation that occur during the procedure. Erik successfully defended his thesis for PhD in 2021.
Main supervisor: Frode Manstad-Hulaas
Assistant supervisor: Reidar Brekken

Arne Kildahl-Andersen
PET and advanced ultrasound in navigated bronchoscopy

Photo: Private

The project is part of the activity in the research group LUNA – Lung Navigation (part of the National Competence Center for ultrasound and image-guided treatment) which is a collaboration between SINTEF, NTNU and St. Olavs Hospital. The group has long track record with electromagnetic navigation integrated in the bronchoscope. Together with the project group, Arne will continue to work on ultrasound bronchoscopy integrated with electromagnetic navigation and PET-CT. A clinical trial of Fraxinus, a navigation software for virtual bronchoscopy will be performed. In addition, Arne will explore the possibilities for improved diagnostics of peripheral lung tumors by combining ultrasound and navigation. Additionally, Arne has been involved in testing Hololens based visualization during bronchoscopic procedures. Both phantom tests as well as a pilot study on one patient have been carried out.
Main supervisor: Håkon Olav Leira
Arne Kildahl-Andersen

Masab Khalid Annaqeeb
Simulation of Energy/related Occupant Behavior in Buildings

Masab Khalid Annaqeeb
Photo: NTNU

The focus of the doctoral research work is on developing occupant behavior (OB) models, to be used in building simulation. In order to improve the understanding of OB, its drivers and influencing factors, the models will be developed in different domains, taking into account the multidisciplinary aspect of OB. To achieve that, the work includes collection of behavioral data with regards to the occupant's surrounding layouts, movement, social influences, and energy-use habits. The collected data is being used to develop databases, and agent-based models to simulate OB in buildings.
Supervisor: Prof. Guangyu Cao

Medical Student`s Research Program, Faculty of Medicine and Health Sciences, NTNU

At the Faculty of Medicine and Health Sciences, NTNU, a separate research programme has been established around the ordinary curriculum of medicine. The research programme involves two additional semesters devoted only to research, and that research is organized in parallel with the medical curriculum.
The research programme is an offer for medical students interested in research and a possible future scientific career, possibly in parallel with clinical activities.
Admission to the research programme takes place after two or three years of medicine studies at NTNU. From the autumn of 2002, a research programme was established at all four medical faculties in Norway, based on the intention to recruit more medical students to research, improving the organization of research education, and promoting scientific attitude for the practise of medicine.

Håvard Ulsaker

We perform a national multicenter study to assess patients that are treated with endovascular aortic repair (EVAR) for thoracoabdominal aortic aneurysms (TAAA). Open surgery for TAAAs are comprehensive operations, and mortality rates have been reported as high as 20% in small volume centers. Many patients are deemed too high risk to undergo open surgery. Recent years' advancement in endovascular techniques has made it possible to treat TAAAs with an endovascular approach. In the study we assess the short and medium term outcomes in patients treated with branched EVAR (t-Branch, Cook Medical) at the Norwegian centers. Patients from all four university hospitals in Norway are included. Mortality, complications and comorbid data are compared with that of open repair patients.

We have also conducted a study in which we compared outcomes in patients treated with the t-Branch and custom-made devices (CMDs) at St. Olavs Hospital. The t-Branch is a standard off-the-shelf stent graft system suitable in 60-70% of TAAAs, while CMDs are patient specific to suit individual patient's aortic and visceral vessel anatomy. The study showed low 30-day mortality, acceptable technical success rates, high medium-term survival, and no significant differences in clinically relevant outcomes between t-Branch and CMD patients.

Additionally, we work with SINTEF on electromagnetic navigation in endovascular procedures. Specifically, we assess how 3D-printed aortic aneurysm models deform during insertion of endovascular equipments, using stiff wires and stent graft delivery systems. By taking the in-procedure aortic deformation into account, we hope to improve the navigational accuracy of the electromagnetic tracking system.

https://www.sciencedirect.com/science/article/pii/S2666688X22000302

Main supervisor: Frode Manstad-Hulaas
Assistant supervisors: Reidar Brekken and Arne Seternes

Håvard Ulsaker
Photo: Norsk medisinstudentforening

Hedda Skogum Riise

The two projects MigriNor and Headache-map are both focused on serum concentration measurements of prophylactic treatment used for primary headache disorders. In the smaller project Headache-map, we aim to investigate adherence to prophylactic treatment for the headache-disorders in general. This is done by taking blood samples from patients visiting the outpatient clinic, measuring the serum concentration of the drug claimed to be in use. MigriNor is an observational study where we do a four-month follow-up of migraine patients initiating prophylactic treatment. The follow-up contains one month baseline before initiating treatment and three months after initiation. After initiation, we collect information about effects, adverse events, as well as blood samples measuring the serum concentration for the prophylactic drug in use. The aim is to describe dose-effect-relationships and potentially be able to use serum concentration measurements to guide decision making and dose regimens in the follow-up of these patients.

These projects are a collaboration between the department of neurology and pharmacology. The main supervisor for my project is Tore Wergeland Meisingset (MD, PhD). Co-supervisors are Melanie Rae Simpson (MD, PhD), Erling Tronvik (MD, professor) and Ketil Arne Espnes (MD, senior consultant).

Hedda Skogum Riise
Photo: Private

Other projects

An important part of the mandate of The Operating Room of the Future is to develop and promote research and development projects in the intersection between scientists, health care personnel and industry. The aim is to create new and original knowledge with new solutions which are useful for the patients. We are in the intersection between science and innovation – between creation of new knowledge and new solutions and their application in daily clinical practice. The collaboration with various clinical disciplines is important to make sure those new solutions, methods, processes and new knowledge is introduced in clinical routine. We have our own infrastructure for the testing of new medical technology and new treatment modalities to create and maintain the bridge between new knowledge and well known routine. FOR has an extensive collaboration with national and international industry through research and development projects.

ELSYS Innovation Project

There is no question whether technology will be essential in the future evolution of healthcare. The question is, do we have the future engineers, eager to put innovative ideas into action? In order to provide further development in medical technology, we need engineers with a spark for healthcare. As FOR is a team with great enthusiasm for medical technology, we take pride in inspiring the future generation of engineers. That is why we wish to direct our attention towards engineering students. In this case, we contact about 120 first year students, studying Electronic Systems Design & Innovation (ELSYS) at NTNU Gløshaugen.
Every year this study program joins forces with a partner from the industry. Together they create an innovation project, where fresh students are challenged to find new and creative solutions of real challenges the industry is facing. It is a great way for students to put their theoretical knowledge into action, as they have to make a prototype by the time the semester ends. At the same time, it is an opportunity for the industry to be inspired by students that may think *outside the box*.

This year, St. Olavs hospital was the chosen industry partner. The project was lead by Sara Edvardsen at FOR, who happens to be a former student at ELSYS herself. The students divided into 24 groups, and were split between different teams/departments at the hospital. These units were FOR 3D-Print Lab, FOR Research and Contracts (Oppdragsforskning), the PET-Centre at the department for Diagnostic Imaging, NTNU OR Lab and the Ambulance Department. The groups were set to identify needs or challenges at the departments, and to prototype a device that could cover the need.

The project resulted in devices to better patient care at the hospital. Several of the groups developed devices to assist health personnel gain knowledge quicker, better the work environment or make processes more efficient and understandable. Some groups also chose to focus on the patient, rather than the procedure. Their devices intended to assure that the patients feel informed, comfortable and well taken care of.

The project began in September, and the students presented prototypes for their concepts in November. The next round of the project is set to occur during the spring semester in 2024. By the end of that semester the students will have to present a finished product the hospital may introduce in common routine.

The ELSYS Conference at NTNU, where students presented their prototypes for the ELSYS Innovation Project. Photo: Jan-Magne Gjerde (FOR)

The effects of tourniquet on muscle strength and function in patients operated with total knee arthroplasty and a multicenter prospective cohort study on Persona total knee system

About 5000 total knee arthroplasties (TKA) are performed annually in Norway. Pain and reduced physical function are present in patients operated with TKA up to a year after surgery and about one of five patients are not satisfied with the outcome from TKA surgery. The use of tourniquet during surgery to minimize hemorrhage, may have impact on pain and physical function. Whether TKA surgery should be performed with or without the use of tourniquet, is a controversial issue in orthopedic surgery today, and there is still no consensus in this field. The overall aim of this project is to improve knowledge about the effects of tourniquet vs. no tourniquet on pain, muscle strength and function. The results from the project might have implications for rehabilitation and the outcome after TKA surgery. This project will investigate early muscle strength and power recovery, neuromuscular recordings, neuronal changes and patient reported outcome measures. 80 patients will be included in this randomized controlled study. The patients are also invited to participate in a multicenter study which evaluates patient- reported outcome measures and survival after TKA using the Persona total knee system. All patients have been included in the study.
The study is initiated by Zimmer Biomet.

Posired

The Research Council granted NOK 16 million to build a hyper-modern operating theater (OR-lab) up at Gløshaugen, in the Department of Energy and Process Engineering's premises at NTNU. Norconsult with Thorgeir Harsem as project manager was commissioned to build the OR-lab.The OR-lab is built with two ventilation systems, so that you can switch between LAF and mixed ventilation or combine both.Furthermore, it is full of various sensor technology that allows you to see particle flows during surgery, etc. There are large windows into the OR-lab so that visitors can stand outside and look in on the experiments that take place there.
Part of the idea is that you can use the operating room as a training arena for surgical teams so that you learn how air with particles and CFU moves when using Hololens glasses, and how behavior inside the operating room affects the ventilation system, among other things.
The living room is furnished with out-dated equipment from St. Olav that would otherwise have been thrown away FOR has contributed by providing equipment and as advisers in the construction process.

Drone project

The Operating Room of the Future ("Fremtidens Operasjonrom", FOR) has collaborated with the NTNU-based drone logistics company Aviant since September 2020. The collaboration led to the first flight from Røros to Trondheim in February 2021, marking the longest autonomous drone flight conducted in Scandinavia (120 KM). The event received national press through DN.no and NRK, and international press through the Massachusetts Institute of Technology (MIT) homepage. The success of the first flight proved the technology feasible and regulations mature and laid the foundation for future work on drone-based logistics in Trøndelag.

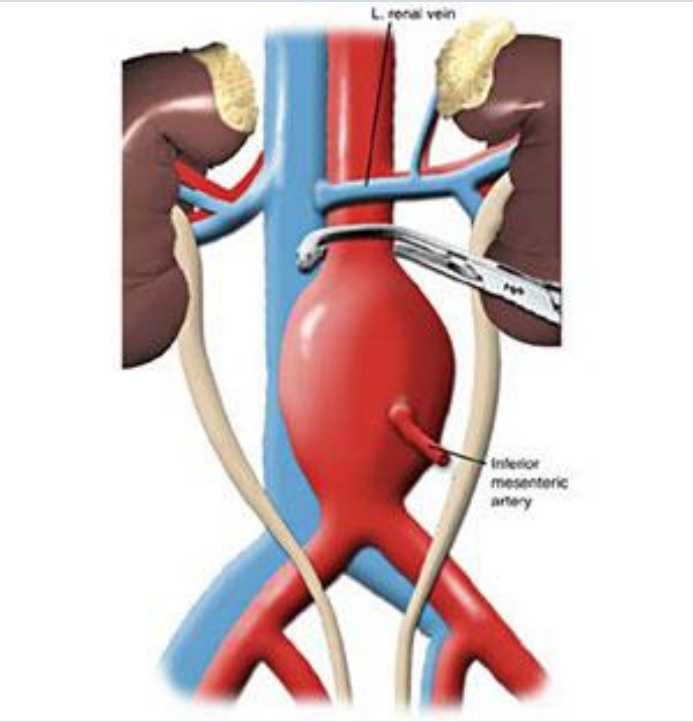
In 2022, FOR was granted innovation funding for the LuftVei project in collaboration with Aviant AS. The collaboration has resulted in transporting 80 biological samples and over 40 trips by drone from Røros to Trondheim, as well as transporting surgical equipment and consumables. As far as we know, this is the first medical payload flown over such long distances in Norway with a drone. LuftVei has received a lot of media attention, including on NRK Kveldsnytt1. The project has also given Helse-Midt a leading position in using drones in Health-Norway and is now leading an application for the Research Council's Pilot Health in collaboration with hospitals from Helse Nord, Helse West, and Helse South-East.

This year's project has demonstrated that drone transport in the health service can improve response times to biological samples because the drones are readily available and are faster than traditional transport alternatives. Thus, the regular test transport by car, which only runs once a day, will no longer represent a bottleneck for the Hospital in Røros. The result of this is shorter interval from diagnosis to treatment for patients. Shipping of surgical equipment and consumables by drone also helps to increase the availability of resources in hospitals. Drones are a need-based solution that can deliver up to four times faster than alternative transport solutions, in addition to cutting transport costs by 90% and reducing emissions of greenhouse gases by 95%.

FOR’s experience with drones has thus positioned Central Norway Regional Health Authority as the leading professional environment within drone logistics in the Norwegian healthcare sector. The projects have proven the technology mature, and regulations open up for more advanced use cases with drones. The project has also documented the negative and positive impacts of using this new transportation medium. We will continue to pay attention to this new method of delivery within the healthcare sector with a great interest in how it can be applied in the future.

The Aviant team
Photo: Aviant

Challenge ischemia during aortic surgery



During open aortic surgery an inevitable step is to clamp the aorta. The consequences are a reduced perfusion distally until the artificial aortic graft is in place and the peripheral circulation is reestablished. The are many physiological consequences of the ischemia- reperfusion injury. Examples thereof are: Free radical formation, platelet aggregation, cell mediated damage, neutrophil infiltration and accumulation etc, etc. Clinically it is seen as reduced Cardio-pulmonary capacity with extended hospital stays and rehabilitation.

During the autumn 2022 FOR has done several experiments in a porcine model to try to overcome the above drawbacks. The project has been led by the leader of the Department of Vascular Surgery at St Olavs University Hospital Dr Frode Aasgaard and Professor Erney Mattsson. The project also has a tight collaboration with “Mittuniversitetet” in Östersund, Sweden.

The project has been very successful and will be followed with observations in humans during the autumn 2023. A new version of this big operation will hopefully be in place during 2024. The project includes devices to be patented. Additional information will be given through FOR and its different channels for news in a close future.

Photo: Erney Mattsson

Scientific articles 2022

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2. Frutos JPd, Pedersen A, Pelanis E, Bouget D, Survarachakan S, Langø T, Elle OJ, Lindseth F. Train smarter, not harder: learning deep abdominal CT registration on scarce data. arXiv:2211.15717, Accepted for publication in PlosONE, February 2022

3. Smit JN, Kuhlmann KFD, Ivashchenko OV, Thomson BR, Langø T, Kok NFM, Fusaglia M, Ruers TJM. Ultrasound-based navigation for open liver surgery using active liver tracking. International Journal of Computer Assisted Radiology and Surgery. 2022, 5:27:1-9.

4. Survarachakan S, Prasad PJR, Naseem R, de Frutos JP, Kumar RP, Langø T, Cheikh FA, Elle OJ, Lindseth F. Deep learning for image-based liver analysis—A comprehensive review focusing on malignant lesions. Artificial Intelligence in Medicine, 2022, 6:9.

5. Kildahl-Andersen A, Hofstad EF, Peters K, Van Beek G, Sorger H, Amundsen T, Langø T, Leira HO. A novel clip-on device for electromagnetic tracking in endobronchial ultrasound bronchoscopy. Minimally Invasive Therapy & Allied Technologies, 2022, 6:24:1-9.

6. Cristina Trocin, Jan Gunnar Skogås, Thomas Langø, Gabriel Hanssen Kiss. Operating Room of the Future (FOR) Digital Healthcare Transformation in the Age of Artificial Intelligence. In: Digital Transformation in Norwegian Enterprises, Springer Nature, 2022, 6:16 (pages: 151).

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8. David Bouget, André Pedersen, Johanna Vanel, Haakon O Leira, Thomas Langø. Mediastinal lymph nodes segmentation using 3D convolutional neural network ensembles and anatomical priors guiding. Computer Methods In Biomechanics And Biomedical Engineering: Imaging & Visualization, 2022, 3:7:1-15.

Live streaming and high-resolution recording in the operating room

NorMIT has built expertise and technology related to recording, broadcasting and live transmissions from the operating room. This means that today we are able to perform high quality live streaming from all operating rooms at St. Olavs Hospital in a cost-effective way without the need for a permanent installation. The production systems we use are mobile solutions that are easily rigged in the operating room and in the conference auditorium. With access to high-speed internet, live surgery and other medical procedures can be shared rapidly with colleagues internally as well as globally. Cost effectivetransmissions and recordings of all forms of medical procedures are now possible, regardless of surgical specialty. We transfer both images and support two-way sound from the operating room to the lecture hall. We also perform recording of the live transfer so that it can be reviewed afterwards.

In 2022 FOR provided the broadcasting support for 4 workshops arranged by the Gynecology Department at St.Olavs Hospital in collaboration with different suppliers of medical equipment. Gynecology departments from 4 different Norwegian hospitals, including Ullevål visited the workshop to learn how St. Olavs Hospital has enabled to perform certain procedures at the out-patient clinic rather than surgically. Each participant of the workshop had the chance to take part in the procedure beside the doctor without admission of the patient, and also to follow the procedure via live broadcasting of images from multiple sources and sound to a different room. The combination of live participation and live broadcast has proven to be a good solution for such workshops.

FOR in media

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https://reitan.no/no/artikkel/4371/jan-gunnar-skogas

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