Abstracts

Medicinteknikdagarna 2024

Oktober 8-10, Göteborg

Innovativ medicinteknik - verktyget för omställning av vård och omsorg

SVENSK MEDICINTEKNISK FÖRENING
MTF

AVANCEZ 1829
CHALMERS

UNIVERSITAS GOTHOBURGENSIS 1891
GÖTEBORGS UNIVERSITET

VÄSTRA GÖTALANDSREGIONEN
SAHLGRENSKA UNIVERSITETSSJUKHUSET

Kommittéer

Organisationskommittén:

Annette Lövefors Daun (Ordförande), Sahlgrenska Universitetssjukhuset
Christofer Larsson, Sahlgrenska Universitetssjukhuset
Henrik Mindedal, Chalmers Industriteknik
Magnus Cinthio, Lunds universitet, MTFs kassör,
Magnus Båth, Sahlgrenska Universitetssjukhuset
Natasha Adler Grønbech, Chalmers
Neda Haj-Hosseini, Linköpings universitet, MTFs MTD-ansvarig

Programkommittén:

Henrik Mindedal (Ordförande), Chalmers Industriteknik
Andreas Fhager, Chalmers & MTF vetenskapligråd
Annette Lövefors Daun, Sahlgrenska Universitetssjukhuset
Eva Forsell Aronsson, Göteborgs universitet
Git Eliasson, LfMT & Södersjukhuset
Jessica Ylvén, Västra Götalandsregionen
Jonathan Converse, Chalmers Industriteknik
Lena Strömberg, Medtech4tech
Maria Asplund, Chalmers, MTFs vetenskaplig sekreterare
Matilda Larsson, Kungliga Tekniska högskolan
Maria Tenje, Uppsala Univ. & MTF vetenskapligråd
Maria Wirenstedt, Region Blekinge & MTFs kursråd
Neda Haj-Hosseini, Linköpings universitet
Niklas Fridolf, Sahlgrenska Universitetssjukhuset
Per Augustsson, Lunds universitet & MTF vetenskapligråd
Petrus Laestadius, Swedish Medtech
Petter Falkman, Chalmers
Stefan Candefjord, Chalmers

Innehåll

Plenarföreläsning

Innovation Pipeline: Concept to Market the Scottish Experience

The innovation landscape is often described as cluttered and route to market for innovators is challenging. Prof Lowe will describe Scotland's approach to supporting innovation to respond to the challenges that healthcare systems face across the world. Success requires building evidence for decision makers from investment through VC and grants, regulatory approval and finally adoption. True triple helix working between academic, health system and industry streamlines the process ensuring companies build products that respond to need and can transform care though the accelerate national innovation adoption pathway.

David Lowe, Professor, NHS Scotland

Biography:
Professor David J Lowe is Clinical Director Innovation University of Glasgow, Emergency Consultant at Queen Elizabeth University Hospital, Glasgow and Clinical Lead for Health Innovation for Scottish Government. David has significant experience of creating the infrastructure and conditions to develop innovative devices, services and solutions with a range of industry and academic partners both UK and worldwide. He is clinical lead for a number of projects within the Digital Health Validation Lab and previously iCAIRD including ensemble based AI techniques for COVID, osteoporosis as well as supporting evaluation and development of AI solutions across a range of imaging modalities. He leads on range of projects including trauma for the STN (thetraumaapp.com), Dynamic COPD (support.nhscopd.scot) and OPERA(early diagnostic heart failure utilising AI). Such projects focus on developing AI/ML clinical decision support by embedding a data driven approach combined with patient co-management into clinical care pathways. David also established the EmQuire research group focusing on data, device and decisions within Emergency Medicine.

Plenarföreläsning

3D-printed metallic bone – leveraging key aspects of additive manufacturing for sustainable implant solutions

Additive manufacturing (AM), or 3D-printing, has revolutionized the way we think about component design, and has also opened up new pathways for creating new material combinations and structures, with less material waste. In the field of biomaterials, it has been used to create patient-specific implant geometries and to design structures with pore sizes and shapes tailored to achieve a certain biological response, for e.g. bone regeneration. However, to achieve a full bone regeneration, a full degradation of the implant material is needed. Here, Mg alloys have emerged as promising materials to replace bone tissue. However, due to their high reactivity and tendency to evaporate at relatively low temperatures, additive manufacturing of these alloys is challenging. Here, I discuss what we have learned on the connection between process parameters and microstructure development for laser beam powder bed fusion of Mg alloys.

Cecilia Persson, Professor Biomedical Engineering, Uppsala university

Cecilia is an internationally recognized researcher in biomaterials science who combines theory, experiments, and technology development. She has several patents and has founded a start-up company based on the results of her research. She has also had several assignments of trust, such as Dean of Engineering at Uppsala University, Panel member at VR and is member of the national University Representative Group of the Wallenberg-funded WISE Program for Sustainable Materials Science. She is also the former President of the Scandinavian Society for Biomaterials (2019-2023)

Cecilia is Director of VINNOVA Competence Centre AM4Life, Additive Manufacturing for the Life Sciences, and focuses a lot of her research on the development of new degradable biomaterials for and through 3D-printing.

Muntliga föredrag

MT-ingenjör - Medicintekniska programvaror

2024-10-09
11:30 - 13:00
MT-ingenjör - Medicintekniska programvaror

M2 - Implementering av AI inom mammografiscreeningen i Region Östergötland

7. Digitalisering & informatik / Digitalization & informatics

Håkan Gustafsson[1]
[1] Region Östergötland

Abstract text*: Region Östergötland har infört AI inom mammografiscreeningen. För de undersökningar där AI bedömt cancerrisken som låg har konventionell dubbelgranskning av alla undersökningar av två bröstradiologer ersatts av granskning av en bröstradiolog + AI.

Utöver detta arbete (som drivits som en prospektiv klinisk studie med etiskt tillstånd) ingår Region Östergötland i den nationella studien VAI-B [1] där vi fått mycket kunskap inom området validering av AI inför kliniskt införande.

Håkan Gustafsson är mycket engagerad i kliniska tillämpningar av AI och validering av AI inför klinisk användning [2].

[1] https://cancercentrum.se/samverkan/vara-uppdrag/forskning/forsknings--och-innovationsprojekt/tre-projekt-for-att-stodja-anvandandet-av-ai/nationell-valideringsplattform-for-ai-inom-mammografiscreening-vai-b/

[2] https://lakartidningen.se/klinik-och-vetenskap-1/kommentar/2023/06/sa-kan-ai-valideras-for-klinisk-implementering/

M3 - Hur kommer de nya EU-lagarna inom cybersäkerhet och AI att påverka medicintekniska produkter?

2. AI, maskininlärning & Big Data / AI, machine learning & Big Data

Ted Strandberg[1]
Håkan Burden[1], Susanne Stenberg[1], Charlotte de Bésche[1]
[1] RISE

Abstract text*: Abstract Medicinteknikdagarna 2024

Hur kommer de nya EU-lagarna inom cybersäkerhet och AI att påverka medicintekniska produkter? Vi går igenom vad de nya lagarna kommer innebära för medicintekniska produkter och senaste status inom standardiseringen.

Med vänlig hälsning

Charlotte de Bésche	Expert medicinteknisk mjukvara
Ted Strandberg	Nationell samordnare (SIS TK318/AG 61) standardisering av cybersäkerhet för produkter
Susanne Stenberg	Regulatorisk expert AI och standardisering AI
Håkan Burden	Regulatorisk expert AI och standardisering AI

Vetenskap/Science - Materials, devices and modelling

2024-10-09
11:30 - 13:00
Vetenskap/Science - Materials, devices and modelling

M4 - In-house versus commercially available 3D planning for corrective osteotomy of the distal radius: a preclinical paired noninferiority study

15. Egentillverkade & specialanpassade medicintekniska produkter / In-house & custom-made medical devices

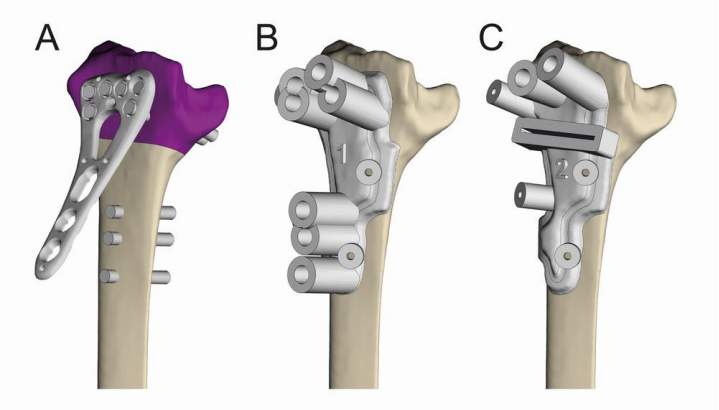
Charlotte Stor Swinkels[1, 2, 3]
Katleen Libberecht[2, 3], Emilia Gryska[2, 3], Peter Axelsson[2, 3], Per Fredrikson[2, 3], Anders Björkman[2, 3]
[1] Medicinsk Fysik och Teknik, Sahlgrenska Universitetssjukhuset
[2] Handkirurgi, Sahlgrenska Universitetssjukhuset
[3] Institutionen för kliniska vetenskaper, Sahlgrenska Akademin, Göteborgs Universitet

Abstract text*: Background: 3D surgical planning and design of patient-specific surgical guides is becoming an established approach in complex skeletal surgery. Most often, the planning and guide design is outsourced to external industrial partners. An alternative approach is to build a dedicated hospital team for 3D planning and guide design. The purpose of this study was to demonstrate the noninferiority of in-house 3D surgical planning compared with externally purchased 3D planning.

Methods: Sixteen consecutive patients with extra-articular distal radius malunions requiring surgery were included in the study. Virtual planning and guide design were done for each patient by the hospital team and independently by an external company. Surgery was simulated on 3D-printed bone models with the two sets of guides. Accuracy was assessed by measuring the 3D transformation between the scanned resulting correction and the planned correction. The predefined acceptable noninferiority margins were 5° volar tilt error and 2 mm ulnar variance error. The dimensional accuracy of the printed guides was assessed before and after sterilisation.

Results: The mean difference between the volar tilt errors of the in-house guides and the externally designed guides was 2.3°. The mean difference between the ulnar variance errors of the in-house guides and the externally designed guides was 0.38 mm. The complete Confidence Intervals for volar tilt error and ulnar variance error lie within the noninferiority margins. Noninferiority could be claimed for the in-house guides. The average distance errors between the virtually designed models, scanned guides and sterilised guides did not exceed 0.3 mm for in-house designed guides.

Conclusions: In this paired noninferiority study, we have demonstrated that a dedicated hospital team can virtually plan surgery and design patient-specific guides for corrective osteotomies of the distal radius with noninferior results compared with those of a commercial supplier.



M5 - Benledningsimplantat - från idé till verklighet

21. Övrigt / Other (specified further down in the form)
Sabine Reinfeldt[1]
Karl-Johan Fredén Jansson[1], Måns Eeg-Olofsson[2, 3], Ann-Charlotte Persson[4], Bo Håkansson[1]
[1] Inst Elektroteknik, Chalmers Tekniska Högskola, Göteborg
[2] Inst Kliniska vetenskaper, Göteborgs universitet, Göteborg
[3] Frölunda Specialistsjukhus, Göteborg
[4] Västra Götalandsregionen, Habilitering och hälsa, Hörselverksamheten, Göteborg

Abstract text*: Bakgrund:

Benledning utnyttjar att vibrationer i skallbenet leds till inneröronen och skapar en hörupplevelse. En av de viktigaste tillämpningarna är i benledningshörapparater som är speciellt lämpliga för patienter med ledningshinder, d.v.s. då hörselnedsättningen har sitt ursprung i ytter-/mellanöra, men också kombinerat med en viss nedsättning i hörselsnäckan samt för ensidig dövhet.

Den mest etablerade benledningshörapparaten har i många år varit den benförankrade hörapparaten (BAHA), som stimulerar direkt i benet genom en hudpenetrerande skruv. Eftersom den har vissa komplikationer kopplat till hudgenomföringen (vilka har blivit färre med utveckling av bl.a. kirurgiska metoder) så har flera implantat utvecklats. I ett samarbete mellan Chalmers och Sahlgrenska har benledningsimplantatet BCI (Bone Conduction Implant) utvecklats och forskats på.

Syfte:
Syftet med det här bidraget är att presentera de studier som har lett fram till att Sentio (Oticon Medical, som bygger på BCI, kommer ut på marknaden under 2024.

Metod:
De prekliniska studierna omfattade bl.a. implantat på skallsimulator, skallben, kadaverhuvud, datortomografibilder, får, BAHA-patienter och normalhörande testpersoner. Syftena har varit att optimera design och att undersöka magnetresonanskompatibilitet, säkerhet, biokompatibilitet och effektivitet. Slutligen har en klinisk studie på 16 patienter genomförts inklusive långtidsuppföljning upp till fem år.

Resultat:
Sammanfattningsvis visar resultaten att BCI är säker och effektiv för patienterna med liknande resultat som med BAHA. Den har fördelar i t.ex. att huden hålls intakt och att den ger mindre rundgång jämfört med BAHA. Den ackumulerade tiden för implantat på plats för alla patienter totalt är 146 år i april 2024, och inga allvarliga adverse events har inträffat.

Slutsatser:
Resan har varit lång från första idé 1998 och start på klinisk studie 2012, och nu ser vi fram emot att Sentio blir tillgänglig för patienter.

M6 - In Silico Assessment of Atrioventricular Node Conduction Properties during Atrial Fibrillation

11. Modellering & simulering / Modelling & simulation
Mattias Karlsson[1, 2]
Frida Sandberg[2], Mikael Wallman[1]
[1] Department of Systems and Data Analysis, Fraunhofer-Chalmers Centre
[2] Department of Biomedical Engineering, Lund University

Abstract text*: **Background:** Atrial Fibrillation (AF) is the most common arrhythmia, associated with a 3.5-fold increased risk of mortality. During AF, the dynamic and rapidly changing conduction properties of the atrioventricular (AV) node play a crucial role in regulating the heart rate. Thus, assessing short-term variations in AV nodal conduction properties could provide novel information for improved diagnosis, prognosis, and treatment optimization on an individual basis.

Purpose: To assess the refractory period (RP) and the conduction delay (CD) of the fast pathway (FP) and the slow pathway (SP) of the AV node with a beat-to-beat resolution for patients suffering from AF using ECG.

Methods: We propose a methodology comprising a network model of the AV node, a particle filter, and a smoothing algorithm. Together, these enable the estimation and uncertainty quantification of the RP and CD of FP and SP of the AV node for each heartbeat from ECG recordings. The methodology was evaluated using simulated data with known ground truth as well as applied to recordings from five patients in the Intracardiac Atrial Fibrillation Database (IAFDB, open access, PhysioNet).

Results: Estimated RP and CD from the simulated data matched the ground truth values with a mean absolute error (± std) for each heartbeat of 207±164 ms for RP in FP, 120±168 ms for CD in FP, 95±113 ms for RP in SP, and 183±167 ms for CD in SP. Furthermore, the resulting RP and CD trends from the endocardial recordings for one patient are shown in Fig 1.

Conclusion: Our model-based analysis enables patient-specific assessment of AV node conduction properties from ECG with a beat-to-beat resolution, offering potential insights for personalized treatment strategies during AF.

Figure text: 'Figure 1. Estimated conduction properties for patient 1, where values ≥ 0.15 are presented with the brightest color for ease of visualization.'

M7 - Enhancing additive manufacturing capabilities with polymer-graphene composite materials

1. 3D printing / 3D printing

Antrea Spanou[1, 2, 3]
Stefan Johansson[2], Cecilia Århammar[3], Cecilia Persson[1]
[1] Division of Biomedical Engineering, Department of Materials Science and Engineering, Uppsala University, Uppsala 751 05, Sweden
[2] Division of Microsystems Technology, Department of Materials Science and Engineering, Uppsala University, Uppsala 751 05, Sweden
[3] Graphmatech AB, Mältargatan 17, Uppsala 753 18, Sweden

Abstract text*: Additive manufacturing promises to revolutionize industrial and healthcare practices, with innovative materials like functional polymers playing a crucial role. Graphene, with its unique properties, makes it a promising candidate for polymeric biomedical composites. In this work we explore the possibilities of graphene composites in additive manufacturing.

Polyvinylidene fluoride filaments, suitable for containing 6.5 wt% graphene nanoplatelets were produced. The composites were 3D printed and tested for l efficacy against *Escherichia coli (E. coli)* and *Staphylococcus aureus (S. aureus)*. Samples with graphene surface exposure showed reduced bacterial attachment within the first hour under a surface contact test. Examination of *E. coli* strains for biofilm formation (48h) on the developed materials revealed no antibacterial effect, likely due to limited graphene nanoplatelet exposure. Surface topologies resulting from various printing configurations and exposure time to bacteria significantly influenced the biological response.

Conductive polyvinylidene fluoride-trifluoroethylene (PVDF-TrFE) – reduced graphene oxide (rGO) composite inks were also developed for direct ink writing. The inks exhibited high electrical conductivity, achieving a percolation threshold at 1.5wt%, and proved suitable for high-resolution printing. The printed structures functioned effectively as electrodes for polymer-based 3D printed piezoelectric devices.

Last but not least, graphene coated polyamide 11 (PA11) powders were developed, suitable for selective laser sintering (SLS). The printed parts exhibited strength and electrical conductivity at an optimal concentration of 0.07wt% of graphene oxide, when compared to the reference. The graphene coating survived the printing process, where graphene oxide/reduced graphene oxide could be seen on the surface of the parts. This could have numerous potential applications in biosensing devices, cell imaging and mapping as well as antibacterial agents.

This study emphasizes the varied potential of polymer-graphene composites, highlighting the critical role of graphene type selection and concentration for specific applications, while demonstrating their diverse benefits and functionalities.

M8 - A novel method to preoperatively predict cerebral hemodynamics during selective antegrade cerebral perfusion

11. Modellering & simulering / Modelling & simulation

Axel Vikström[1]
Anders Eklund[1, 2], Martha Johannesdottir[3], Jan Hellström[3], Anders Wåhlin[1, 2, 4], Laleh Zarrinkoob[5], Jan Malm[6], Micael Appelblad[3], Petter Holmlund[1, 4]
[1] Umeå University - Department of Diagnostics and Intervention, Biomedical Engineering and Radiation Physics
[2] Umeå University - Umeå Center for Functional Brain Imaging
[3] University Hospital of Umeå
[4] Umeå University - Department of Applied Physics and Electronics
[5] Umeå University - Department of Diagnostics and Intervention, Surgical and Perioperative Sciences
[6] Umeå University - Department of Clinical Science, Neurosciences

Abstract text*: *Introduction*: Selective antegrade cerebral perfusion (ACP) is a protective procedure during cardiopulmonary bypass where only the brain is perfused. ACP can be performed unilaterally or bilaterally, but there is no consensus on when to use each method despite highly varying collateral arterial systems among patients. In this study, we present a novel method for preoperatively predicting cerebral perfusion pressures and flows during ACP with the aim to provide a tool that can aid in this decision-making.

Method: The new method is based on computational fluid dynamics (CFD) with subject-specific data input of arterial anatomy and blood flow. The model was tested on five patients eligible for aortic arch surgery (65±7 years, 3 men) who preoperatively underwent computed tomography angiography (CTA) and 4D flow magnetic resonance imaging (MRI). From the imaging data, CFD simulations estimated the patient's vascular resistances. The boundary conditions of the CFD model could then be adjusted to reflect the intraoperative situation, predicting the perfusion pressure during ACP. The predicted pressures were compared to that measured intraoperatively during both unilateral and bilateral ACP. Measured right carotid pressure was used as a reference and the pressure measured in the left carotid artery was the main outcome variable. A sensitivity analysis was also performed.

Results: There was no difference between predicted and measured left carotid pressures during unilateral (-0.5 (5.0) mmHg (p=1)) or bilateral (-4.0 (2.1) mmHg (p=0.13)) ACP. The pressure predictions were most sensitive to collateral artery size and pre-to-intraoperative changes in cerebral territorial resistances, the latter accounted for by measured changes in viscosity. Predicted pump flow was overestimated in three subjects and stress the importance of accurate peripheral resistance estimations.

Conclusions: This study tested the feasibility of our method for preoperative pressure predictions during ACP, and presents key features needed for accurate modelling.

M9 - Sound to guide cells

8. Medicintekniska produkter för in vitro-diagnostik / In-vitro diagnostic medical devices

Cecilia Magnusson[1]
Richard Soller[1], Ola Jakobsson[1], Oskar Andersson[1], **Per Augustsson**[1]
[1] Lunds universitet

Abstract text*: By combining acoustic fields and liquid flows in microchannels we develop tools to chart and separate biological particles based on their bio-mechanical properties. I will present an overview of three ongoing projects where acoustic forces are utilized to separate blood cells.

We studied the packing behavior of whole blood in a sound field. We discovered that cells self-organize such that red blood cells occupy a region nearest the acoustic pressure node while cancer cells migrate to the plasma interface. This can be done in a flow-through device and more than 90% of red blood cells can be removed in continuous flow while recovering >50% of the target cells. [1]

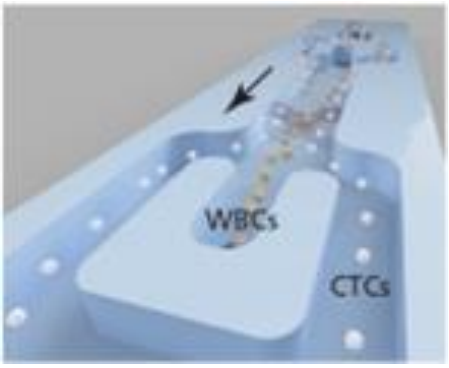
In a second project, we developed a method to separate and measure the acoustic properties of thousands of single cells by tracking their location in a media that forms a gradient in acoustic properties. The cells migrate due to the sound field until reaching their point of zero acoustic contrast. From single-cell properties, we can predict the behavior of cells in any medium and acoustic field and design and optimize separation schemes. [2]

In another project, we showed that we can enrich clusters of circulating tumor cells from white blood cells by acoustic separation, Fig 1. We analyzed blood from 12 patients with advanced-stage prostate cancer and compared that to blood from 20 healthy donors. We found that circulating tumor cell clusters in most patients but in very few of the control subjects. [3]

Our vision is that we will be able to integrate the different unit operations for cell separation that we have demonstrated into one process flow, thus building a system that can take whole blood as input and highly refined sub-populations of cells as output.

References

[1] Soller, in https://acoustofluidics.net/archive/materials/Acoustofluidics_2023_Materials.pdf (2023).
[2] https://doi.org/10.1038/ncomms11556 (2016).
[3] https://doi.org/10.1021/acs.analchem.3c05371 (2024).



MT-sektorn - Pengar förenklar, när idé blir lösning

2024-10-09
11:30 - 13:00
MT-sektorn - Pengar förenklar, när idé blir lösning

M10 - Call for research and development projects in medical technology from Barncancerfonden

21. Övrigt / Other (specified further down in the form)

Anders Höglund[1]

[1] Barncancerfonden (The Swedish Childhood Cancer Fund)

Abstract text*: Summary

Barncancerfonden (The Swedish Childhood Cancer Fund) calls for proposals for projects in medical technology. The purpose is to highlight and solve problems related to medical technology relevant for children with cancer, and to enable adaption of existing medical technology to children with cancer.

Barncancerfonden finances projects expected to lead to increased survival, reduced acute or late effects, and increased quality-of-life during and after treatment for children with cancer.

Description of the call

Barncancerfonden defines medical technology as medical products except pharmaceuticals and biotechnology. This includes child-adapted design of existing products to facilitate medical treatment of children.

Projects can be up to 3 years. Barncancerfonden finances fundamental research projects, development projects, and projects for clinical adaption for children. Fundamental research projects and development projects should demonstrate how the results may be applied within five years. Implementation grants may also be applied for. Such applications should aim to implement a new evidence-based health care or treatment method for children at the clinic.

Eligibility to apply

Projects are applied for by a constellation of partners where relevant clinical and technical competence are represented. One of the partners is main applicant and the other partners are co-applicants. The main applicant for a research project must hold a Swedish doctoral degree or an equivalent foreign degree. Applicants for the other project categories do not need a doctoral degree. Companies may be co-applicants in the proposal but not grant recipients.

Evaluation criteria

Submitted applications are evaluated based on the criteria research problem, methodology, merits of the applicants/feasibility, relevance for children with cancer, and, when applicable, the scientific report.

Application documents

A complete application is submitted via the application system. Refer to the web page of Barncancerfonden www.barncancerfonden.se/en/for-researchers/ for more information about the call and the last day for application.

MT-ingenjör - Uppkoppling av utrustning för överföring av data till journal

2024-10-09
14:15 - 15:35
MT-ingenjör - Uppkoppling av utrustning för överföring av data till journal

M11 - Sammanhållen miljö för MTP

7. Digitalisering & informatik / Digitalization & informatics

Karin Rydén[1]
[1] Västra Götalandsregionen

Abstract text*: Inom vården sker en snabb utveckling mot en mer uppkopplad och digitaliserad miljö. MTP har gått från att vara fristående utrustning till att kunna kopplas upp mot regionala system. Detta ställer krav på att MTP utvecklas med möjlighet till uppkoppling samtidigt som användning av uppkopplad MTP ställer krav på IT-miljön. Denna utveckling ger nya möjligheter, dels genom att stötta regionala vårdprocesser, dels genom att stödja sammanhållen vårdinformation, standardisering och realtidsdokumentation.

Inom Västra Götalandsregionen pågår ett arbete med att skapa en sammanhållen miljö för MTP. Syftet är att möjliggöra patientsäkra automatiserade vårdprocesser i Västra Götalandsregionen.

För att skapa en sammanhållen miljö för MTP behöver Västra Götalandsregionen arbeta mer tillsammans och sammanhållet inom området. Det behöver finnas en gemensam struktur för bland annat beslutsvägar, mandat, rutiner och riktlinjer, standarder, prioriteringsprinciper och ekonomi. Den tekniska miljön behöver vara sammanhängande med väl fungerande, patientsäkra medicintekniska lösningar. Kompetens och resurser tas tillvara regionalt och det behöver finnas möjlighet till utbildning och annan utveckling.

För att nå målet behöver Västra Götalandsregionen:

- säkra att informationen i de medicintekniska produkterna är tillgänglig och kvalitetssäkrad
- säkerställa att MT-lösningarna är patient- och driftsäkra och stödjer automatiserade vårdprocesser
- ta tillvara på den kunskap som finns och skapa en ökad sammanhållen MTP-kompetens
- uppnå kostnadseffektivitet
- standardisera arbetssätt, system och utrustning på rätt nivå

M13 - P4H Tekniska Ekosystem för Monitorering och Terapi

7. Digitalisering & informatik / Digitalization & informatics

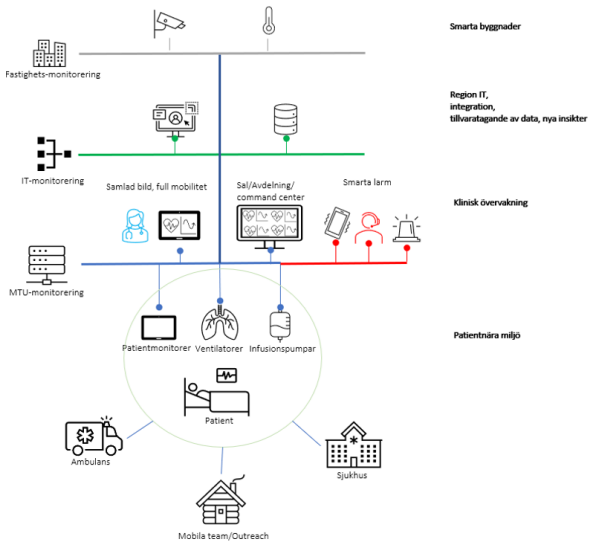
Martin Kral[1]
Anna Larsson[1], Leif Wennström[2], Valon Hysenaj[2], Kjell Andersson[2], Johan Åhlén[3], Per Bundy[3], **Anders Grundin**[4], Ola Heeren[4], Patrik Larsson[4], Johannes Jansson[4], Fredrik Hedlund[5], Björn Lagnevik[6]
[1] Region Stockholm
[2] Västra Götalandsregionen
[3] Region Skåne
[4] Region Västerbotten
[5] Region Örebro Län
[6] Innovation Skåne

Abstract text*: P4H Tekniska Ekosystem för Monitorering och Terapi är ett samarbete mellan Region Stockholm, Västra Götalandsregionen, Region Västerbotten, Region Skåne, Region Örebro län och Innovation Skåne. Målet är att skapa en gemensam målarkitektur för ett tekniskt ekosystem för medicintekniska produkter (MTP) som används för monitorering och terapi.

Läs förslaget på målarkitektur här: https://lnkd.in/gktZ3Dg5

PLATTFORMENS FUNKTIONER
- Förenklad anslutning av MTP.
- Standardiserad datainsamling från MTP.
- Standardiserad lagring av mätdata från MTP för retrospektiv analys.
- Dubbelriktad kommunikation med MTP för ökad automation.

TEKNISK GRUND
- Plattformen baseras på IHE-profiler, som är standarder för kommunikation och integration av MTP. De specifika specifikationerna som används som referensarkitektur är:
    - IHE Devices – Standardiserar kommunikation och integration av MTP.
    - Speciell fokus på IHE SDPi- möjliggöra interoperabilitet mellan ”point-of-care”-enheter.



M14 - Medical Device Connectivity and System Interoperability in Europe must be secure and effective

16. Säkerhet, standarder & regulatoriska frågor / Safety, security, standards & regulatory affairs

Fabrice Dabilly[1]
[1] Fabrice Dabilly, Head of R&D, Clinical Insight & Integration, Philips

Abstract text*: Healthcare-related cybercrimes are on the rise and impact not only patients and healthcare providers, but also entire populations. For example, the 2024 ransomware attack on Change Healthcare in the USA forced several medical practices into bankruptcy, reducing the availability of services in its communities. And, in 2020, cybercriminals attacked Vaastamo in Finland to extort the provider, threatening to disclose patients' confidential mental health and psychotherapy records.

The complexity of medical and care information systems (MCIS) used by providers presents opportunities for malicious actors to penetrate an organization's network, crawl its IT infrastructure and seize assets, with further potential to disrupt the ability to deliver care. Providers strive to be resilient to such threats with the support of technology producers and regulators making medical devices and information systems as secure as possible. Medical device manufacturers, in particular, have a significant role to play, which entails incorporating 'security-by-design' principles into their monitoring and therapy products as required by laws and directives such as those mandated in the European Commission's Medical Device Regulation (MDR).

Implementation of new legislation and related cybersecurity requirements creates unique challenges for all parties, and particularly for manufacturers who must meet the provisions of the ever-evolving regulatory framework. 'Security-by-Design' is important when producing medical devices used within connectivity and interoperability solutions. There are proven and reliable practices to support hospital clients in protecting medical device data and providing a safe environment in several aspects.

System connectivity and interoperability need to be kept simple to remain effective, while MCIS subsystems are called upon to provide more and more insights supporting better care decisions. The promise of the next generation architecture is to decouple the data producers (the medical devices) from the data consumers (the clinical applications) using a medical device information platform (MDIP) that acts as an isolating backbone.

Vetenskap/Science - AI and machine learning

2024-10-09
14:15 - 15:45
Vetenskap/Science - AI and machine learning

M15 - Assessment of Smartphone-Based Third-Generation Acoustic Reflectometry for Middle Ear Effusion Detection: A Comparative Study

2. AI, maskininlärning & Big Data / AI, machine learning & Big Data

Fredrik Öhberg[1, 2]
Ragnar Englund[1, 2], Mimmi Werner[3], Nils Östlund[1, 2], Marcus Karlsson[1, 2], Karolina Jonzén[1], Göran Mannberg[1], Manfred Lindmark[2], Thorbjörn Lundberg[4]
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[2] Institutionen för diagnostik och intervention, Umeå universitet
[3] Institutionen för klinisk vetenskap, Umeå universitet
[4] Institutionen för folkhälsa och klinisk medicin, Umeå universitet

Abstract text*:
Introduction Currently, there are global challenges in diagnosing middle ear diseases, encompassing both under- and overdiagnosis. A crucial aspect of the diagnostic process involves assessing the presence of middle ear effusion (MEE). Previous studies have highlighted several limitations in the existing methods for this assessment, which are often underutilized in primary care settings. This underscores the need for a more user-friendly and simplified alternative.
The objective of this study was to assess a novel smartphone-based method for detecting MEE, termed third-generation acoustic reflectometry (TGAR). We evaluated its diagnostic accuracy and specific outcome measures relative to both first- and second-generation acoustic reflectometry techniques.
Methods Forty participants, aged over 1 year, presenting with ear-related symptoms underwent TGAR examination and wideband tympanometry administered by the researcher. Various sound variables such as band power, entropy, amplitude, and spectral gradient angle were compared across different sound types. The diagnostic precision in predicting MEE was analyzed using an otologist's clinical assessment of middle ear status as the reference, based on the standard 226 Hz tympanometry curve and relevant medical records.
Results The differences in measured variables among sound stimuli were predominantly modest. Significant disparities were noted when comparing band power, amplitude, and spectral gradient angle between ears with and without MEE, as well as when comparing entropy among different sound types. Brown noise exhibited better overall diagnostic precision compared to chirp and impulse sounds, particularly when using amplitude and spectral gradient angle as indicators of MEE. Applying a cutoff value of 121.5° for angle and -9.6 dB for amplitude yielded optimal sensitivity (80% and 90%, respectively) and specificity (71% and 82%, respectively) for detecting MEE, see figure 1.
Conclusions TGAR demonstrates comparable diagnostic accuracy to tympanometry in predicting MEE, offering several practical advantages.

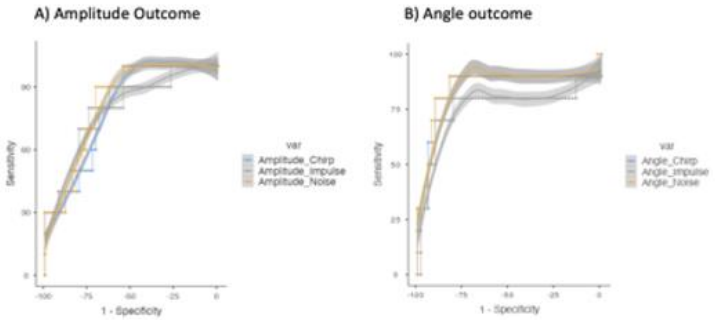


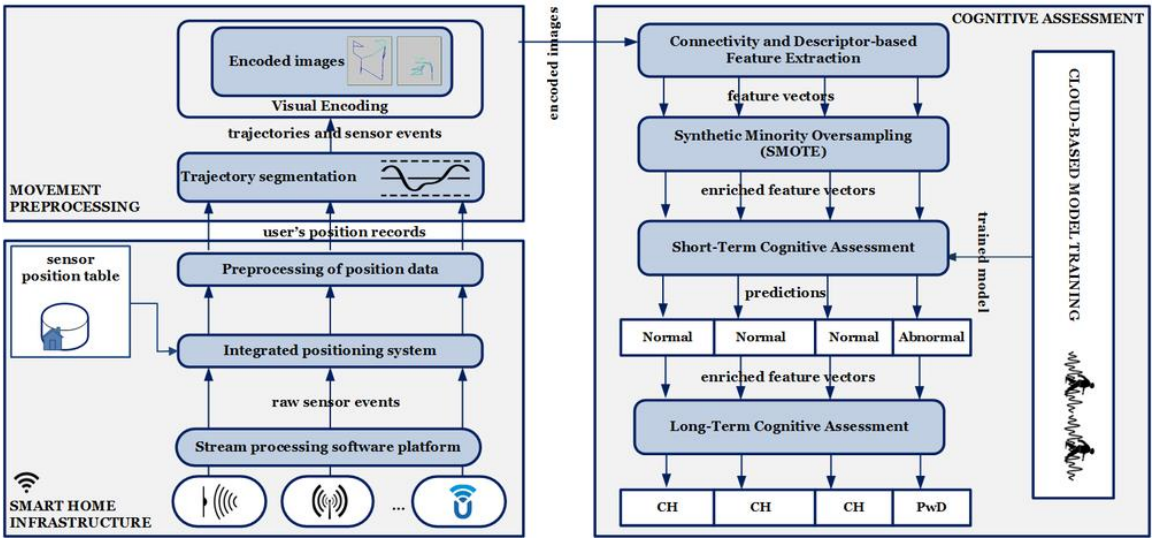
Figure 1: Illustration of the ROC-curves for amplitude outcome (A), as in first-generation AR, and spectral gradient angle outcme (B), as in second-generation AR. The larger the area under the curve, the higher overall diagnostic accuracy.

M16 - Non-invasive Cognitive Assessment in Smart-Homes via Visual Encoding and Synthetic Movement Traces Data Mining

12. Avancerad sjukvård i hemmet / Advanced healthcare at home

Samaneh Zolfaghari[1]
Annica Kristoffersson[1], Mia Folke[1], Maria Lindén[1], Daniele Riboni[2]
[1] School of Innovation, Design, and Technology, Mälardalen University
[2] Mathematics and Computer Science Department, University of Cagliari

Abstract text*: The ubiquity of sensors in smart-homes facilitates the support of independent living for older adults and enables cognitive assessment. Notably, there has been a growing interest in utilizing movement traces for identifying signs of cognitive impairment in recent years. In this study, we introduce an innovative approach to identify abnormal indoor movement patterns that may signal cognitive decline. This is achieved through the non-intrusive integration of smart-home sensors, including passive infrared sensors and sensors embedded in everyday objects. The methodology involves visualizing user locomotion traces and discerning interactions with objects on a floor plan representation of the smart-home, and employing different image descriptor features designed for image analysis tasks and synthetic minority oversampling techniques to enhance the methodology. This approach distinguishes itself by its flexibility in effortlessly incorporating additional features through sensor data. A comprehensive analysis, conducted with a substantial dataset obtained from a real smart-home, involving 99 seniors, including those with cognitive diseases, reveals the effectiveness of the proposed functional prototype of the system architecture. The results validate the system's efficacy in accurately discerning the cognitive status of seniors, achieving a macro-averaged -score of 72.22% for the two targeted categories: cognitively healthy and people with dementia. Furthermore, through experimental comparison, our system demonstrates superior performance compared with state-of-the-art methods.



M17 - Utveckling och utvärdering av ett digitalt gränssnitt för ett AI-baserat beslutsstöd för ambulanspersonal vid bedömning av trauma

6. Diagnostik- & beslutsstödsystem / Diagnostic & decision support systems

Anna Bakidou[1]
Stefan Candefjord[1], Bengt Arne Sjöqvist[1]
[1] Institutionen för Elektroteknik, Chalmers tekniska högskola, Göteborg, Sverige

Abstract text*: Bakgrund och syfte

Forskargruppen *Care@Distance – Remote and Prehospital Digital Health* vid Chalmers tekniska högskola studerar hur digital teknik kan appliceras i den prehospitala vården för att stödja personalen och öka precisionen i beslut. Vid många akuta tillstånd är tid till korrekt behandling viktigt, vilket ställer krav på effektiva verktyg så att ambulanspersonalen snabbt och korrekt kan bedöma en patients hälsostatus och risk.

I en tidigare studie har On Scene Injury Severity Prediction (OSISP) modeller baserade på artificiell intelligens (AI) visat potential att förbättra identifieringen av allvarligt skadade traumapatienter jämfört med dagens beslutsstöd. För att kunna använda OSISP modellerna i ambulanssjukvården går vi nu vidare med att utveckla ett digitalt gränssnitt för dessa modeller. Effektiv interaktion mellan användare och system är väsentligt, vilka faktorer som är viktiga för att uppnå god interaktion med ett AI-baserat beslutsstöd är dock en öppen forskningsfråga. Studien syftar därmed till att utveckla ett digitalt gränssnitt som stödjer effektiv interaktion mellan ett OSISP beslutsstöd och ambulanspersonal.

Metod

Studien delades upp i tre delar. Först studerades avsedd användning genom att ta fram en kundresekarta (eng. *customer journey map*) för traumarelaterade ambulansuppdrag. I det andra steget utfördes en litteraturgenomgång för att samla in data om interaktion med AI system, och semistrukturerade intervjuer genomfördes med experter för att kartlägga erfarenheter av att designa beslutsstöd för den prehospitala vården. Slutligen användes lärdomar från del ett och två som underlag vid design av ett digitalt gränssnitt för OSISP modellerna.

Resultat och slutsats

Studien kommer att generera en kundresekarta, identifiera hur beslutsstödet kan användas kliniskt, sammanställa viktiga faktorer att kommunicera till användaren för god användbarhet, samt ett rekommenderat digitalt gränssnitt som införlivar OSISP modellerna i ambulanstjänsters IT-system.

Slutsatser från studien utgör underlag vid utvecklingen av en prototyp, som därefter kan användas i användartester, samt att fungera som inspel till projekt med närliggande mål.

M18 - Weakly supervised slide-level analysis of paediatric brain tumour histology images

2. AI, maskininlärning & Big Data / AI, machine learning & Big Data
Christoforos Spyretos[1, 2]
Iulian Emil Tampu[1, 2], **Neda Haj-Hosseini**[1, 2]
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[2] Center for Medical Image Science and Visualization, Linköping University, Sweden

Abstract text*: Paediatric brain tumours are the second leading cause of cancer-related deaths in children. Pathologists use whole slide images (WSIs) and molecular profiles to diagnose these tumours. Deep learning can be used to analyse histology features, helping pathologists make quicker and more accurate diagnoses. A dataset with 1019 subjects and 1898 H&E slides was used and 6 largest tumour groups were selected for the analysis. The data was subject-wise split between training (80%), validation (10%), and test (10%) sets. Clustering-constrained attention multiple instance learning (CLAM) and hierarchical image pyramid transformer (HIPT) deep learning models were trained to perform tumour-type classification. CLAM aggregates WSIs' extracted features using either a ResNet50 model pre-trained on ImageNet, or a ViT model pre-trained on the TCGA cohort. HIPT leverages the natural hierarchical structure inherent in WSIs extracting and aggregating features at two levels (256×256 and 4096×4096), using ViT models pre-trained on the TCGA cohort. Experiments were conducted using a 10-fold cross-validation and assessed using accuracy, F1-score and Matthew's correlation coefficient (MCC).

The highest performance was obtained using CLAM-ResNet50 (accuracy=0.66± 0.04, MCC=0.54±0.04) versus CLAM-ViT (accuracy=0.65 ± 0.05, MCC=0.53 ± 0.06) and HIPT (accuracy=0.64 ± 0.04, MCC=0.51 ± 0.06). In conclusion, reasonable results could be achieved for a multiclass prediction of the diagnosis on the WSIs using CLAM-based deep learning models with the ResNet50-based feature extractor achieving slightly higher performance than the ViT-based one. The slide-level models overall show a higher performance and efficiency compared to patch-based models. In the next step, feature extractors from histology foundation models trained on in-domain immense datasets will be used to capture a broad spectrum of histology features [1].

[1] Christoforos Spyretos et al. " Early fusion of H&E and IHC histology images for pediatric brain tumor classification". In: MICCAI Workshop on Computational Pathology with Multimodal Data (COMPAYL). 2024.

M19 - External validation of a machine learning based classification algorithm for ambulatory heart rhythm diagnostics using smartphone-photoplethysmography

2. AI, maskininlärning & Big Data / AI, machine learning & Big Data

Jonatan Fernstad[1, 2]
Emma Svennberg[3], Peter Åberg[1], Katrin Kemp Gudmundsdottir[1], Johan Engdahl[1, 2]
[1] Karolinska Institutet, Dept of Clinical Sciences, Danderyd University Hospital, Stockholm, Sweden
[2] Dept of Cardiology, Danderyd University Hospital, Stockholm, Sweden.
[3] Karolinska Institutet, Dept of Medicine, Huddinge, Karolinska University Hospital, Stockholm, Sweden.

Abstract text*: Aims: Smartphone-photoplethysmography (PPG) can be used for heart rhythm diagnostics. According to current guidelines, ECG verification is required for a new diagnosis of atrial fibrillation (AF). The aim of this study was to evaluate the diagnostic performance of an automatic machine learning (ML) based algorithm for heart rhythm diagnostics using smartphone-PPG recorded by patients with AF in an unsupervised ambulatory setting.
Methods: Patients undergoing direct current cardioversion for treatment of AF or atrial flutter (AFL) were asked to perform one-minute heart rhythm recordings post-cardioversion at least twice daily for 30 days. All participants were provided with an iPhone 7 smartphone running the CORAI Heart Monitor PPG application simultaneously with a single-lead ECG recording (KardiaMobile). A support vector machine (SVM) algorithm trained on recordings made in a separate cohort classified heart rhythm from smartphone-PPG recordings compared to simultaneous ECG recordings.
Results: The SVM classifier was trained on data from 153 patients with 11,749 PPG recordings, of which 5,873 (50.0%) were labelled as AF and 5,876 (50.0%) as sinus rhythm (SR), as assessed by manual reading. In the validation cohort, 280 patients, with a median age of 69.0 years (31% women), registered 18,005 simultaneous PPG and ECG recordings. Recordings interpreted as AFL on ECG (2.0%), as having insufficient quality on ECG (4.9%) or PPG (2.8%), and low certainty algorithmic classifications (1.2%) were excluded, leaving 16,057 PPG recordings. Algorithm classification of the smartphone-PPG recordings in the validation cohort diagnosed AF (sensitivity) in 99.7% and SR (specificity) in 99.7% of the recordings, with an overall accuracy of 99.7%. F1-score was 99.4% and area under the ROC curve (AUC) was 0.999.
Conclusion: A machine learning based algorithm for automatic heart rhythm diagnostics showed excellent diagnostic performance for smartphone-PPG recordings in an unsupervised ambulatory setting, minimizing the need for ECG verification in cardioversion populations.

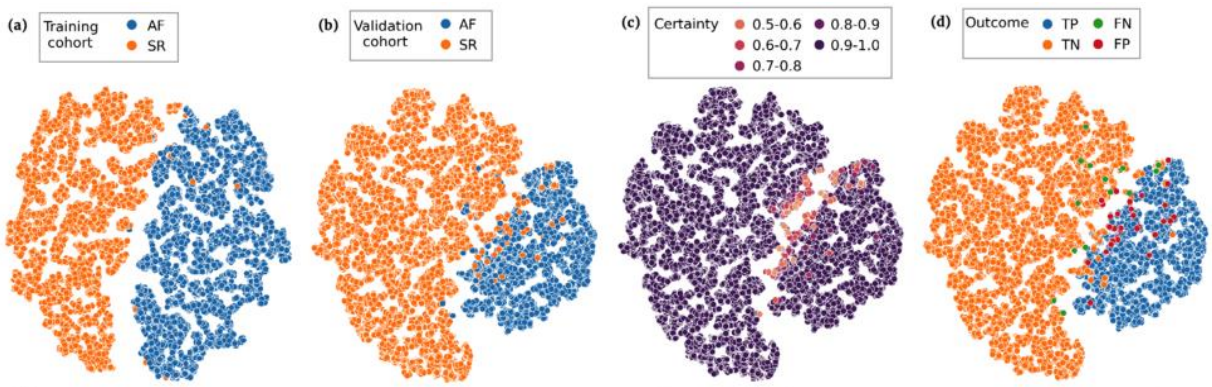


Figure 1. Visualization of all the smartphone-PPG recordings included in **(a)** the training cohort and **(b)** the validation cohort using a t-SNE algorithm that reduces each PPG recording to a single point in 2D space clustering similar PPG recordings together, showing separation between PPG recordings where the heart rhythm is SR and where it is AF. Diagnostic performance of a ML-based automatic algorithm trained on PPG recordings in the training cohort and externally validated on PPG recordings in the validation cohort are visualized in **(d)** and the algorithm's prediction certainty for the PPG recordings are shown in **(c)**.

PPG: photoplethysmogram **t-SNE**: t-distributed stochastic neighbor embedding **SR**: sinus rhythm **AF**: atrial fibrillation **ML**: machine learning
TN: true negative **FN**: false negative **TP**: true positive **FP**: false positive

M20 - Early Characterization of Stroke Using Video Analysis, Machine Learning and Eye Tracking

2. AI, maskininlärning & Big Data / AI, machine learning & Big Data

Eddie Ström[1]
Samuel Ollila[1], Robin Khatiri[1], Jacob Westerberg[1], Teodor Svensson[1], **Hoor Jalo**[1], Stefan Candefjord[1], Bengt-Arne Sjöqvist[1]
[1] Department of Electrical Engineering, Chalmers University of Technology, Gothenburg

Abstract text*: Stroke is one of the leading causes of disability and mortality globally, caused by a decrease or interruption in oxygen supply to the brain. The outcome for a stroke patient largely depends on the time to treatment, making rapid stroke diagnosis crucial. One way to classify stroke is through the National Institutes of Health Stroke Scale (NIHSS).

This study focuses on digitizing and classifying stroke symptoms based on the NIHSS test, with a specific focus on eye movements through video analysis, machine learning (ML), and eye tracking, aiming to potentially facilitate the work of prehospital care.

Due to the limited access to data from stroke patients, videos (n=99) were recorded by healthy volunteers mimicking the gaze palsy following the NIHSS test. Some eye movements are more challenging to be mimicked such as nystagmus, which is a visual disorder characterized by involuntary and repetitive movements of the eyes. Nystagmus eye movement videos were thus synthetically generated (n=65 using Blender and Adobe After Effects software). The videos were then verified by a stroke specialist. Several ML algorithms were tested and evaluated such as convolutional neural network (CNN), deep neural network (DNN), gated recurring unit (GRU) and long short-term memory (LSTM) using the recorded and synthetic data.

The use of synthetic data led to a bigger dataset for training and evaluating the models, which is critical for achieving good performance and reliable stroke characterization. LSTM algorithm achieved the best performance, with 88% accuracy, 87.7% sensitivity, 94.1% specificity and 86.7% F1-score, which was therefore considered the most optimal algorithm to use for this purpose.

In summary, the results of the project shows the feasibility of using ML and video analysis to digitize and classify the eye movement of stroke. However, further research is needed to enhance the results and increase reliability in clinical applications.

MT-sektorn - Utveckling av medicinteknik, från idé till patientnytta

2024-10-09
14:15 - 15:45
MT-sektorn - Utveckling av medicinteknik, från idé till patientnytta

M21 - Health Technology Assessment and Health Economy of medical devices in Sweden and South Africa

19. Upphandling & implementering / Procurement & implementation

Tinashe A. Chikunichawa[1]
John Paul Kulumba[1], Sara Grobbelaar[1], Mikael Persson[1, 2, 3, 4]
[1] Stellenbosch University
[2] Chalmers University of Technology
[3] Gothenburg University
[4] Chalmers Industriteknik

Abstract text*: Stroke is a critical and public health concern, impacting global economic development. Annually, approximately 15 million people endure a stroke, with 5 million succumbing to it and another 5 million facing permanent disability. However, 70% of strokes and 87% of both stroke-related deaths and disability-adjusted life-years occur in low-income and middle-income countries contributing to an estimated global cost of US$700 billion yearly. Notably, the average age for a stroke in Africa is 57 years, markedly lower compared to developed countries like Sweden, where the average age is 75 years.

In the Western Cape Province of South Africa, the persistent challenge lies in efficiently diagnosing and treating strokes across both private and public health sectors. The late presentation time to healthcare providers and the absence of precise and timely diagnostic tools lead to treatment delays, resulting in poorer patient outcomes. A comprehensive health technology assessment (HTA) is essential to evaluate the effectiveness, safety, cost-effectiveness, and broader implications of adopting advanced diagnostic tools tailored to TBIs and strokes in this context.

Our primary research goal is to assess the feasibility and effectiveness of a Swedish-developed advanced diagnostic technology, the Strokefinder MD100, within the Western Cape Province of South Africa. This evaluation seeks to understand how this technology can be integrated into the existing healthcare system (private and public), aiming to enhance patient outcomes while considering economic feasibility and implications for healthcare providers.

Conducting a region-specific HTA could offer evidence-based recommendations vital for policy-making and resource allocation. These findings hold immense potential to significantly enhancing patient outcomes within the public healthcare system of the Western Cape Province.

This presentation illustrates the process, approach and results of this significant project.

MT-ingenjör - Tillverkning och praktiska exempel

2024-10-10
08:30 - 09:55
MT-ingenjör - Tillverkning och praktiska exempel

M22 - Egentillverkning av LoKAS – en diagnostisk utrustning för mätning av riktningshörsel för kliniskt bruk

15. Egentillverkade & specialanpassade medicintekniska produkter / In-house & custom-made medical devices

Fredrik Stillesjö[1]
Jonas Ekeroot[2], Katarina Unger[2], Åsa Klingstedt Sylwan[2], Åsa Sahlberg[2], Ulrica Fjärstedt[1], Mattias Holmgren[1]
[1] Medicinsk Teknik, Akademiska Sjukhuset
[2] Hörsel-Balansmottagningen, ÖNH-kliniken, Akademiska Sjukhuset

Abstract text*: Bakgrund
Vid diagnostiska undersökningar av patienter med hörselnedsättning har patientens förmåga att lokalisera ljud från olika riktningar och med olika frekvensinnehåll fått ökad klinisk betydelse. En undersökning av marknaden för att upphandla en sådan medicinteknisk produkt visade att ingen sådan är tillgänglig, utan de flesta som finns utvecklade är forskningsutrustningar.

Syfte
Syftet med detta arbete är att via egenutveckling konstruera en klinisk mätutrustning för ljudlokalisering och sätta den i klinisk drift.

Material och metoder
Ett system kallat LoKAS konstruerades genom inköp av ljudutrustning och utveckling av tillhörande programvara i programmeringsmiljön Python. Statistiska beräkningar utfördes i programvarumiljön R.

Resultat och diskussion
LoKAS utvecklades och testades med hjälp av en frivillg grupp medarbetare vid Hörsel-Balansmottagningen, Akademiska Sjukhuset. Resultaten var i linje med de som hittats i litteraturen. Efter att utrustningen testats genomfördes en egentillverkningsprocess vid Medicinsk Teknik med tillhörande riskanalys. Erfarenheter från denna process presenteras och även kommentarer kring den revision från RISE som genomfördes efter att egentillverkningen satts i klinisk drift.

Bildtext: LoKAS (Lokalisering Akademiska Sjukhuset)- utrustning för mätning av riktningshörsel vid Hörsel-Balansmottagningen, Akademiska Sjukhuset

M23 - Egentillverkning av MTP – ett sätt att hjälpa de mest utsatta patienterna när marknaden inte kan

15. Egentillverkade & specialanpassade medicintekniska produkter / In-house & custom-made medical devices

Jacob Lidman[1]
Björn Hagström[1]
[1] Sahlgrenska Universitetssjukhuset

Abstract text*: Medicinsk fysik och teknik (MFT) kontaktades av hjärtmottagningen då de behövde hjälp att hitta en ersättningsprodukt för en utgående produkt. Det gällde en infusionspump som används för intravenös behandling av pulmonell arteriell hypertension. Det är ett ovanligt tillstånd där kontinuerlig infusion av läkemedel är livsavgörande för patienterna. De pumpar som finns på marknaden och som är godkända att använda vid intravenös infusion är stora och klumpiga, till skillnad från den gamla som var väldigt liten. De tillgängliga pumparna skulle därför kraftigt begränsa patienternas rörlighet och därmed försämra deras livskvalitet.

Målet var att MFT skulle stödja hjärtmottagningen i egentillverkningen av en infusionspump som kan användas vid intravenös infusion och som inte begränsar patientens liv.

En marknadsanalys genomfördes för att undersöka utbudet av ambulatoriska sprutpumpar på marknaden. En nyare modell av den nuvarande pumpen fanns men som endast är godkänd för subkutan infusion. Det bedömdes dock att det troligtvis skulle gå att utöka den avsedda användningen av den nya modellen till att inkludera även intravenös infusion. Riskanalysen som gjordes visade på flera risker med att utöka den avsedda användningen av pumpen. Samtliga risker kunde hanteras så att riskvärdet blev lågt nog för att nyttan ska överstiga risken. Med hjälp av riskanalysen och en plan för produktförvaltning möter pumpen MDRs allmänna krav på säkerhet och prestanda.

Jämfört med tidigare pump har verksamheten idag bättre koll på hur pumpen ska användas och vilka risker som finns. Det finns en tydlig plan för produktförvaltning och säkerhetsuppföljning, vilket gör att avvikelser kan förhindras och att verksamheten har tillgång till snabbare teknisk support genom MFT. Verksamheten äger nu själva pumparna och är därmed fria att välja olika läkemedelsleverantörer, vilket möjliggjort en besparing på 1,6 miljoner per patient och år. Projektet har möjliggjort att SU fortsatt kan behandla patienter med PAH intravenöst utan att kraftigt försämra deras livskvalitet.

M24 - Specialanpassning trakealkanyler på DS

15. Egentillverkade & specialanpassade medicintekniska produkter / In-house & custom-made medical devices

Ulrika Eidenstam[1]
[1] Ulrika Eidenstam

Abstract text*: Det är nu 50 år sedan Överläkaren Gillis Andersson på Anestesi och Intensivvårdskliniken vid Danderyds sjukhus började hjälpa poliopatienter med muskulär hypoventilation. Det var en pionjärverksamhet att starta kronisk invasivt andningsstöd. Att sköta trakelkanyl och ventilator i hemmet ställer en hel del krav på kunnande, organisation och uppföljning. Redan i starten upptäcktes att det för denna patientgrupp ofta behövdes anpassning av kanylen för att optimera ventilation, och tal, minska risken för skador i trakea

MT på DSAB har sedan starten levererat specialanpassade kanyler till Anestesikliniken och materialen har varit silver, plast och silikon. Anpassningarna har utgått från patientens behov, såväl medicinska som komfort och estetik

1998 kom de första kvalitetsdokumenten på plats som styrde tillverkningen, då var tillverkningen anpassad efter MDD och lagen om MTP SFS1993:584. Sedan 2018 har MT jobbat med att MDR-anpassa tillverkningen och idag är Danderyds sjukhus registrerad som tillverkare av specialanpassade produkter hos Läkemedelsverket.

Arbetet sker i samarbete med läkare vid NRC på DSAB och sedan 1 år finns möjligheten att göra 3D-rekonstruktioner från CT-bilder och i 3D simulera kanylplacering. Detta har utökat möjligheten att hjälpa till med bedömning och att göra förslag på anpassning på distans.

Idag kan MT erbjuda beställande enheter ute i landet möjligheten att på distans göra en konsultation och en anpassad kanyl, baserad på 3D-rekonstruktion och skicka till beställande enhet för att prova och bedöma anpassningen på patient.

M25 - Framtagande av kvalitetsledningssystem för reprocessing av engångsprodukter inom Region Östergötland

15. Egentillverkade & specialanpassade medicintekniska produkter / In-house & custom-made medical devices

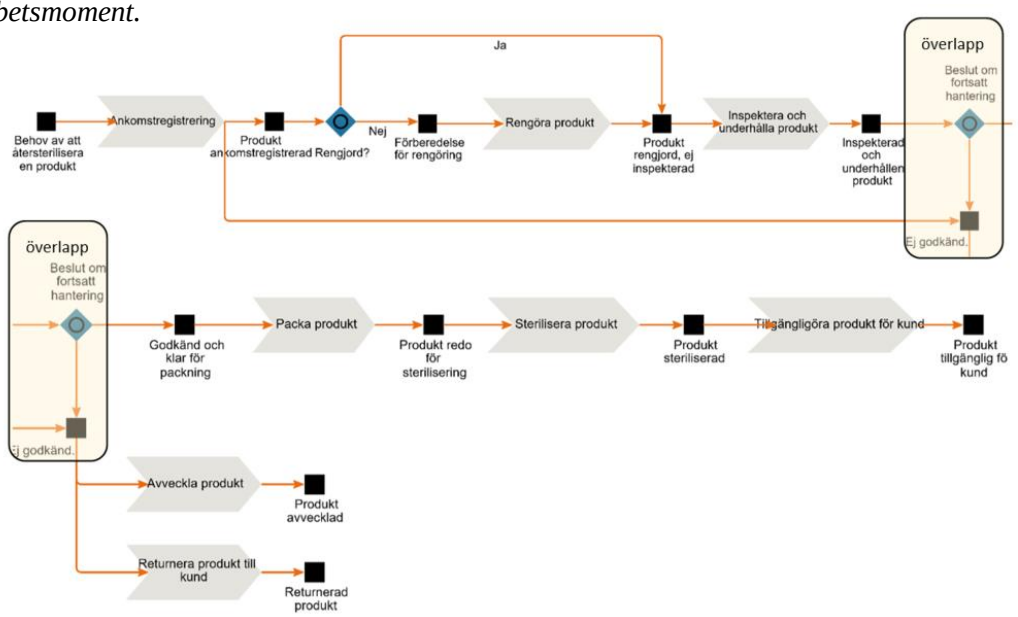
Linda Rosén[1]
Lina Larsson[1], Ia Mälman[1], Malin Hienmert[1]
[1] Region Östergötland

Abstract text*: Inom Region Östergötland har ett beslut om att skapa förmåga att reprocessa engångsprodukter tagits. För uppgiften skapades en grupp bestående av två erfarna steriltekniker, två förändringsledare och processutvecklare samt en sakkunnig i regelverket som omger reprocessing. Arbetet startade i augusti 2023 utifrån målbild och krav från genomförandeförordningen för reprocessing. Initialt genomfördes en gapanalys som därefter resulterade i en aktivitetsplan och kommunikationsplan för framtagandet av kvalitetsledningssystemet. Ett tidigt vägval/beslut som togs var att resultatet av arbetet skulle vara visuellt och lättförståeligt. För det här ändamål användes 2c8 som verktyg för att visualisera processer och dess tillhörande dokumentation. Ett exempel på gränssnittet visas i Figur 1 nedan. Under hösten fokuserade arbetsgruppen på att identifiera och dokumentera den steriltekniska enhetens huvudprocesser och att skapa grundläggande förutsättningar beträffande lokaler, personal och utrustning. Under våren 2024 har fokus legat på stödprocesser som framför allt är kopplade till det ansvar som regionen övertar från den ursprungliga tillverkaren, exempelvis säkerhet och prestanda.

För att lyckas med implementeringen har också en stor del av arbetet fokuserat på förankring hos ledning och medarbetare.

Vi kommer i den här presentationen rapportera om de erfarenheter som vi har erhållit under arbetets gång, samt demonstrera resultatet av vårt arbete.

Figur 1. Översiktlig bild av huvudprocesskarta (här uppdelad i två delar för att förenkla läsbarheten) som medarbetarna på sterilcentralen möts av. De grå fälten är klickbara och genererar att man kommer ner till en nedbrytning av arbetsuppgifterna. För att få information om ett visst arbetsmoment kan man klicka på informationsknappen. Då kommer man till rutinbeskrivning för respektive arbetsmoment.



Vetenskap/Science - Diagnostics

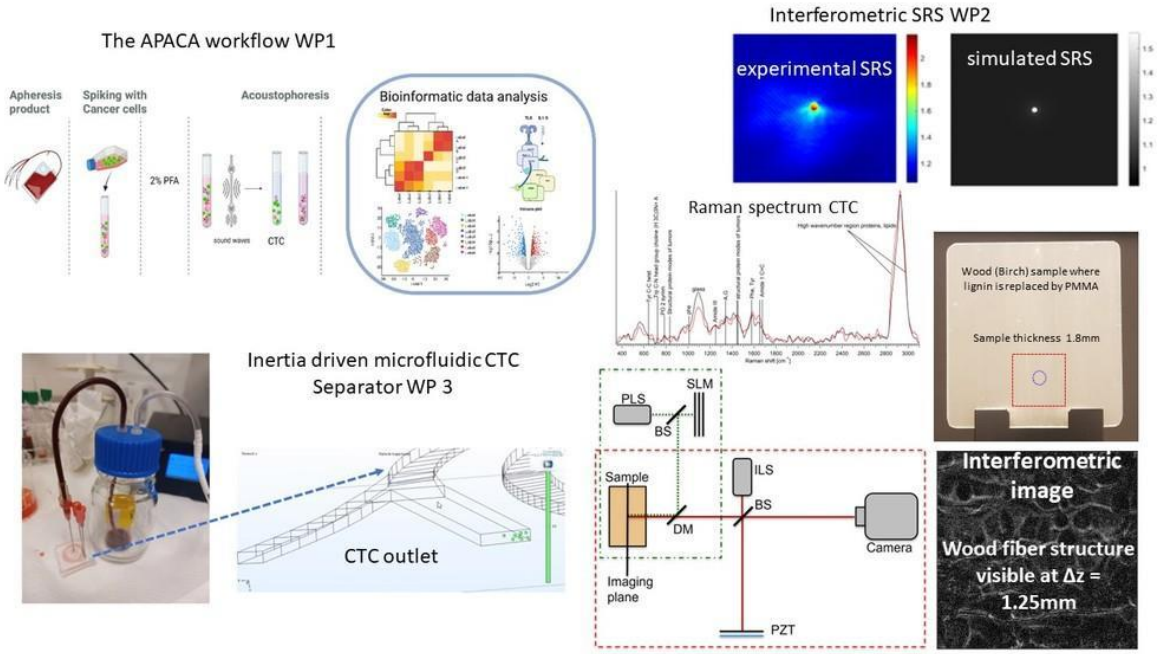
2024-10-10
08:30 - 10:00
Vetenskap/Science - Diagnostics

M26 - Separation and Characterization of Circulating Tumor Cells to detect prostate cancer metastasis

9. Optik-, ultraljuds- & mikrovågslösningar / Optics, ultrasound & microwave solutions

Kerstin Ramser
Andreas Josefsson, Jasmina Cassals-Terré, Maria Tenje, Stefania Caragnano, Dirce Pineda Vazquez, Joel Wahl, Mikael Sjödahl

Abstract text*: Today, there is no cure for metastasized prostate cancer (PC). Personalized therapy based on isolation and identification of circular tumor cells (CTC) may offer the potential to treat PC metastasis. Tailoring therapy through identification of CTC phenotype and genotype to individuals could ultimately enable earlier detection, side effect-free treatment, and increased survival rates. High throughput online systems to detect and analyze CTCs are highly sought after, but their development encounters several challenges. The number of CTC in whole blood is extremely low, there are 1-10 CTCs among 10 million white blood cells and one billion of red blood cells. The major concern of today's state of the art methods is poor sensitivity; the rareness of CTCs in a small blood volume can lead to false negative cases even in metastatic setting. This project has the aim to deliver a new way to isolate and study CTCs. The first step in this project is to develop an inertia driven microfluidic system enabling fast separation and investigation of CTCs from whole blood. Secondly, a novel optical imaging technique based on interferometry combined with stimulated Raman scattering (SRS), in short interferometric SRS, will be developed that may the ability to identify the phenotype of CTCs. Thirdly, the performance of the technique will be compared to current standard procedures in a clinical setting. Presently, shipped frozen apheresis samples from the APACA-study at Umeå University are used for Raman spectral studies at Luleå University of Technology. There, Raman spectra are registered with a continuous wave (cw) laser (l=532nm or 789nm) to define the relevant spectral Raman bands of CTCs regarding their geno-, and phenotype. A brief overview of the latest results on Raman spectroscopic investigations of CTCs and the development of the microfluidic system will be given. Future strategies will be presented.



M27 - Identifying Consistent Spectral Features in Brain Tumor Tissue: A Multivariate Analysis of Data from a Raman Probe and Microscopy System

6. Diagnostik- & beslutsstödsystem / Diagnostic & decision support systems

Dirce Pineda Vazquez[1]
Joel Wahl[1], Elisabeth Klint[2], Martin Hallbeck[3], Peter Milos[4], Jan Hillman[4], Karin Wårdell[2], Kerstin Ramser[1]
[1] Department of Engineering sciences and Mathematics, Luleå university of technology.
[2] Department of Biomedical Engineering, Linköping University.
[3] Department of Clinical Pathology and Biomedical and Clinical Sciences, Linköping University.
[4] Department of Neurosurgery and Biomedical and Clinical Sciences, Linköping University.

Abstract text*: The prevalence of brain tumors is 3-7/100,000 worldwide. It is the highest in northern Europe. Tumor recurrences often happen at the initial resection site and are linked to the extent of tumor removal during the first surgery. Our research aims to implement a handheld Raman probe system to enhance in vivo detection of low-grade tumor tissue during neurosurgery. Although techniques such as fluorescence-guided resection have facilitated more extensive tumor removal, they depend on a fluorescent precursor molecule like 5-ALA (5-aminolevulinic acid). However, the sensitivity of 5-ALA in distinguishing tumor tissue from normal tissue varies, sometimes necessitating reliance on microscopic inspection and tissue texture. A handheld Raman probe system could provide further insights into the molecular composition of tissue without requiring any labels. In our study, 27 patients scheduled for surgery at Linköping University Hospital were included (EPM 2020-01404). We measured 969 spectra using a Raman microscopy setup from 16 patients and 1,125 spectra from 11 patients using a Raman probe system. All measurements were conducted ex vivo on freshly resected samples in a setup adjacent to the operating room. The spectra from the respective systems have been analyzed using multivariate statistical methods to identify spectral features from biomarkers, notably carotenoids, and variations in spectral features related to bonds in proteins and lipids.

M28 - Microwave Diagnostics for Neurological Disorders

6. Diagnostik- & beslutsstödsystem / Diagnostic & decision support systems

Seyed Moein Pishnamaz[1]
Xuezhi Zeng[1], Hana Dobsicek Trefna[1], Mikael Persson[1, 2], Andreas Fhager[1]
[1] Department of Electrical Engineering, Chalmers University of Technology
[2] Department of Clinical Neuroscience, University of Gothenburg

Abstract text*: Microwave diagnosis is a potential complement for CT and MRI to diagnose safely, fast, portably, and reliably. In this presentation, we present our latest advances for the following two applications aimed at diagnosing neurological disorders using microwaves.

· Microwave detection of ischemic stroke:

Prehospital detection of the stroke type and determination of the thrombectomy candidates are two challenging medical diagnosis tasks. For the former, the aim is to rule out the bleeding, while the latter aims to find out if the thrombosis is in the large arteries or not. In this project, the blockage in the large brain arteries in an animal model is diagnosed using microwave antennae operating in below 1 GHz band. A newly developed algorithm detects changes in the signals passing through the ischemic side of the brain compared to the baseline after injection of a contrast agent.

· Microwave monitoring of shunt malfunction in hydrocephalus children:

Children who are diagnosed with brain tumours are prone to develop hydrocephalus. To prevent this, a shunt is placed in the skull to drain the excessive amount of CSF into the stomach. 4 out of every 10 shunts malfunctioned in the first year. Therefore, the function of the shunt should be monitored continuously. Microwave diagnosis is a safe way to prevent extra exposure to ionizing X-rays used in CT scans.
This project aims to modify the MD100 Strokefinder developed by Medfield Diagnostics AB to use it on children. The gap between children's small heads and antennae is filled with a solid flexible matching medium to maximise power penetration to the head. A multi-layer phantom representing the dimension of a child with dynamical ventricles is made and slight enlargement of the ventricles is detected by comparing to the baseline.

M29 - Förstärka personcentrerad rehabilitering med biomedicinsk radar

3. Bioelektronik & sensorer / Bioelectronics & sensors

Xuezhi Zeng[1]
Gunilla Kjellby Wendt[1, 2]
[1] Institution Elektroteknik, Chalmers Tekniska Högskola, SE 412 58, Göteborg
[2] Verksamhet Arbetsterapi och Fysioterapi, Sahlgrenska Universitetssjukhuset, SE 431 80, Mölndal

Abstract text*: Enligt Världshälsoorganisationen (WHO) lever cirka 16 % av världens befolkning med någon form av funktionshinder. Bland dessa lider en betydande del motoriska funktionsstörningar. Individer med nedsatt motorisk funktion stöter ofta på svårigheter med vardagliga aktiviteter som att greppa föremål, att gå och löper därmed en ökad risk att drabbas av fall. Rehabilitering spelar en avgörande roll för att ge dessa individer möjlighet att återvinna funktion, självständighet, förbättra sin livskvalitet och återintegrera sig i samhället.

Rehabilitering är evidensbaserad där bedömning spelar en grundläggande roll. En omfattande bedömning av patientens tillstånd är avgörande för att identifiera funktionsnedsättningar, upprätta funktionella mål och utveckla individualiserade behandlingsplaner. Regelbunden omvärdering gör det möjligt att övervaka framstegen och modifiera insatser efter behov för att optimera rehabiliteringsresultaten. En kritisk aspekt av bedömningsprocessen är utvärderingen av kroppsfunktion och aktiviteter, som ger avgörande insikter om patientens fysiska förmåga och begränsningar. Traditionella bedömningar av kroppsfunktion och aktiviteter bygger huvudsakligen på observationer av vårdgivare, vilket leder till variationer i resultat och ökad risk för subjektivitet. Dessutom stöter dessa metoder ofta på precisions och tillförlitlighetsbegränsningar, vilket hindrar effektiviteten av rehabiliteringsinsatser. Dessa bedömningar utgör dock de grundläggande delarna av individens rehabiliteringsprogram.

Ett paradigmskifte inom rehabilitering är nödvändigt för att adressera dessa begränsningar och utveckla mer effektiva bedömningsmetoder och arbetssätt. Centralt för denna transformation är att integrera tekniska innovationer i rehabiliteringsprocessen. Nya teknologier, såsom biomedicinsk radar, presenterar en lovande lösning för billiga, tillgängliga och objektiva bedömningar av funktionella förmågor. Vi presenterar en ny metod som integrerar biomedicinsk radar i standardiserade funktionstester för kvantitativ bedömning av kroppsfunktioner. Syftet är att optimera bedömningen av funktioner för att uppnå en bättre individanpassad, personcentrerad rehabilitering.

M30 - Utveckling av system för mikrovågsdetektion av muskelrupturer

6. Diagnostik- & beslutsstödsystem / Diagnostic & decision support systems
Laura Guerrero Orozco[1]
Andreas Fhager[1]
[1] Chalmers university of technology

Abstract text*: Upp till 30 % av skadorna som diagnosticeras av läkare inom idrottsmedicinen är muskelrupturer. De är vanliga i sporter som sprint, löpning, fotboll och friidrott och inträffar ofta i musklerna på baksidan av låret, hamstringsmusklerna. Denna typ av skador diagnostiseras med en kombination av fysisk undersökning och avbildning med hjälp av MRI eller ultraljud. I många fall anses muskelrupturer inte vara tillräckligt akuta och kostnaden förknippad med MRI-avbildning anses inte motiverad, och ultraljud är inte alltid tillräckligt specifik Detta gör att många drabbade inte får korrekt diagnos och behandling. Odiagnostiserade små och medelstora muskelbristningar är särskilt förrädiska då det är lätt hänt att man återgår till sport och träning för tidigt och slår upp skadan ytterligare och orsakar en betydligt större bristning med betydligt längre rehabiliteringstid. För att förbättra diagnosen av muskelbristningar behövs därför ett system med låg kostnad och som gärna är lättillgängligt.

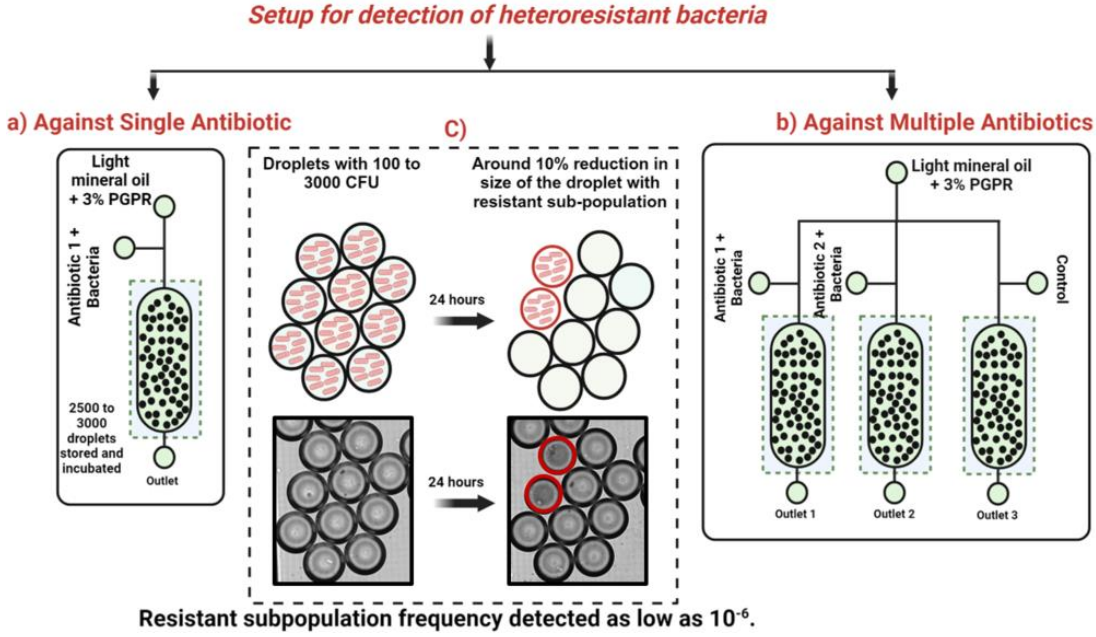
Vi utvecklar ett mikrovågsbaserat system för diagnos av muskelbristningar. Specifikt är målet att mäta den blodsutgjutelse som åtföljer en muskelruptur, för att därigenom upptäcka förekomsten av bristning. Systemet består av en halvcirkelformad uppsättning antenner som omger låret och som används för mikrovågsmätningar. Signalerna propagerar genom låret och påverkas på sin väg av de olika vävnaderna, inklusive potentiell blödning. Signalerna som når mottagarantennerna kan analyseras för att fastställa förekomsten av blödning. Vi har tillverkat och testat en prototyp med vävnadsliknande fantomer och en rekonstruktionsalgoritm inspirerad av radartekniker. Resultaten är lovande och nuvarande inriktning är att utveckla en prototyp som är lämpad för kliniska studier.

M31 - Droplet Microfluidics-Based Detection of Hetero-Resistance in Bacteria

8. Medicintekniska produkter för in vitro-diagnostik / In-vitro diagnostic medical devices

Sagar Agnihotri[1]
Nikos Fatsis-Kavalopoulos[2], Maria Tenje[1], Dan Andersson[2]
[1] Department of Materials Science and Engineering, Science for Life Laboratory, Uppsala University, Uppsala, Sweden
[2] Department of Medical Biochemistry and Microbiology, Uppsala University, Uppsala, Sweden

Abstract text*: Population heterogeneity in bacterial phenotypes such as antibiotic resistance is increasingly recognized as a medical concern. Heteroresistance (HR) is a phenomenon where in a main population of susceptible cells there exist small resistant subpopulations and during antibiotic exposure, these resistant may be selected and cause treatment failure. Due to the low frequency and instability of these resistant subpopulations, standard tests for antibiotic susceptibility testing are unable to reliably detect them and hence new diagnostic methods are required. We have developed a new 3D-printed droplet microfluidics-based method that can detect resistant subpopulations with a frequency as low as 10^{-6}. The microfluidic device consists of two parts, the droplet generation part which is a T-junction with an inlet of oil, and an inlet of aqueous phase (*E. coli* in MH broth + antibiotic) (**figure 1a**). The second part is a droplet storage and incubation section that can hold around 2000 to 3500 droplets. In the case of the multiplex chip **(figure 1b)**, similar dimensions are used along with multiple droplet generators and storage/incubation chambers. Each droplet is encapsulated with around 1000 to 5000 bacteria depending on antibiotics used, droplet size, colony-forming units per milliliter (CFU/mL), and the frequency of the resistant subpopulation. The droplets with resistant cells can grow in the presence of antibiotics, which results in a 10% reduction in droplet size as compared to the droplets without any growth as shown in schematic **figure 1c**. The size reduction is detected by microscopy. With a multiplex chip, we can detect HR for clinical strains of *E. coli* against multiple antibiotics, including cefotaxime, tetracycline, and gentamicin.



MT-ingenjör - Verksamhetsutveckling och spårbarhet

2024-10-10
10:30 - 11:50
MT-ingenjör - Verksamhetsutveckling och spårbarhet

M32 - Varför är kvalitetsledning nödvändigt på en medicinteknisk avdelning?

18. Organisation, processer och arbetssätt / Organization, processes and working methods

Leo Lantz[1]
[1] Södersjukhuset

Abstract text*: Efter många år av arbete med kvalitetsledning på medicintekniska avdelningar och medicintekniska företag berättar jag om erfarenheter och lärdomar i praktiken. Under 2022 genomförde två exjobbare från KTH en undersökning för att kartlägga vilken typ av standard för ledningssystem man borde följa på en medicinteknisk avdelning. Föredraget svarar på frågor som hur viktigt det är att vi arbetar med kvalitetsledning och om det är viktigt att vi certifierar en medicinteknisk avdelningen.

M33 - Verksamhetsutveckling för Medicinsk Teknik

18. Organisation, processer och arbetssätt / Organization, processes and working methods

Fredrik Nordenstam[1, 2]
[1] LfMT Nätverket för verksamhetsutveckling
[2] Sahlgrenska Universitetssjukhuset

Abstract text*: Nätverket för verksamhetsutvecklning vill visa på hur arbetet med verksamhetsutveckling kan se ut i en region och hur detta sprids till andra regioner genom nätverket. Exempel är:
- ett nytt verktyg för processkartläggning som används inom Sahlgrenska Universitetssjukhuset.
- Enkäter som samlar in information och rutiner i vissa ämnen.

M34 - MT och IT arbetar i gemensamma processer mot samma mål

18. Organisation, processer och arbetssätt / Organization, processes and working methods

Git Eliasson[1]
Helen Holst[1]
[1] Södersjukhuset AB

Abstract text*: Medicinsk teknik och IT på Södersjukhuset arbetar nu i samma processer med leveransmodell för produktion, innovation och utveckling med fokus på system och applikationer och tillhörande utrustning. Efter kompetenskartläggning och skapande av nya gemensamma forum för beslut har staben för Utveckling och Teknik inte behövt genomföra omorganisation. Istället arbetar Medicinsk teknik, IT och sjukhusgemensam utvecklingsavdelning tillsammans i de tre leveransströmmarna.

I Region Stockholm används en central leverantör av IT-tjänster som ställer stora krav på den lokala MT- och IT-organisationen kunskap inom beställning av infrastruktur, nätverk, arkitektur och incidenthantering för system och applikationer som ofta också lyder under det medicintekniska regelverket.

Föredraget beskriver hur framtagning av den nya leveransmodellen gick till och hur det fungerar idag.

M35 - Förstudie spårbarhet av medicintekniska produkter (MTP) i Västra Götalandsregionen

16. Säkerhet, standarder & regulatoriska frågor / Safety, security, standards & regulatory affairs

Mia Isacson[1]

[1] Västra Götalandsregionen

Abstract text*: Västra götalandsregionen (VGR) har behov av en strategi för nivå på spårbarhet för MTP samt vilken information (masterdata) som behövs för olika kategorier och användningsområden av medicintekniska produkter (MTP). Resultatet av förstudien som genomfördes 2023 ska användas som underlag för att identifiera åtgärdsbehov, prioritera och planera fortsatt arbete med strategier, styrande dokument, krav och lösningar för spårbarhet gällande MTP i VGR.

Utifrån intervjuer och worshops beskrivs övergripande kartläggning av nuvarande spårbarhetsnivåer och beskrivning av behov utifrån olika regionala perspektiv. Förslag på målbild och förslag på fortsatt arbete att närma sig målbilden har tagits fram.

Vetenskap/Science - Standards, innovation support and processes

2024-10-10
10:30 - 12:00
Vetenskap/Science - Standards, innovation support and processes

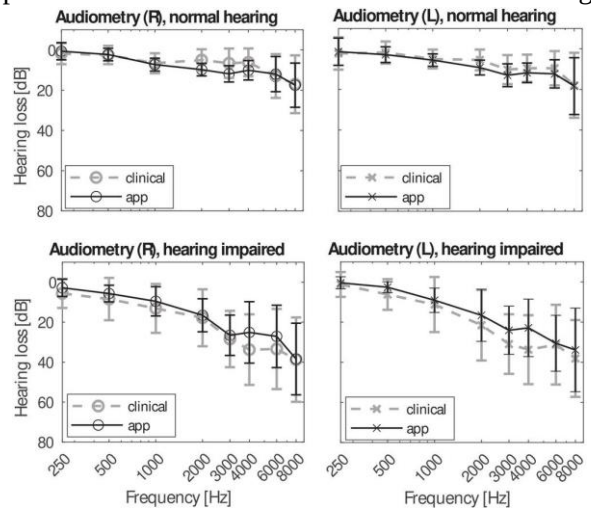
M36 - Validating an Android App for Automated Audiometry: Comparing App-Based Results with Clinical Audiograms

13. Innovation & translationell medicinteknik / Innovation & translational biomedical engineering
Ghazaleh Ghaffari[1, 2]
Fredrik Öhberg[2, 3], Mimmi Werner[4], Per Hallberg[1, 2, 3], Amin Sarermi[1]
[1] Department of Applied Physics and Electronics, Umeå University.
[2] Department of Biomedical Engineering R&D, University Hospital of Umeå, Region Västerbotten.
[3] Department of Diagnostics and Intervention, Biomedical Engineering and Radiation Physics, Umeå University.
[4] Department of Clinical Sciences, Otorhinolaryngology, Umeå University.

Abstract text*: Pure tone audiometry is the gold standard for assessing hearing impairment, and the hearing thresholds at frequencies between 125 and 8000 Hz are reported in an audiogram. Tone audiometry is conducted by licensed audiologists with calibrated equipment in a soundproof room. Several mobile applications have been developed to automate the process and enable people to perform it at home. However, since these applications are typically software-based without an explicit coupling to the hardware characteristics of different connected headphones, the true sound intensities are unknown.

In this study, an Android mobile app has been developed that adapts to the specific frequency response of the connected headphones and performs pure tone audiometry using von Bekesy's method. 22 normal-hearing (9 males, 13 females, mean age=48.0, SD=14.9) and 16 hearing-impaired (10 males, 6 females, mean age=58.2, SD=6.2) participants were recruited. Pure tone audiometry was conducted by an experienced audiologist according to the ISO standard 8253-1:2010. The app-based audiometry test was conducted using SONY WH-1000XM3 headphones in a quiet room. The two test results were statistically analyzed in IBM SPSS using paired t-test and Pearson correlation with a two-tailed test of 0.05 significance level.

As the figure below shows, the app-based method yields similar results as compared to the clinical method. The difference between the two methods was 5.1 and 7.3 dB in terms of mean absolute error (MAE) for the normal hearing and hearing-impaired groups respectively, when averaged over all frequencies. The t-test showed no significant difference between the two results at any of the measured 8 frequencies. The correlation between the two results was highly significant ($p<0.001$) and consistently strong across all frequencies, with an average correlation of $r=0.73$. These findings indicate that the app can provide an accurate estimate of the clinical audiogram.



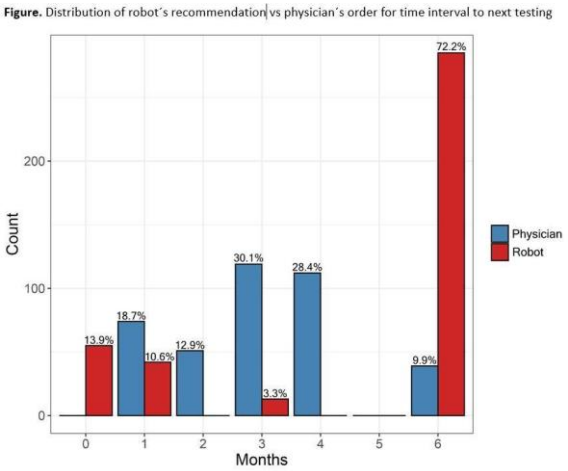
M37 - Development of an automated process for monitoring of amiodarone treatment

6. Diagnostik- & beslutsstödsystem / Diagnostic & decision support systems

Birgitta I Johansson[1]
Jonas Landahl[2], Karin Tammelin[3], Erik Aerts[4], Christina Lundberg[3], Martin Adiels[3], Martin Lindgren[1, 3], Annika Rosengren[1, 3], Nikolaos Papachrysos[3], Helena Filipsson Nyström[5], **Helen Sjöland**[1, 3]
[1] Department of Medicine, Geriatrics and Emergency Medicine, Sahlgrenska University Hospital/Östra, Gothenburg, Sweden
[2] Department of Digital Development, Sahlgrenska University Hospital, Gothenburg, Sweden
[3] Department of Molecular and Clinical Medicine, Institute of Medicine, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden
[4] Chalmers University of Technology
[5] Department of Internal Medicine and Clinical Nutrition, Institute of Medicine, University of Gothenburg, Sweden

Abstract text*: Aim: Amiodarone treatment requires repeated laboratory evaluations of thyroid and liver function due to risk of side effects. Robotic process automation represents the use of software robots to automate repetitive and routine tasks. We aimed to develop such a robot using a diagnostic classification algorithm for amiodarone follow-up.
Methods: We designed a robot and clinical decision support system based on expert clinical advice, aligned with current best practices in thyroid and liver disease management. The robot provided recommendations on the time interval to next laboratory testing and management suggestions for the physician, who was serving as a human-in-the-loop responsible for patient management. The robot was studied in parallel with the existing manual routine follow-up of amiodarone treatment.
Results: After iterative technical improvements a robot prototype for validation was compared with physicians' orders (n=390 paired orders). The recommended time interval to next follow-up was mean (standard deviation [SD]) 4.5 (SD=2.4) vs. 3.1 (SD=1.4) months for robot vs. physician ($p<0.0001$). While normal laboratory findings resulted in recommended follow-up in 6 months by the robot (72.2%) this was only ordered in 9.9% by the physician. Physicians' orders clustered between 3-4 months (58.5%) (Figure). All patients diagnosed with new side effects (n=12) were correctly detected by the robot, whereas only 8 by the physician.
Conclusions: An automated process constitutes a technically and medically reliable alternative to present management of amiodarone follow-up. It may reduce manual labour, frequency of laboratory testing and detect side effects with increased precision, thereby reducing costs and enhancing patient value.

Figure: Distribution of robot´s recommendation vs physician´s order for time interval to next testing



M38 - Kliniska prövningar av medicintekniska produkter – Kliniska Studier Sverige

21. Övrigt / Other (specified further down in the form)
Ebba Brann[1]
[1] Västra Götalandsregionen

Abstract text*: Abstract
Kategori: Kliniska prövningar
MT-sektorspåret
Författare: Arbetsgruppen för kliniska prövningar av medicintekniska produkter, Kliniska Studier Sverige
Presentatör: Arbetsguppen för kliniska prövningar av medicintekniska produkter, Kliniska Studier Sverige
Vi ber att få återkomma med namn på presentatör/er. Kommunikationen för abstractet sker genom en representant för gruppen.

Kliniska prövningar av medicintekniska produkter – Kliniska Studier Sverige

Kliniska studier Sverige (KSS) är ett nationellt samarbete mellan Sveriges sex sjukvårdsregioner och stöds av Vetenskapsrådet. Syftet är att utveckla och erbjuda stöd för forskning i hälso- och sjukvården.

Klinisk prövning är ett moment som oftast ingår i utvecklingen av en medicinteknisk produkt. KSS har utvecklad stöd för kliniska studier inklusive kliniska prövningar av medicintekniska produkter i form av en webbplats med information och mallar. På webbplatsen finns även ”Feasibility Sweden” som är en nationell tjänst för forskare och life science-företag som ger en väg in och svar på studieförfrågningar till den svenska hälso- och sjukvården.

Förslag på ämnen att presentera:

Vad är definitionen av en klinisk prövning av en medicinteknisk produkt?

Vilket stöd finns på KSS?

Vad är monitorering av en klinisk prövning av en medicinteknisk produkt?

M39 - Standarder för medicinteknik och regulatorisk efterlevnad

16. Säkerhet, standarder & regulatoriska frågor / Safety, security, standards & regulatory affairs

Jenny Acaralp[1]
Lena Morgan[1]
[1] Svenska Institutet för standarder

Abstract text*: Ny europeisk lagstiftning för medicintekniska produkter, Medical Device Regulation (MDR) och In vitro-diagnostik (IVDR) ökar behovet av harmoniserade standarder, vad kännetecknar en harmoniserad standard och hur kan en harmoniserad standard hjälpa till med att uppfylla krav som ställs på medicintekniska produkter i MDR och IVDR?

Vi ger exempel samt redogör för det senaste inom den processen, vilka standarder har blivit antagna som harmoniserade standarder och vilka är under framtagning.

Vi berättar även om pågående nya arbeten och sådant som ligger litet längre fram. Hur ska man tänka kring standardisering vid innovation av nya tekniker. Vi ger några exempel, bland annat hur man har arbetat kring standardisering inom området organ on chip.

M40 - SahlBEC lab - ett unikt samverkanslabb för medicinteknisk forskning

13. Innovation & translationell medicinteknik / Innovation & translational biomedical engineering

Andreas Fhager[1]
Justin Schneiderman[2, 3], Mikael Persson[1, 2, 4], Mikael Elam[2], Henrik Mindedal[4]
[1] Institutionen för elektroteknik, Chalmers tekniska högskola, Göteborg
[2] Sektionen för klinisk neurovetenskap, Institutionen för neurovetenskap och fysiologi, Sahlgrenska akademin, Göteborgs universitet, Göteborg
[3] Innovationsplattformen, Sahlgrenska Universitetssjukhuset, Västra Götalandsregionen, Göteborg
[4] Chalmers Industriteknik, Göteborg

Abstract text*: SahlBEC Lab (Sahlgrenska Biomedical Engineering Collaboration Laboratory) är en världsunik labbmiljö som byggs upp vid Bild och Interventionscentrum (BOIC), Sahlgrenska universitetssjukhuset. Syftet med labbet är att möjliggöra spetsforskning där vård, företag och akademiska tekniska och medicinska forskargrupper samverkar i gemensamma projekt för att utveckla nya medicintekniska lösningar.

SahlBEC lab består av dubbelskärmade väggar, vilket gör labbet både elektriskt och magnetiskt avskärmat från omgivningen. Inne i labbet kan man därför utföra experiment med känslig mätutrustning utan att störas av elektriska och magnetiska fält från omgivningen, och man kan utföra hypertermiexperiment med mikrovågsutrustning utan att riskera att störa omgivningen.

Labbet är primärt designat för mätningar med biomagnetiska sensorer för MEG och MKG (Magnetoencefalografi och Magnetokardiografi) och för mikrovågsbaserad hypetermibehandling samt mikrovågsdiagnostik. SahlBEC lab är utrustat för att kunna arbeta med rena labbexperiment, såsom utveckling av utrustningar och prototyper men också för att genomföra patientstudier.

SahlBEC lab har tillkommit på initiativ av de tidigare parterna i MedTech West och arbete har pågått sedan 2018 och efter att drabbats av förseningar på grund av COVID-19 samt tekniska utmaningar så börjar labbet bli färdigt att tas i drift. Labbet är till stor del finansierat av ett anslag från Tillväxtverket, men de tre parterna i projektet, Chalmers, Sahlgrenska akademin vid Göteborgs universitet (SA/GU) samt Sahlgrenska universitetssjukhuset har även skjutit till varierande del av finansieringen.

I detta föredrag berättar vi om tillkomst och byggnation, samt ger en översikt av den forskning och utveckling som möjliggörs i denna unika labbmiljö.

M41 - Design of an MDR-Compliant Ultra-Wide Band Hyperthermia System

16. Säkerhet, standarder & regulatoriska frågor / Safety, security, standards & regulatory affairs

Mattia De Lazzari[1]
Robin Nilsson[1], Hana Dobšíček Trefná[1]
[1] Chalmers Tekniska Högskola

Abstract text*: The beneficial effects of adding hyperthermia (HT) to established cancer therapies, such as chemotherapy and radiotherapy, are well-documented. The therapeutic efficacy of HT is closely linked to the thermal dose delivered, which depends on the quality of heating achieved. Therefore, it is essential that HT devices adhere to the latest quality and safety standards. The European Medical Devices Regulation (MDR) 2017/745 establishes stringent quality and safety requirements for medical devices in Europe.

At Chalmers University, we are developing an Ultra-Wide Band HT system intended for treating head and neck malignancies, operating between 200 to 800 MHz, compliant with these regulations. The system comprises four main components: a treatment monitoring station, signal generators and amplifiers, applicators, and temperature monitoring devices. A feedback control block ensures precise real-time control over treatment delivery.

The design process follows the V-Model for product development. In this model, the left arm represents the requirements of the system at different development phases, initially at a general level, then for each subsystem and individual component. The right arm then describes the validation against these requirements. More than thirty different standards regarding electrical and biological safety, as well as relevant guidelines developed by various societies are applicable in this process.

Special attention is given to electromagnetic compatibility, following IEC 60601 and IEC 61000 standards. We recognized the eventual EM interference between different components as one of the major concerns associated with inaccuracies at heat delivery at almost all system levels. To mitigate these risks, we implemented practical solutions such as EM-shielded compartments to house sensitive components like phase shifters. Additionally, a control box has been designed to provide continuous feedback control over phase and amplitude, compensating for any deviations caused by external EM disturbances.

Vetenskap/Science - Medical imaging & image processing

2024-10-10
13:15 - 14:45
Vetenskap/Science - Medical imaging & image processing

M42 - Applying digital twins and additive manufacturing in septoplasty

11. Modellering & simulering / Modelling & simulation

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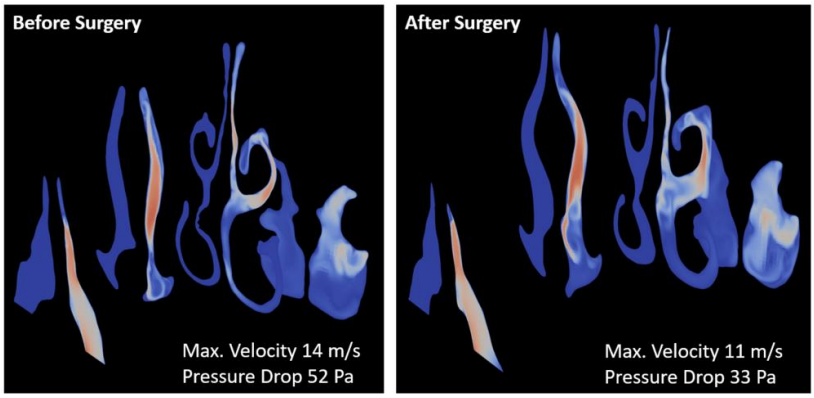
Abstract text*: Digital twins, along with computational fluid dynamics (CFD) and additive manufacturing, are novel approaches aimed at enhancing the success rate and satisfaction of patients undergoing septoplasty. These methodologies are presently in the developmental phase at Chalmers, GU and Sahlgrenska with the purpose to enable doctors to quantify nasal air flow, assess breathing conditions before and after surgery, and provide guidance for optimal surgical procedures or the decision to forego surgery. Currently, the optimal utilization of these approaches by medical practitioners and the extent to which in-vitro twins accurately replicate in-vivo patient conditions remain unclear. The objective of the current work is to assess digital twins and CFD simulations of nasal air passages for pre- and post-surgery conditions and to compare the results with clinical assessments.

The patient's conditions before and after surgery were assessed with visual inspection, rhinometry, rhinomanometry and CBCT scans. These scans were then used to make 3D computer models (digital twins) of the nasal airways. These models were made by applying image segmentation and semiautomated processing in 3D Slicer software package. The CFD analysis of the flow in these digital twins before and after surgery was performed. Our CFD approach, which was earlier validated in work [1], successfully predicted the flow, pressure distribution, and nasal resistance of the 3D models. Figure below show contours of velocity magnitude in different cross-sections of the nasal channel before and after surgery. CFD simulations can help to quantitatively diagnose nasal air flow and resistance, especially in the obstructed cavity, and improve the success rate of surgery and patient satisfaction.

Keywords: septoplasty, nasal airways, nasal resistance, rhinomanometry, digital twin, CFD

[1] Pawade A. (2021) Computational modeling of airflow in a human nasal cavity, MSc thesis, Chalmers University of Technology.



M43 - 3D Diffusion Image Acquisition with Motion Offsetting and Navigation-Dependent Segmentation (DIAMONDS)

10. Medicinsk bild & bildbehandling / Medical imaging & image processing

Jens Johansson[1, 2]
Kerstin Lagerstrand[2, 3], Hanna Hebelka[1, 4], Stephan Maier[1, 5]
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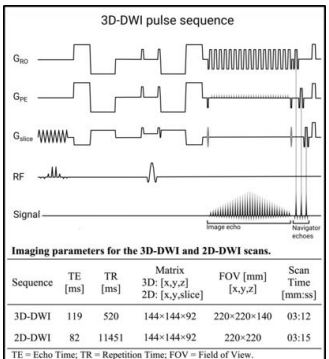
[2] Department of Medical Physics and Biomedical Engineering, Sahlgrenska University Hospital
[3] Department of Medical Radiation Sciences, Sahlgrenska Academy, University of Gothenburg
[4] Department of Radiology, Sahlgrenska University Hospital
[5] Department of Radiology, Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA

Abstract text*: Introduktion Diffusion-weighted imaging (DWI) predominantly relies on a single-shot 2D acquisition, which is inherently prone to low SNR and low spatial resolution. For high-resolution DWI, a 3D acquisition delivers superior SNR[1,2]. Such approach, however, requires a multi-shot acquisition, for which motion-induced shot-to-shot phase variations result in signal drop-outs and ghosting artifacts. The use of motion-compensated diffusion gradients, which minimize phase variations, is a viable option to enable single thick-slab 3D-DWI with whole brain coverage[3]. However, residual phase variations remain. This study investigated whether 1D navigator echoes suffices to correct residual phase errors in single thick-slab segmented 3D-DWI.

Method Single-slab 3D-DWI brain data with 1,5 mm^3 isotropic resolution were collected on a 3 Tesla GE Premier scanner using an in-house developed 3D-DWI sequence with first and second order motion-compensated gradients and 1D navigator echoes. The navigator data was used to perform constant phase correction in the 3D k-space. The final reconstruction-step was performed with a non-uniform FFT and iterative parallel-imaging reconstruction[4] with *l2*-regularisation, using the BART-toolbox[5]. For comparison, 2D-DWI data with matching scan time were acquired. Three diffusion directions and b = 0 and 1000 s/mm^2 were employed in all scans.

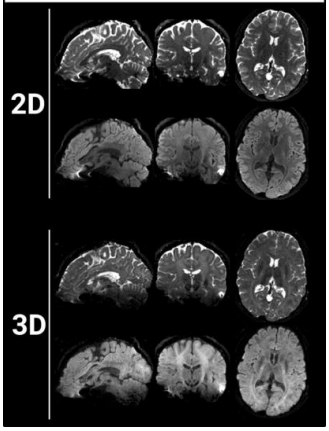
Results and Discussion We demonstrated that 1D navigators may suffice to monitor and correct for residual phase variations in thick-slab brain 3D-DWI. This is appreciated by the absence of motion-induced artifacts in the 3D-DWI images. The superior SNR for 3D-DWI, compared to 2D-DWI, can be visually appreciated for the b = 0 s/mm^2 images. The b=1000 s/mm^2 images would require a more elaborate SNR analysis to decide the SNR advantages. Unlike multi-slab 3D-DWI, the present work collected one slab which eliminates the problem with slab-boundary artifacts. Single thick-slab 3D-DWI with high isotropic resolution and high SNR reduces partial volume effects and could aid in the investigation of small lesions.



Imaging parameters for the 3D-DWI and 2D-DWI scans.

Sequence	TE [ms]	TR [ms]	Matrix 3D: [x,y,z] 2D: [x,y,slice]	FOV [mm] [x,y,z]	Scan Time [mm:ss]
3D-DWI	119	520	144×144×92	220×220×140	03:12
2D-DWI	82	11451	144×144×92	220×220	03:15

TE = Echo Time; TR = Repetition Time; FOV = Field of View.



References(contact author)

M44 - Magnetoencephalography (MEG) and on-scalp MEG in Western Sweden

10. Medicinsk bild & bildbehandling / Medical imaging & image processing

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[2] Innovationsplattformen, Sahlgrenska University Hospital, Västra Götalandsregionen
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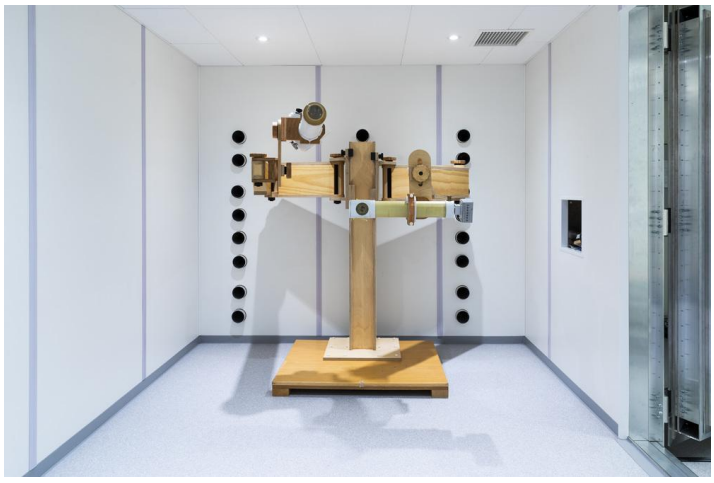
[5] Chalmers Industriteknik

Abstract text*: On-scalp magnetoencephalography (on-scalp MEG) enables an unsurpassed combination of spatiotemporal resolution in functional neuroimaging. Western Sweden is arguably the birthplace of on-scalp MEG, where pioneering 2-channel on-scalp MEG recordings with high critical temperature superconducting quantum interference devices (high-Tc SQUIDs) were first published in early 2012. A strong collaboration between Chalmers University of Technology, the Sahlgrenska Academy at the University of Gothenburg, and the Sahlgrenska University Hospital (SUH) has led to the development of a 7-channel on-scalp MEG system; a 21-channel system is presently being constructed. Together with the Swedish National Facility for Magnetoencephalography (NatMEG) at the Karolinska Institute, we benchmarked our hardware vs. the state-of-the-art and showed improved sensitivity to neural activations that are of importance to both neuroscience researchers as well as clinical neurophysiologists. In parallel, we have conducted a number of conventional MEG studies at NatMEG, including on autism spectrum disorders and stress-related cardiovascular disease risk, with an eye towards translation to our on-scalp MEG hardware. In the future, the intergration of the Sahlgrenska Biomedical Engineering Collaborative Laboratory (SahlBEC Lab) into the Department of Radiology at SUH will provide a new home for our on-scalp MEG research and development, where we aim to continue to generate new insights into brain function in health and disease.

Photo: Our on-scalp MEG hardware in the magnetically shielded room at Sahlgenska Biomedical Engineering Collaboration Laboratory, Sahlgrenska University Hospital Department of Radiology, (photo by Ines Sebalj, Sahlgrenska University Hospital).



M45 - Assessment of MR-system specific geometric distortion with a large field-of-view phantom (FOV) for determination of acceptable radiotherapy planning.

10. Medicinsk bild & bildbehandling / Medical imaging & image processing

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Maja Sohlin[2], Maria Ljungberg[2]
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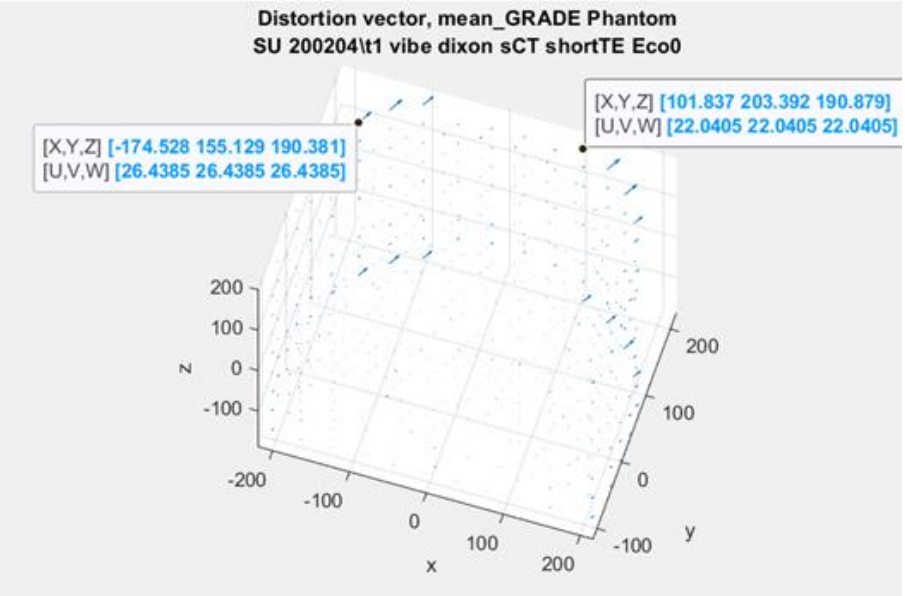
Abstract text*: a) Correspondence: lars.filipsson@gu.se

ABSTRACT
Introduction: MR system-specific distortions consist of main magnetic field inhomogeneities and gradient system nonlinearities. The geometrical accuracy in MR images is especially important for radiation therapy planning purposes.
Purpose: To quantify the MR system geometric distortions.
Methods: Measurements were performed on a Siemens MAGNETOM Aera 1.5 T using a GRADE phantom (Spectronic Medical), and a T1 weighted Dixon Vibe sequence with echo times; TE1 2.39ms and TE2 4.77ms. The effect of distortion correction techniques in the system was evaluated using in-house developed MATLAB code and software from the phantom vendor. The FOV where structures have a geometrical distortion < 1mm was determined, as this has clinical relevance.
Results: For objects within a radius 200mm from the magnet isocenter (FOV of 400mm) the mean observed distortion was 0.63 mm and 0.77 mm, for TE1 and TE2. Without the use of the MR scanners built in distortion correction, the mean observed distortion was 6.88 mm and 6.92mm, for the two TE: s respectively. If the maximal observed distortion is evaluated instead of the mean, the FOV was limited to 200mm for distortion < 1mm. At the periphery of the FOV (for instance at z=+/-186mm) the main magnetic field inhomogeneity component was 12% of the total distortion.
Conclusion: The work shows methods to quantify, separate and visualize the MR system-specific geometric distortions for use in radiation therapy planning, to estimate the accuracy.
Fig. 1 Distortion vectors (U, V, W [mm]) for magnet coordinates (X, Y, Z [mm]).



M46 - Ellipsoidal magnetic nanoparticles increase displacement in magnetomotive ultrasound?

9. Optik-, ultraljuds- & mikrovågslösningar / Optics, ultrasound & microwave solutions

Jules Reniaud[1]
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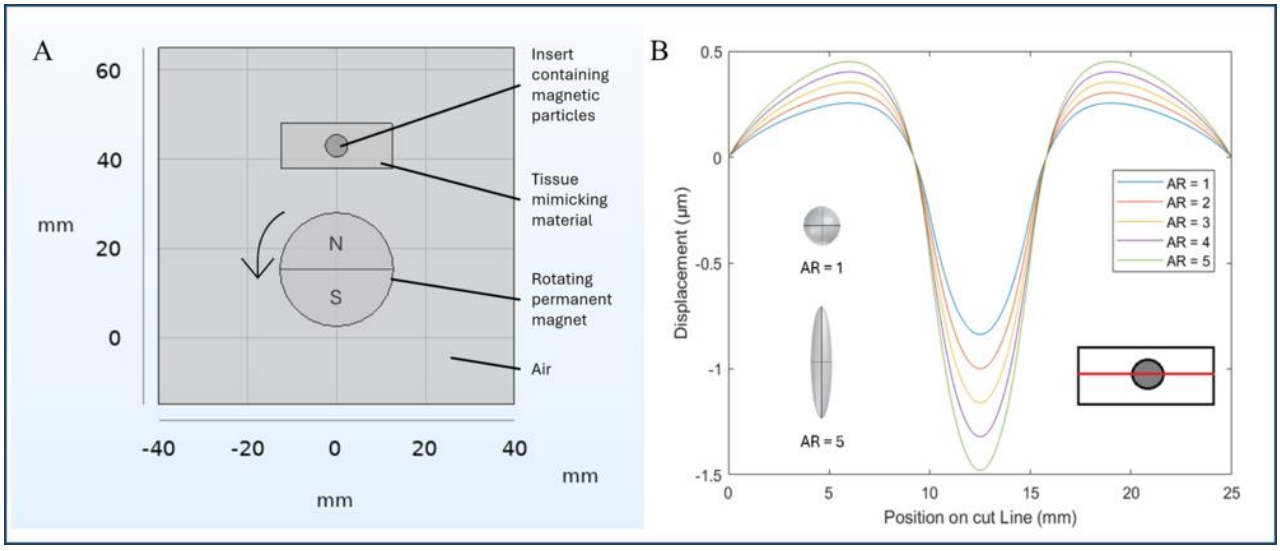
Abstract text*: Magnetomotive Ultrasound (MMUS) is an imaging technique used to detect the presence of a magnetic contrast agent. An external time-varying magnetic field creates an oscillation of the agent, in turn producing tissue motion, detectable with ultrasound. MMUS has applications in cancer detection, but low particle concentration and distance limit the sensitivity. We propose to modify particle shape to increase sensitivity, suggesting ellipsoids. Indeed, altering particle geometry affects the magnetic field inside the particle and by extension the force pulling the particles and the induced motion. This also affects the particle's magnetic moment and therefore the torque applied on the surrounding tissues. We here report on a finite element analysis to investigate the effect of particle shape on magnetomotion.

A magnetic object in the proximity of a magnet sees a total magnetic field that varies with the object's shape. The total magnetic field within a particle was expressed as the sum of the external magnetic field and a geometry dependent perturbation. This was computed with a finite element analysis software (COMSOL, Version 6.1, COMSOL AB, Stockholm, Sweden) for a single ellipsoidal particle in a magnetic field to obtain a so-called demagnetizing function. A geometry dependent expression of the force was obtained from the demagnetizing function and used as input in a second model (panel A). Displacement induced by particles with different aspect ratio (AR) was compared. The single particle model was also used to compute the magnetic torque for different AR.

For the same iron content, particles with a higher AR showed a larger displacement in a gel-based tissue-mimicking phantom material (panel B). The force originating from the magnetic moment of a single microparticle and pressing on its surroundings was estimated to be in the range of a few thousands piconewtons.



M47 - Ultra-High frequency ultrasound – a novel way to delineate aganglionosis and ganglionosis in in Hirschsprung's disease

10. Medicinsk bild & bildbehandling / Medical imaging & image processing

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Tebin Hawez[2, 3], Tobias Erlöv[4], Kristine Hagelsteen[2, 3], Louise Tofft[2, 3], Tomas Jansson[1, 5], Magnus Cinthio[4], Christina Graneli[2, 3], Pernilla Stenström[2, 3]
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[2] Department of Clinical Sciences/Pediatrics, Lund university, Sweden
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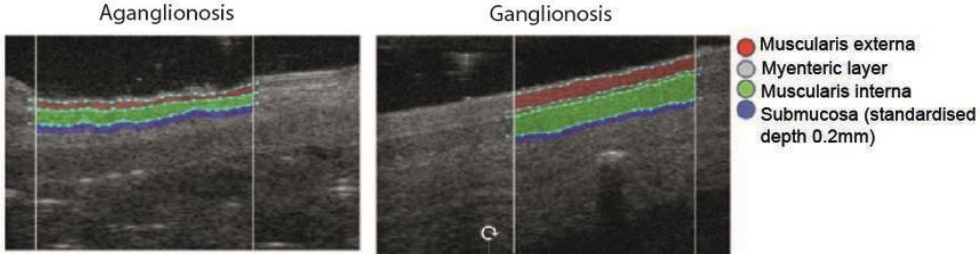
Abstract text*: Introduction: Hirschsprung's disease (HD) is a congenital disease characterized by the lack of nerve cells in the bowel wall (aganglionosis), commonly in the rectum and adjacent colon. It is a life-threatening condition that is treated only surgically. It is a rare disease with an incidence of 1:5000 newborns, but ten times more children need to be investigated to exclude the disease. Biopsies are mandatory to confirm/reject aganglionosis i.e; both in first diagnostics and then during surgery. Biopsy analyzing implies several days of waiting for a potential HD diagnosis, as well as prolonged anaesthesia times and in-exact diagnostics during surgery. An instant and safer method is desirable. Ultra-high frequency ultrasound (UHFUS) has recently been proven to accurately map bowel wall histoanatomy. The aim with this study was to investigate the possibility to distinguish between aganglionic and healthy ganglionic bowel segments using UHFUS.

Method: Resected bowel specimens of 23 children operated for rectosigmoid HD, were examined ex-vivo using the Visualsonics Vevo MD ultrasound scanner and the UHF70 transducer (50 MHz center frequency), providing a 30 μm resolution.

Results: In ganglionic compared to aganglionic bowel wall the thickness of the muscularis interna bowel wall layer was significantly greater (0.512 vs 0.317 mm; $p<0.001$; CI 0.148 to 0.289), the ratio of thickness muscularis interna/externa was higher (1.196 vs 0.762; $p=0.011$; CI 0.085 to 0.596), the submucosa's echogenicity (brightness) was lower (B-mode amplitude: 100.5 vs 114; $p<0.001$; CI -21.8 to -8.7), and the ratio of B-mode amplitudes externa/submucosa was higher (1.143 vs 1.034, $p=0.015$; CI 0.0 to 0.2).

Discussion: Delineation between aganglionosis and ganglionosis seems feasible using UHFUS imaging. The results indicate a potential of UHFUS to be used as an instant diagnosis method for HD and supports further in-vivo research.

Figure: UHFUS ultrasound images of aganglionic and ganglionic bowel wall in the same patient.



MT-sektorn - Utbildning

2024-10-10
13:15 - 14:45
MT-sektorn - Utbildning

M48 - Nationell forskarskola i Hälsoinnovation för att stärka kompetensförsörjning i medicintekniska företag och offentlig sektor

14. Medicinteknisk utbildning / Biomedical engineering education

Lina Lundgren[1]
Agneta Welin[2], Bodil Landstad[3], Jens Nygren[1], Ingela Bäckström[3], Maria Lindén[4], Peter Anderberg[5, 6], Petra Svedberg[1], Sofi Fristedt[7]
[1] Högskolan i Halmstad
[2] Högskolan Väst
[3] Mittuniversitetet
[4] Mälardalens Universitet
[5] Blekinge Tekniska Högskola
[6] Högskolan i Skövde
[7] Jönköping University

Abstract text*: Den nationella forskarskolan i Hälsoinnovation startade 2022, där sju lärosäten tillsammans med företag, regioner och kommuner har gått samman för att skapa en forskarskola med målet att stärka konkurrenskraft och kompetensförsörjning inom området. Fjorton doktorander som är anställda vid företag, region eller kommun har blivit antagna till en forskarutbildning vid något av lärosätena, och forskarskolan utgör sammanhanget och nätverket för dessa doktorander.

De projekt som ingår i forskarskolan spänner över flera discipliner, och studerar exempelvis utveckling, användning och implementering av medicintekniska lösningar i hälso- och sjukvården. Nätverket har genomfört workshops om vilka värden forskarskolan tillför de olika intressenter som medverkar, och detta vill vi presentera.

När organisationer gör satsningar för att medarbetare ska få forskningskompetens, skapas individuella värden som handlar om kunskapsutveckling och kompetenshöjning. Medarbetaren får möjlighet att ligga i framkant och får tillgång till nya perspektiv. Även de akademiska handledarna och organisationens mentorer tillförs värde i form av ökad kunskap och förståelse för andra samhällsaktörer. Doktorandens roll blir en brobyggare mellan akademi och organisationerna, och i detta sammanhang lyfts vikten av att organisationen får möjlighet att utveckla sin forskningskompetens och beredskap att emot nya perspektiv.

På organisationsnivå skapas viktiga värden i form av ny kunskap genererat genom olika doktorandprojektet, som ofta har fokus mot att utveckla nya arbetssätt, tjänster och produkter. Även om resultatens impact ligger långt i framtiden, identifieras ändå viktig samhällsnytta genom innovation och potential till förbättring av människors hälsa. Genom forskarskolans multidisciplinära ansats, lyfts också vikten av att förstå hur andra vetenskapliga områden relaterar till det egna, och vikten av att bygga nätverk och relationer som kan komma att bli viktiga i framtiden.

Forskarskolan i Hälsoinnovation pågår till 2027, och ett nytt intag med doktorander planeras under 2025. Genom att analysera nyckelfaktorer för värdeskapande kan forskarskolor utforma sina aktiviteter för att maximera effekten av deltagande.

M49 - Certifiering av ingenjörer/civilingenjörer/tekniker inom medicinteknik

21. Övrigt / Other (specified further down in the form)

Bjorn-Erik Erlandsson[1]
Caroline Hagström[2], Git Eliasson[3], Siw Frediksson[4], Hans Johansson[5]
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[3] Medicinsk teknik, Södersjukhuset, Region Stockholm
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Abstract text*: Bakgrund
En utredning gjordes 1996, SOU[i], av behörigheter inom hälso- och sjukvården. MTF drev frågan om att yrkesgruppen medicintekniska ingenjörer borde ha legitimation. Sjukhusfysiker blev ett legitimerat yrke. Medicintekniska ingenjörer blev inte legitimerade då man ansåg att de arbetar längre från patienten samt att ingen harmoniserad gemensam utbildningsbakgrund fanns. En ledamot av utredningen gav ett särskilt yttrande; *”Jag anser att de bedömningskriterier som ligger till grund för sjukhusfysikers legitimation även kan vara relevanta för sjukhusingenjörer”*.

Varför certifiering

Patientsäkerhet
Patientsäkerhetsfrågorna inom hälso- och sjukvården är prioriterade. I de industrialiserade länderna är det ca 10 % av patienterna som inte får korrekt behandling med anledning av brister i patientsäkerheten.

Ny teknik – möjligheter och risker
Medicintekniska ingenjörer är delaktiga i säkerhetsarbetet. Under de senaste årtiondena har introduktion av ny informationsteknik medfört nya utmaningar för den tekniska säkerheten i hälso- och sjukvården. Ett av skälen är att informationstekniken integreras i medicintekniska produkterna och i komplexa sammankopplade system. Introduktion av AI som integrerad del i tekniska system eller självständig mjukvara ökar kraven på teknisk kompetens.

Certifiering – kompetensutveckling
För att förbättra säkerheten vid användning och hantering av medicintekniska produkter är det viktigt att medicintekniska ingenjörer har nödvändig kompetens. Ett sätt att uppnå hög kompetens inom medicinteknik är kontinuerlig kompetensutveckling med möjligheten till att kunna certifiera sig men då krävs tillgång till kvalificerad utbildning och träning. I Sverige genomförs certifiering till medicinska ingenjörer/civilingenjörer/basnivå av MTF. IFMBE/CED[ii] redovisar program for certifiering för kliniska ingenjörer och WHO[iii] pekar på att det finns i certifierings- och ackrediteringsprogram för BME.

[i] SOU 1996: 138 Ny behörighetsreglering på hälso- och sjukvårdens område m.m.
[ii] J. Wear; IFMBE/CED recognition of certification/registration programs for clinical engineering practitioners, J Global Clinical Engineering Vol.2 Issue 2: 22-25; 2020.
[iii] Human resources for medical devices, the role of biomedical engineers. WHO Medical device technical series, 31 August 2022.

Postrar

P1 - Towards generalizable image classification models for detecting middle ear diseases

2. AI, maskininlärning & Big Data / AI, machine learning & Big Data
Manfred Lindmark
Thorbjörn Lundberg, Mimmi Werner, Paolo Soda, Christer Grönlund, **Fredrik Öhberg**

Abstract text*: Diagnosing ear diseases from images of the tympanic membrane (TM) has emerged as a promising application for deep learning-based classification models. While several studies report high diagnostic accuracy, these models often struggle to generalize to external data that does not match the image characteristics of the training data. This study aims to evaluate methods for enhancing model generalizability. We achieve this by training artificial neural networks on images from three distinct cohorts and validating them on two external test sets.

We used five cohorts of TM images from different countries, captured with different instruments at different times and with different image processing, resulting in a large heterogeneity between them. Artificial neural networks for binary (normal/abnormal) classification were then trained on the first three cohorts. The last two data sets were used for evaluating the models. We explored several strategies to improve generalizability, including image pre-processing, data augmentation, and different network architectures (convolutional neural networks and Vision Transformer). Additionally, we manually re-evaluated the open datasets by correcting misclassifications and removing low-quality samples.

The effects of each investigated factor and their interactions were determined through a full factorial experimental design and analysis of variance (ANOVA). Our best model achieved an accuracy of 82% (with sensitivity at 74% and specificity at 87%) on external cohorts. In contrast, the same network trained without augmentation and using non-processed datasets yielded an accuracy of 72% (with sensitivity at 77% and specificity at 69%). Both of these results were from the best network architecture using optimized training hyperparameters.

Our findings highlight the significant impact of network choice, augmentation strategy, as well as data correction and verification on model generalizability.

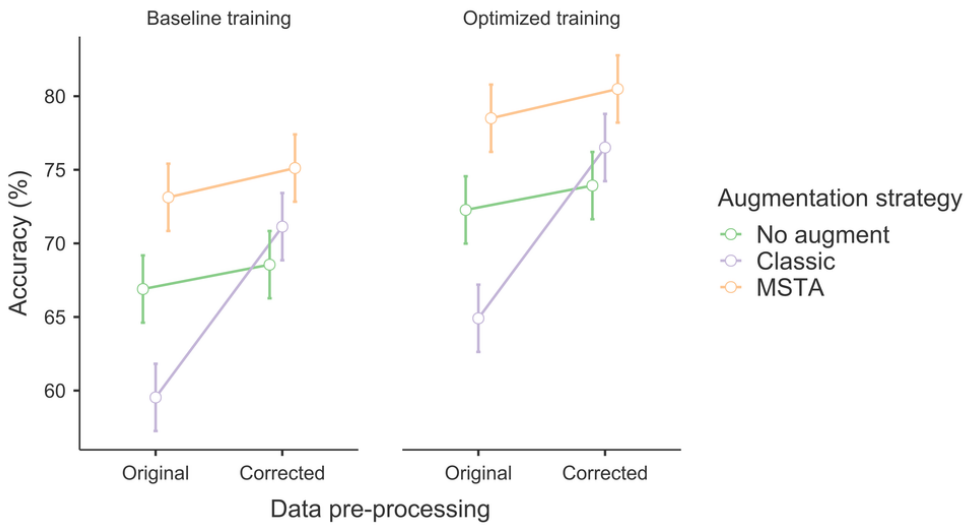


Figure 1: Estimated marginal means plot of model accuracy on external test set with 95% confidence intervals. The model is “EfficentNet v2 s” and the variables are data pre-processing method, augmentation strategy and training hyperparameters.

P2 - Fabrication process and conducting material evaluation for miniaturization of TIME implants

3. Bioelektronik & sensorer / Bioelectronics & sensors

Hanna KARLSSON-FERNBERG

Abstract text*: The last 20 years have provided significant advances in the development of bionic limbs to restore lost body parts. To date, there have been several examples of integrating the bionic limb into the patient's nervous system for controlling the prosthetic, giving the functionality and sensation of a natural limb [1][2][3]. The TIME (transversal intrafascicular multichannel electrodes) has demonstrated a high potential for use in applications such as bionic limbs, as it is implanted straight through the nerve to create direct contact with the nerve fibers, which has been shown to increase the signal-to-noise ratio of recordings as well as the stimulation and recording selectivity [4]. However, as with all implanted neuroelectronic devices, there are challenges associated with the foreign body reaction (FBR), resulting in a fibrous capsule enclosing the implant, significantly reducing its effectiveness [5]. To overcome these challenges, this study explores microfabrication processes to realize smaller, high-channel-count implants. This also includes evaluating suitable conducting materials to mitigate challenges associated with smaller features, such as increased resistance, which can result in increased crosstalk. To achieve finer features, lithographic patterning methods such as photo-, laser- and e-beam lithography were implemented and optimized for flexible polyimide probes. With electrical test structures for four-point probe measurements, the lithographic methods could be compared, and the material aspects related to miniaturization were evaluated. Moreover, with the test structures, Au was compared with Pt of varying thicknesses in terms of conductance metal lines, which showed that Au could be an appropriate replacement for Pt to mitigate the effect of increased resistance. Future work includes the evaluation of the long-term electrical stability of the metallization by testing crosstalk in tightly spaced conducting lines stored in a PBS buffer. Crosstalk will be assessed as a function of conducting line width as insulating polyimide layer width.

P3 - Subdural Implant for Direct Current Stimulat of the Spinal Cord

3. Bioelektronik & sensorer / Bioelectronics & sensors

Lukas Matter
Bruce Harland, Brad Raos, Brittany Hazelgrove, Darren Svirskis, Maria Asplund

Abstract text*: Spinal cord injuries (SCI) hinder the communication between brain and peripheral nerves, often leading to a permanent loss of motor and sensory functions. Direct current electric fields (dcEFs) were shown to guide axons to grow across the SCI. Hence, dcEFs can be applied to the injured spinal cord to regenerate axons towards their preinjury target location. At their natural target, axons can build functional connections which have the potential to regenerate body functions. However, the application of dcEFs is challenging because the applied current can induce toxic concentrations of stimulation byproducts (e.g., pH changes, reactive oxygen species, metaloxides) via redox reactions. To circumvent this challenge, we leveraged the superior DC capabilities of sputtered iridium oxide films (SIROF), in an ultrathin flexible implant. We positioned the implant in the subdural space of a rat because simulations of the electric field distribution during direct current stimulation show that the cerebrospinal fluid shunts the applied current and thus reduces the field strength within the cord and its precision. We use the thin-film subdural implant and supercapacitive electrode materials to administer a stronger, more penetrative, and safer daily electric field treatment for 12-weeks in rats with thoracic SCI comapred to previous studies. Treated rats had improved hind limb function in an open field from week 5 onwards.

P4 - Integrating Raman Spectroscopy and Self-Organizing Maps for the Identification of Malaria Biomarkers in Infected Mouse Models

6. Diagnostik- & beslutsstödsystem / Diagnostic & decision support systems

Joel Wahl
Henrik Barestrand, Rashmi Mishra, Dirce Pineda Vazquez, Oliver Billker, Kerstin Ramser

Abstract text*: Malaria is a mosquito-borne infectious disease that results in half a million fatalities annually, with a significant proportion of these deaths being young children. Analyzing blood samples for malaria requires a well-equipped laboratory and skilled personnel due to the need for sample preparation, where infected cells are sparse, with the majority of cells being unaffected. Our goal is to integrate Raman spectroscopy—a label-free optical technique that measures the molecular composition of a sample—with self-organizing maps (SOM) to evaluate features and identify naturally occurring biomarkers for malaria. SOM is an unsupervised machine learning technique that produces a low-dimensional representation of a higher-dimensional dataset while preserving the data's topological structure. In this study, we applied SOM to Raman spectroscopic data from mice infected with malaria. The mice were infected, and their red blood cells (RBCs) were harvested at various times after the parasite's development in the host. We measured 238 independent resonance Raman spectra of the RBCs using a 532 nm laser. Following the Raman measurements, the infection rate, or parasitemia, was estimated using fluorescence microscopy. This data, along with control measurements and spectra from the midguts of malaria-carrying mosquitoes, were used to train a SOM for feature evaluation. The SOM successfully identified spectral features, enabling the discovery and characterization of potential biomarkers associated with the disease. Our study showcases the efficacy of integrating self-organizing maps (SOM) with Raman spectroscopy to explore spectral features, providing a promising avenue for identifying and characterizing potential biomarkers.

P5 - Sandlådor för forskare och beslutsfattare - testmiljöer för ökad interoperabilitet inom sjukvården

7. Digitalisering & informatik / Digitalization & informatics
Mattias Seth
Stefan Candefjord, Bengt Arne Sjöqvist

Abstract text*: Utvecklingen av artificiell intelligens (AI) och Informations- och kommunikationsteknologier (IKT) har revolutionerat vårt sätt att interagera med vår omvärld. Idag kan du med enkla svep och tryck få tillgång till ett stort utbud personanpassat innehåll av filmer, musik och nyheter. Denna utveckling har fört med sig en explosion av digitala applikationer och tjänster som används av miljontals användare världen över, varje dag.

Även om hälsovårdssektorn har sett en ökning i nya hälsoapplikationer, med över 250 nya mobila hälsoapplikationer varje dag, ligger sjukvården fortfarande efter i digital anpassning jämfört med andra sektorer. Bland orsakerna till detta är komplexiteten i vårdrelaterade data och höga krav på säkerhet och sekretess.

För att öka interoperabiliteten inom den offentliga sektorn mellan EU's medlemsländer har Europeiska kommissionen introducerat "The Interoperable Europe Act". Samtidigt satsar den svenska regeringen på att utveckla en nationell digital infrastruktur för sjukvården, med syfte att göra hälsoinformation mer tillgänglig inom vårdkedjan. Trots dessa initiativ saknas det tydliga konkreta åtgärder för att realisera dessa mål.

Vid Chalmers tekniska högskola driver forskargruppen Care@Distance olika projekt byggda på det s.k. ASAP konceptet (Acute Support Assessment and Prioritizing) som stöder FoU där data fusion, AI/ML och beslutsstöd är viktiga komponenter. Ett av dessa projekt är utvecklandet av en sandlåde-miljö, kallat ASAP Digital Health Sandbox (DHS). DHS bygger på moderna teknologier och öppna standarder, så som FHIR, CDS Hooks och Docker, där DHS kan användas för att utvärdera AI lösningar i realistiska användarscenarios.

Genom ett "drap-and-drop" användargränssnitt kan användare skapa olika simuleringsscenarios genom att kombinera algoritmer, applikationer och tjänster. DHS kommer att utvärderas inom ASAP Point of Care (PoC) projektet, ett trippelhelixsamarbete mellan akademin, offentlig sektor och industri.

I presentationen kommer vi beskriva arbetet med DHS, vilka val vi har gjort och varför, samt hur en On Scene Injury Severity Prediction (OSISP) algoritm kan utvärderas i DHS.

P6 - Pioneering Instrument for Intraoperative Cancer Detection in Resected Prostate

8. Medicintekniska produkter för in vitro-diagnostik / In-vitro diagnostic medical devices

Olof Lindahl
Anders Bergh, Börje Ljungberg, Britt M Andersson, András Gorzsás, Tomas Bäcklund, Urban Edström, Göran Mannberg

Abstract text*: Purpose

Prostate cancer (PCa) remains a significant health challenge, affecting both men and their families. Surgical removal of the prostate, radical prostatectomy (RP), is a common curative treatment. However, incomplete removal of cancer tissue during RP can lead to subsequent therapies and negatively impact patient outcomes. Our project aims to address this challenge by developing an innovative instrument and method for detecting cancer cells on the surface of the resected prostate during surgery.

Method

Our approach involves creating a real-time decision support system for surgeons. By analyzing the resected prostate tissue during surgery, our instrument provides critical information about the presence and distribution of cancer cells. This data guides surgical decisions, such as nerve- and vessel-sparing techniques, to minimize complications and improve patient outcomes. Our approach combines two cutting-edge technologies: fiber-optic Raman spectroscopy (tissue molecular content) and a tactile resonance sensor (tissue stiffness). The instrument assesses human prostate tissue ex vivo, providing real-time feedback to surgeons.

Results and Discussion

The proposed instrument has the potential to revolutionize RP procedures. By reducing the time delay associated with post-surgery histopathology, we enhance treatment efficiency. Surgeons can make informed decisions during surgery, ensuring complete cancer removal while minimizing risks to sexual function and urinary health. Stiffness data are predicting prostate cancer with an area under the curve of 0.74 and in a current study the preliminary data indicate that Raman spectra predicts extra prostatic growth of cancer.

Conclusion

Our pioneering instrument (patent pending) represents a significant advancement in cancer surgery. By combining precision, real-time feedback, and patient-centric outcomes, we aim to improve the quality of life for PCa patients and contribute to global healthcare sustainability. Additionally, our method is adaptable to other cancer types, making it a versatile solution for addressing major cancer forms.

P7 - Determination of skin metabolic rate of oxygen consumption from measurements of microcirculation parameters

9. Optik-, ultraljuds- & mikrovågslösningar / Optics, ultrasound & microwave solutions
Andisheh Etminan
Marcus Larsson, Ingemar Fredriksson, Sara Bergstrand, Carl Johan Östgren, Tomas Strömberg, Hanna Jonasson

Abstract text*: Cardiovascular Diseases (CVDs) can lead to changes in the microcirculation, but there is increasing interest in the role of microcirculation in the development of CVD. Skin microcirculation has been measured within SCAPIS (the Swedish CArdioPulmonary bioImage Study) in 3809 participants aged 50-65 years. The microcirculatory parameters, speed-resolved perfusion, oxygen saturation, and red blood cells (RBCs) tissue fraction were quantified using a non-invasive, optical system (PeriFlux 6000 EPOS, Perimed AB). Oxygen transport in the microcirculation during baseline (5 min), occlusion (5 min), and post occlusion (10 min) was modelled using the measured microcirculatory parameters. Tissue metabolic rate of oxygen consumption (tMRO2) was estimated as a function of concentration of deoxyhemoglobin and blood flow (for the steady state situation, baseline) and rate of changes of deoxyhemoglobin (for the start of the occlusion period). Results showed that maximum deviation of tMRO2 from baseline during the whole process was on average 4.5×10^{-4} mM/s, which is in the same range as that of other studies. In conclusion, tissue metabolic rate of oxygen consumption can be estimated using microcirculation parameters. tMRO2 can further reveal information regarding microcirculatory function as a factor in CVD development.

P8 - Mikrovågsdetektion av inre blödningar i skalle, bröst och buk

9. Optik-, ultraljuds- & mikrovågslösningar / Optics, ultrasound & microwave solutions
August Ekman
Andreas Fhager, Mikael Persson

Abstract text*: Ett vanligt resultat av fysiskt trauma är inre blödningar, vilket kan ge permanenta skador eller vara livshotande. Behandling måste ofta ges snabbt men det är inte alltid tydliga symptom visar sig. Det blir därför mycket viktigt med teknik som kan detektera denna typ av skador. Sådan teknik är inte minst intressant inom försvaret, men då ställs ytterligare krav på att systemet är portabelt, snabbt, enkelt att använda, och inte minst robust. Detta är krav som mikrovågsbaserade system är mycket väl lämpade att uppfylla.

Tidigare projekt har redan använt mikrovågsteknik för detektion av inre blödningar. I detta projekt vidareutvecklar vi denna teknik och anpassar den till de krav som ställs av tillämpning inom försvaret. Vi presenterar här vårt arbete med detta och i synnerhet hur vi med simuleringar och mätningar på fantom utvärderar olika antenner för att hitta en kandidat som är lämplig för detta tillämpningsområde.

P9 - Assessing Image Quality Metrics for Global Sound-Speed Estimation in Ultrasound

10. Medicinsk bild & bildbehandling / Medical imaging & image processing

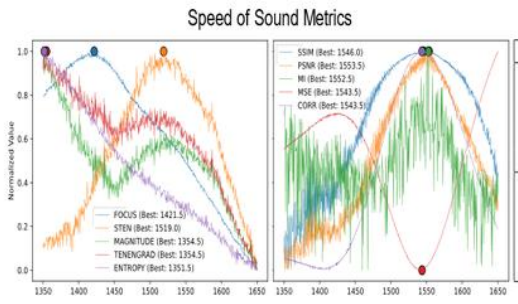
Roman Denkin
Orcun Goksel

Abstract text*: Background and Motivation
Ultrasound imaging accuracy is challenged by assumptions about the speed of sound (SoS) in imaged media. Several methods have proposed global SoS estimation through optimization of quality metrics. This study compares various single-frame and multi-frame metrics for SoS estimation in simulations and phantom data.

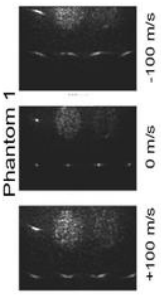
Methods
We analyzed data from k-Wave simulations, the CIRS 040GSE phantom and a custom CIRS SoS phantom. Virtual-source acquisitions were used to evaluate single-frame image quality and dual-frame comparison metrics. Single-frame metrics included Focus (FFT-based)[1], Entropy, Tenengrad, Magnitude (an isotropic gradient variation), and our proposed ST-Ten (a smoothed, thresholded Tenengrad metric designed to reduce speckle noise effects). Dual-frame metrics comprised Structure Similarity Image Metric (SSIM)[2], Mean Squared Error (MSE), Peak Signal-to-Noise (PSNR), Mutual Information (MI), and Correlation. To assess robustness to region-of-interest, metrics were evaluated for 16 equi-depth layers.

Results/Discussion
Metrics were evaluated in 0.5 m/s increments within [1350,1650] m/s. For image-quality metrics, our proposed ST-Ten showed the best performance, with phantom errors up to 21 m/s. Among dual-frame comparison metrics, MI and Correlation demonstrated notable accuracy. Dual-frame metrics were superior in layered estimation and substantially outperformed single-frame metrics in SoS estimation.
Our study reveals that dual-frame comparison metrics, particularly MI and Correlation, offer superior performance in metric optimization-based SoS estimation compared to single-frame image quality metrics. While our proposed ST-Ten showed promise among single-frame metrics, the overall results suggest that dual-frame methods are more robust for this application. These findings were consistent across global and layered estimations, with additional tests using multiple compounded frames corroborating these results.

[1] "Image Sharpness Measure for Blurred Images in Frequency Domain" Procedia Engineering, 2013.
[2] "Image Quality Assessment: From Error Visibility to Structural Similarity," IEEE Transactions on Image Processing, 2004.



	Global Sound Speed Estimation			Sound Speed Estimation (Layered)		
Method	Simulation	Phantom 1	Phantom 2	Simulation	Phantom 1	Phantom 2
Focus	-144.0 ±108.6	-118.5	-158.5	-20.4 ±52.4	-116.7 ±38.2	-138.1 ±44.5
Entropy	-132.0 ±113.1	-187.5	42.5	-31.1 ±111.4	-51.0 ±102.8	4.4 ±69.8
Tenengrad	-91.5 ±136.9	-185.5	-158.5	-31.5 ±56.0	-131.9 ±72.9	-124.3 ±50.7
Magnitude	-84.8 ±140.9	-185.5	-158.5	-41.7 ±59.9	-107.6 ±82.0	-138.5 ±35.9
ST-Ten	**-9.3** ±3.5	**-21.0**	**10.5**	**-9.7** ±41.9	**-27.6** ±40.2	**-3.6** ±28.9
SSIM	-6.3 ±12.0	6.0	**-0.5**	-1.6 ±5.7	**-3.4** ±38.4	-3.2 ±14.2
MSE	-13.2 ±1.9	**3.5**	-4.5	-3.8 ±3.2	-73.6 ±102.9	23.0 ±56.7
PSNR	9.2 ±6.2	13.5	-5.5	0.8 ±7.0	-7.1 ±45.2	-3.4 ±19.9
MI	**-1.8** ±9.0	12.5	3.5	-0.9 ±4.1	-4.6 ±21.8	**-1.8** ±3.9
Correlation	**-1.8** ±1.4	**3.5**	**0.5**	**-0.6** ±4.6	8.4 ±24.0	-2.4 ±3.2



P10 - Neuromorphometric signatures of diseases affecting the brain

10. Medicinsk bild & bildbehandling / Medical imaging & image processing
Rolf A. Heckemann

Abstract text*: Various conditions, including brain-specific and systemic diseases, can alter the brain's structural configuration. Neurological diseases like Alzheimer's and Parkinson's, stroke, epilepsy, and brain tumors can cause both focal and disseminated changes. Systemic diseases, particularly autoimmune conditions, can also affect the brain. These changes impact overall brain function and contribute to cognitive and neurological signs and symptoms.

Magnetic resonance (MR) imaging is the modality of choice for detecting and monitoring structural brain changes. In practice, visual image interpretation by trained experts (radiologists) is most commonly used to extract diagnostic information from the images. While human experts perform well at detecting focal changes, assessing volume changes in anatomical structures is much harder. Automatic image analysis software can fill this gap by providing radiologists with accurate, quantitative morphometry information. How such measurements, or imaging biomarkers, can aid diagnostic decision-making is a topic of active research.

The author has developed machine-learning models for brain morphometry, specifically Pincram and MAPER. Pincram generates binary masks that distinguish between brain and non-brain portions in an MR image. MAPER further segments the brain portion into anatomical regions – the most common configuration delineates 120 regions covering the whole brain. Pincram and MAPER enable the extraction of numerous measurements with biomarker potential.

This presentation will feature images, segmentations, and visualizations illuminating the process of imaging biomarker discovery for selected conditions that are currently under investigation: Alzheimer's disease, epilepsy, Graves' disease, and rheumatoid arthritis.

Learners will be able to describe the impact of these conditions on the brain's structure, gain knowledge about automatic brain morphometry as a biomarker discovery tool, and familiarize themselves with advanced machine-learning models for analysing brain images.

P11 - Speed-of-Sound as a Novel Quantitative Imaging and Characterization Method

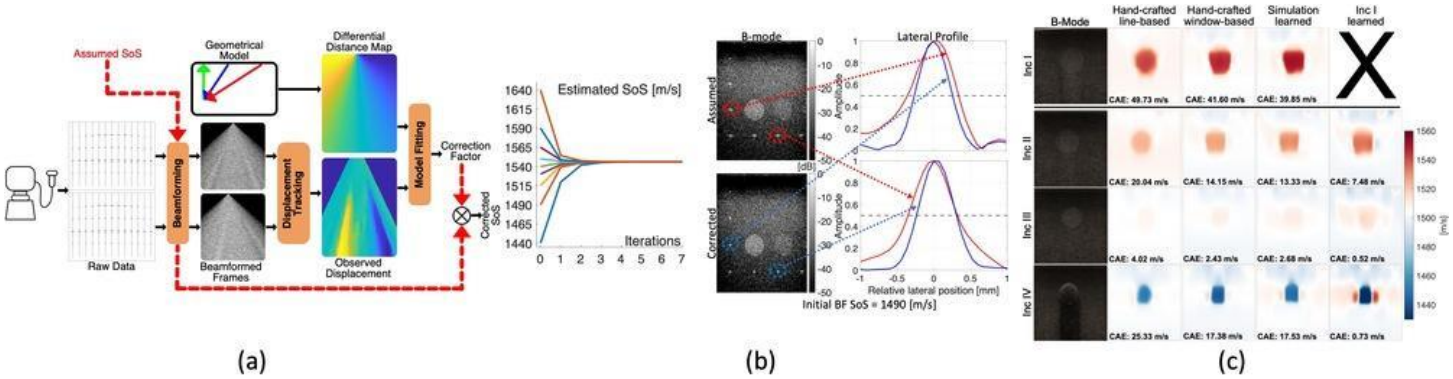
10. Medicinsk bild & bildbehandling / Medical imaging & image processing
Can Deniz Bezek
Orcun Goksel

Abstract text*: Ultrasound (US) is a widely used medical imaging modality due to its low cost, non-ionizing nature, and real-time capabilities. Typical B-mode US images depict the reflectivity of tissue structures, which provide only qualitative information. In contrast, biomechanical characteristics such as shear modulus, estimated via ultrasound elastography, offer quantitative tissue information. Speed-of-sound (SoS) is an alternative quantitative biomechanical marker related to bulk modulus and may therefore provide complementary or independent information about tissue composition and pathology.

Several methods have been proposed for estimating a single (global) SoS value and reconstructing local (spatial) SoS maps. Some of these methods rely on transmission-based US computed tomography, which, however, requires bulky and expensive setups, is complicated to operate, and necessitates suspending the anatomy in a water bath. Other methods rely on additional hardware, such as an acoustic reflector add-on. In contrast, we develop pulse-echo mode US methods for imaging tissue SoS that are applicable on conventional US machines and transducers.

In this abstract, we first introduce a novel technique for global SoS estimation (as illustrated in Fig. (a)), which is important for both the quality and accuracy of B-mode images as well as local SoS reconstructions. We then demonstrate the accuracy of our method in a tissue-mimicking phantom, show resolution improvements in B-mode images (Fig. (b)), and highlight the potential utility of our global SoS estimation technique for breast density classification.

Pulse-echo mode local SoS imaging relates speckle shifts (time delays) to SoS distributions through a forward model matrix L. The reconstruction quality depends on the accuracy of L. We propose a novel data-driven approach for learning this model. In a tissue-mimicking phantom, we demonstrate that the model can be learned from a single example, significantly improving reconstruction quality, as shown in Fig. (c), evaluated by Contrast Absolute Error (CAE).



P12 - Exploring the extracellular diffusion MR signal dependence on diffusion time and cell geometry using MC simulations

11. Modellering & simulering / Modelling & simulation

Lukas Lundholm
Mikael Montelius, Oscar Jalnefjord, Maria Ljungberg

Abstract text*: Purpose This study aimed to investigate how diffusion time and cell geometry affect the extracellular (EC) signal in diffusion MRI (dMRI) using Monte Carlo simulations. It tested the accuracy of the tortuosity limit assumption, which suggests no diffusion time dependence, in the EC space for commonly measured diffusion times[1] and evaluated its impact on modeling results.

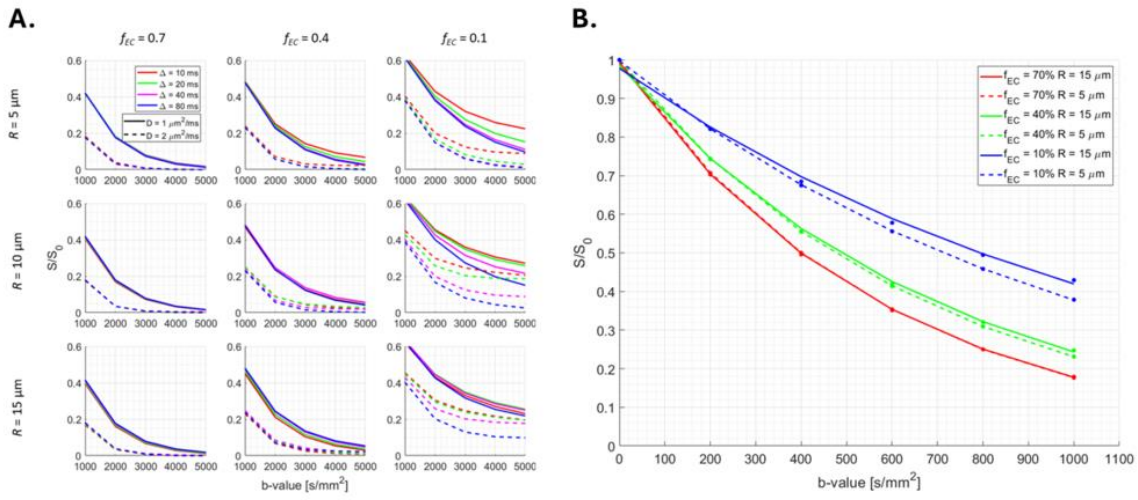
Methods 3D models of EC space, made with MATLAB, and Disimpy[2] simulations explored dMRI measurements across cell geometries. EC signals for PGSE acquisitions included different cell radii, EC volume fractions, and intrinsic diffusion coefficients, incorporating elastic cell membrane reflection and excluding intracellular entry and T2 effects, with varied gradient timings and b-values.

Results and Discussion Results showed that the EC signal in dMRI is time-dependent at high b-values and low EC volume fractions (Fig 1). Data indicated less time dependence with longer diffusion times and confirmed that cell geometry significantly impacts the effective EC diffusion coefficient.

Conclusion The findings indicate that the tortuosity limit assumption for the EC space might not be valid for closely packed cell geometries in dMRI. However, the intracellular signal likely dominates in such scenarios, reducing the practical effect on model fitting. The study also underscores the importance of careful consideration when setting the EC diffusion coefficient in dMRI modeling.

Figure 1. A) Shows EC signal simulations affected by extracellular volume fraction (f_{EC}) and cell size (R) under varying time settings. Higher b-values and lower f_{EC} increased diffusion time sensitivity. B) Shows EC signals across different f_{EC} and R with consistent gradient timings. It includes data markers and monoexponential fits, emphasizing the effective diffusion coefficient's dependency on cell geometry.

References 1. Reynaud, O. *Front Phys* 5, 58 (2017) **2.** Kerkelä, L. *et al. J Open Source Softw* 5, 2527 (2020)



P13 - A long-lasting hydrophilic coating for medical devices that prevents biofilm formation

13. Innovation & translationell medicinteknik / Innovation & translational biomedical engineering

Per Wirsén
Linda Bergström, Ana Romero, Serhiy Surkov, Jan Tejbrant, Åsa Wang, Narmin Asadli, Graeme Brookes

Abstract text*: Introduction
CytaCoat has invented a unique grafting process that provides a permanent, covalently bound hydrogel coating that can be applied to polymer based medical devices. The hydrophilic coating effectively prevents fouling and biofilm formation without releasing any substances.

Healthcare-associated infections (HCAIs) caused by bacterial biofilm on medical devices are a significant risk for patients and costs healthcare systems billions each year. Bacterial biofilm is linked to 80% of chronic infections and to 65% of all Healthcare associated infections, e.g., Catheter Associated Urinary Tract Infection (CAUTI). There is currently no effective coating of medical devices on the market that prevents biofilm.
The first devices being coated are urinary Foley catheters and wound care materials.

Innovation
CytaCoat's unique coating process is based on a simple and cost-effective UV activated polymerization process and bonding of a proprietary anti-fouling ligand.

With our Pilot Plant, we are able to develop, test and optimise coating processes, which enables us to develop different coatings that can be applied to a broad range of medical devices.

In-house and external laboratory experiments demonstrate decreased fouling and formation of biofilm - Extracellular Polymeric Substances (EPS), produced by bacteria.

Conclusions
The CytaCoat coating is anti-fouling and effectively prevents biofilm formation for up to 30 days of both Gram-negative, Gram-positive bacteria as well as fungi, such as Candida.

- The CytaCoat coating does not alter the device classification under MDR, in contrast to antimicrobial coatings.
- The CytaCoat Foley Catheter is continually lubricious, offering comfort during use with low risk of tissue trauma.
- The CytaCoat Foley Catheter is currently being evaluated in a first clinical trial (safety study), conducted at Sahlgrenska University Hospital and Capio Gastro Center Göteborg, and is in the process of being CE marked.
- Wound care products featuring the CytaCoat technology are in development.

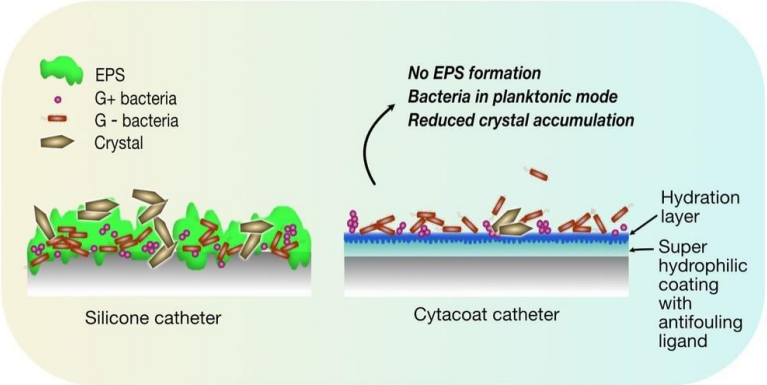


Figure: Mode of Action of the CytaCoat coating.

P14 - Real-time Biosignal Processing and Feature Extraction from Photoplethysmography Signals for Cardiovascular Disease Monitoring

14. Medicinteknisk utbildning / Biomedical engineering education

Saad Abdullah
Annica Kristoffersson, Maria Lindén

Abstract text*: Photoplethysmography (PPG) signals offer a non-invasive and cost-effective means for monitoring cardiovascular health. However, extracting clinically relevant information from these signals in real-time poses significant challenges. This paper presents a novel biosignal processing unit that utilizes the PPGFeat MATLAB toolbox to perform real-time signal processing and feature extraction from PPG signals, enabling continuous cardiovascular disease (CVD) monitoring and analysis. We propose a system that interfaces with PPG sensors to acquire raw signals in real-time. The PPGFeat toolbox provides an interactive user interface, it identifies high-quality signals based on their signal quality indices (SQIs) and performs segmentationThe segmented PPG signals are then preprocessed by PPGFeat to remove noise and artifacts, smooth the waveforms, and correct baseline drift using a Chebyshev type II 4th order, 20 dB filter with a frequency range of 0.4–8 Hz. After preprocessing, a novel algorithm within PPGFeat is employed to accurately extract key fiducial points from the filtered PPG signals and their first and second derivatives. These include systolic peaks, diastolic peaks, onsets, and dicrotic notches, as well as inflection points, maxima, and minima on the derivative waveforms. Utilizing these extracted points, PPGFeat computes a comprehensive set of features, including pulse transit time, augmentation index, stiffness index, various magnitudes, and time intervals. These features characterize the PPG signal's morphology, timing intervals, and other relevant characteristics. These features are continuously streamed as output, providing a real-time stream of biomarkers and indicators for CVD analysis and monitoring. The resulting biomarkers and features can be fed into machine learning models or rule-based systems for real-time CVD identification, risk stratification, and monitoring applications. By utilizing PPGFeat's robust algorithms and proven accuracy, the proposed biosignal processing unit enables efficient real-time extraction of clinically relevant information from PPG signals, paving the way for improved cardiovascular health monitoring and personalized healthcare solutions.

P15 - Skin Cancer Diagnosis through Machine Learning: An Educational Tool for Improved Detection

14. Medicinteknisk utbildning / Biomedical engineering education
Saad Abdullah
Parveen Ghafoor, Kehkashan Kanwal, Abdelakram Hafid, Annica Kristoffersson

Abstract text*:
Skin cancer is a rapidly growing and potentially deadly form of cancer, making early detection crucial for improved patient outcomes. This study introduces a machine learning-based educational system designed to aid early detection of skin cancer. The system leverages machine learning techniques to analyse skin lesion images from the ISIC-ISBI 2016 and 2017 datasets providing a non-invasive and cost-effective alternative to traditional biopsies. The primary objective of this dataset collection was to generate an automated prediction of lesion segmentation boundaries using dermoscopy images, where each image has a manual tracing of lesion boundaries done by an expert. To accommodate the diverse images acquired using many different devices, pre-processing and segmentation using OTSU thresholding isolate the region of interest, followed by extraction of detailed features such as texture, shape, and color. Principal component analysis (PCA) refines these features. An SVM ensemble classifier, trained on labeled images and evaluated on the ISIC-ISBI datasets, distinguishes cancerous from non-cancerous lesions. The system achieves an impressive 95.73% accuracy, a 95.51% average similarity rate in segmentation, and a low mean squared error (MSE), demonstrating its effectiveness. This system operates in real-time as a user-friendly application executable on any desktop computer, tablet, or laptop. The application takes an image as input, pre-processes it, and extracts relevant features. Using this feature matrix, the classifier determines whether the input image indicates a malignant or benign melanoma. The output provides a clear label of 'cancerous melanoma' or 'benign melanoma' for each analyzed image. This system offers significant educational value for dermatology students and doctors. It can be used for hands-on learning and classroom training, enabling accurate diagnosis without the need for invasive biopsies. The system's potential portability makes it a valuable tool for resource-limited settings and large-scale educational initiatives focused on skin cancer detection.

P16 - Easier access to miniaturized electronics for design

15. Egentillverkade & specialanpassade medicintekniska produkter / In-house & custom-made medical devices

Marcus Ek

Abstract text*: Easier access to miniaturized electronics for designMTD 2024 – Abstract

Marcus Ek, Head of Engineering & Development, Norautron AB
IPC Certified Interconnection Designer

Electronics DevelopmentElectronic components are getting smaller and more powerful

- More's Law
- Materials development
- Chemical development
- Mobility
- Wireless
- Connected
- Long runtime
- Wearables

History – 100 years of electronics

- 1920 Point to Point
- 1925 The first wooden "PCB"
- 1950 Double-sided PCBs
- 1970 Solder mask on printed circuit boards
- 1980 Surface-mount components
- 1990 Digital tools for construction
- 2000 Integration, miniaturization, mobility
- 2020 High Density Assemblies (<0,5mm pitch/Chip size Components)

Availability of miniaturizationTesterday; Mobile phones as an example

- They were built using traditional technology until the early 90s
  When smaller phones needed more functionality,
  specialized manufacturing lines were required
- Smartphones are built in fully specialized factories
  Low mix – high volume

Today

- Miniature components (<1mm) can today be handled in traditional assembly hardware
- Chip 0201 and 01005 (0.4x0.2mm)
- Semiconductors with pitch 0.4mm and less
- Laminate; "rigid"<0.4mm
- Flex and flex-rigid <0.2mm

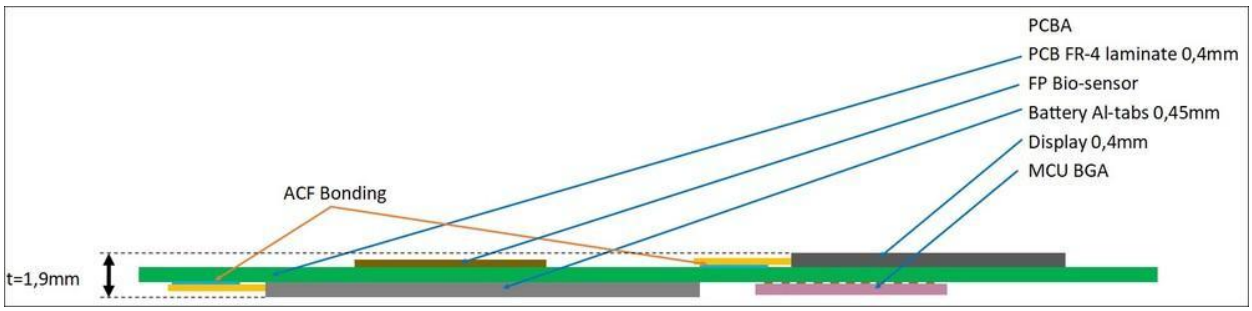
- Soldering replaced by ACF (bonding with conductive adhesive) for connection of non-solderable materials (f.i. Aluminium)
- Thin battery cells <0.5mm
- Thin screens <0.5mm
- PCB internalized antenna elements and coils

Conclusion – Today Update

- Miniature electronics are today available for designers to design and produce at costs equivalent to traditional electronics, also in small series

Example; PCBA with biometric sensor (attached figure PCBA_MTD2024.jpg)

- RF-MCU with integrated BTLE
- Qi charging coil, integrated in PCB
- NFC antenna, integrated in PCB
- 27mAh ceramic accumulator cell, 0,45mm
- 1" e-ink display
- 2-sided assembly, total thickness <2mm



P17 - Transducer shielding for improved bone conduction stimulated auditory brainstem response measurements

15. Egentillverkade & specialanpassade medicintekniska produkter / In-house & custom-made medical devices

Karl-Johan Fredén Jansson
Bo Håkansson, Thomas Rylander, Sabine Reinfeldt

Abstract text*: Background

Bone conduction (BC) stimulation in auditory brainstem response (ABR) investigations are needed to assess an objective hearing evaluation of patients who are suffering from conductive hearing loss. However, at low frequencies, large currents in the transducer (speaker) will generate magnetic fields causing artifacts being picked up by electroencephalogram (EEG) electrodes attached to the patient's head.

Objective
The aim of this study was to evaluate passive and active shielding alternatives to reduce the electromagnetic artifact arising from the transducer during BC stimulated ABR.

Methods
Synthetic measurements of BC stimulated ABR was performed both with and without shielding using the Eclipse system from Interacoustics A/S (Denmark). Tone burst stimuli at different frequencies and intensities were evaluated for passive and active shielding. Furthermore, the electrical properties of the active shielding apparatus were evaluated by electrical circuit analysis. Also, the artifact will be compared for three transducers: Radioear B71, Radioear B81 and a B250 prototype transducer.

Results
The artifact was on average reduced by approximately by 50% at 250 Hz using passive shielding and further improved using the active shielding. It was also discovered that B250 required less current at 250 Hz than B71 and B81 to generate the same hearing level, which resulted in an additionally reduced artifact at that frequency. The low current in B250 at 250 Hz, resulted in a lower artifact as compared with B71 and B81. At frequencies above 500 Hz, the artifact rapidly decayed and had less impact on the ARB response for all transducers. The inherent design of the balanced electromagnetic separation transducer in B250 and B81 partly reduce the artifact as compared with conventional variable reluctance type transducers like the B71.

Conclusion
By using passive shielding the artifact is reduced by approximately 50% and it can be further reduced with active shielding.

P18 - The Emboless® venous chamber efficiently reduces air bubbles. A randomized study of chronic hemodialysis patients

16. Säkerhet, standarder & regulatoriska frågor / Safety, security, standards & regulatory affairs
Per Gustav Magnus Jonsson

Abstract text*: Background : When blood passes the extracorporeal circuit, air microbubbles (MBs) enter the patient. Venous chambers in clinical use have limited capacity in eliminating MBs from entering the return bloodline during hemodialysis (HD) and MBs end up as microemboli in lung, heart, and brain.

The aim was to compare the Fresenius 5008 (F5008) and the Emboless® venous chambers regarding the elimination of MBs in the return bloodline during HD.

Method: Twenty patients performed 40 paired dialyses randomized to start with either the F5008 or Emboless. Of 80 HD, 32 also performed hemodiafiltration (HDF). Dialyzers, blood-pump speed, HD or HDF, and ultrafiltration were the same between the pairs. The numbers of MBs were measured with an ultrasound device at the 'Inlet' and 'Outlet' of the venous chamber (Each series included 95 size ranges of each 5µm diameter from 20-500µm). The percentage of MBs eliminated was compared with Wilcoxon test.

Results: During HD, the median elimination of MBs in the Outlet was -39% with the F5008 (n=3807) and -76% with the Emboless (n=3805) venous chambers ($p<0.001$). During HDF, the median change of MBs in the Outlet versus the Inlet was -28% with the F5008 (n=1549) and -70% with the Emboless (n=1517) venous chambers ($p<0.001$).

Discussion: Leakage of air is of bio compatibly concern. Air do induce clotting. The infused air have no clinical benefit. It is now shown that leakage och micro air can be automatically reduced. Emboless® may be used in any application where reduction of micro air is wanted. Unique improved performance is possible!

Conclusion: Fewer MBs and subsequently fewer microemboli entered the patient using the Emboless® compared to the Fresenius 5008 venous chamber during HD, as well as during HDF. In considering previous autopsy studies, our results support less tissue damage in the patients when using the Emboless® venous chamber.

FIG 1: Boxplot of median during HD treatment.

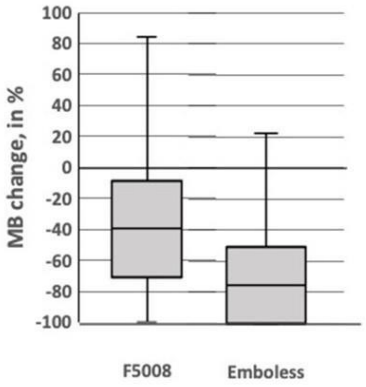
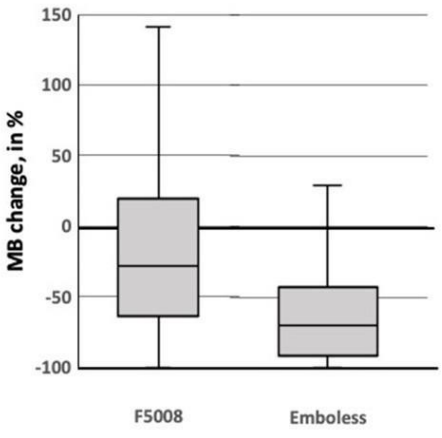


FIG 2 Boxplot of median during HDF treatment.



P19 - Samskapad smart textil -baserad biofeedbackintervention för rehabilitering av handfunktion efter stroke i hemmiljö

20. Vård, monitorering och behandling på distans / Care, monitoring and treatment at distance

Leif Sandsjö
Li Guo, Maria Muñoz-Novoa, Anna Björkqvist, Peiman Khorramshahi, Mats Nilsson, Morten B. Kristoffersen, Margit Alt Murphy

Abstract text*: Omkring 80% av personer med stroke har nedsatt hand/armfunktion. Efter rehabilitering under den subakuta fasen finns det vid utskrivning ofta stora möjligheter till ytterligare förbättringar genom fortsatt regelbunden och frekvent träning i hemmet. Biofeedback är en etablerad träningsform som ger användaren omedelbar återkoppling på exempelvis sin muskelaktivering genom att den muskelelektriska signalen (EMG) från t ex hand/armmuskulatur visas på en bildskärm. Via en nyutvecklad *sleeve* med textilintegrerade elektroder som träs över den påverkade armen och kopplas till en smartphone/tablet kan användaren utföra biofeedbackträning på egen hand i hemmet. Denna biofeedbackintervention kan bidra till ökad motivation att träna genom att träningsprogram kan individualiseras och gradvis anpassas till hur rehabiliteringen framskrider samt, inte minst, att träning enkelt kan utföras i hemmiljö.

Syftet med denna studie är att personer med stroke, kliniker, forskare och teknikutvecklare tillsammans samskapar en biofeedbackbaserad intervention som möjliggör träning av hand/armfunktion efter stroke i hemmiljö.

Metod: Projektets deltagare görs till medskapare av biofeedbackinterventionens olika delar genom ett aktivt deltagande i utvecklingsarbetet (*participatory action research co-design approach*). Stor vikt läggs vid att skapa ett klimat där alla deltagare känner sig trygga i att ge förbättringsförslag och att dessa värderas och tas om hand i samskapandeprocessen.

Resultat: Studien, som är i inledningsskedet, har hittills resulterat i en textillösning som ger bra signalkvalitet vid de tester som genomförts med forskare, utvecklare och kliniker. En app för EMG-biofeedbackträning är framtagen för iOS och Android som ger möjlighet att sätta individuella träningsmål utgående från användarens aktuella muskelstatus. Appen ger också möjlighet att monitorera träningsresultat på distans genom att användarens alla träningsresultat görs tillgängliga via en molnlösning. Pilottester med personer med stroke planeras genomföras vid klinik och i hemmiljö under hösten/vintern.

Slutsats: Genom att biofeedbackinterventionens alla nyckelkomponenter kan vidareutvecklas inom projektgruppen skapas unika möjligheter att vara följsam till de förändringsbehov som kommer fram i samskapandeprocessen.

P20 - Segmentering av medicinteknisk utrustning i nätverket

21. Övrigt / Other (specified further down in the form)
Rasmus Engblom Strucke

Abstract text*: Hur säkerställer vi att vårdinformation är tillgänglig och samtidigt säker med fler och fler MT-utrustningar, integrationer och mjukvaror i nätverket?

Redovisning av exjobb utfört våren 2024.

P21 - Elektromedicinsk Jordfelsbrytare

21. Övrigt / Other (specified further down in the form)
Marcus Eklund
Per Jonsson@regionvasterbotten.se

Abstract text*: Bakgrund: Jordfelsbrytare som normalt används i elinstallationer frånkopplar automatiskt för läckströmar på **30 mA** eller mer och kan därför inte skydda mot mikroshock. Medicintekniska skyddstransformatorer reducerar läckströmmar genom galvanisk separation men kan inte bryta om läckströmmarna ändå blir för höga. I den situationen saknas bra lösningar.
Syfte: Konstruera ett skydd mot mikroshock som fungerar enligt första felfalls principen.
Metod & Avsedd användning: En prototyp, benämnd elektromedicinsk jordfelsbrytare, som både reducerar läckströmmar vid normal drift och automatisk frånkopplar vid ett första fel har tagits fram. Utöver de grundläggande säkerhetsfunktionerna möjliggör digital teknik fler funktioner, till exempel att MT-ingenjören ställer in vid vilken läckström frånkoppling triggas för att prototypen enkelt ska kunna anpassas till den elektromedicinska utrustningens klassning (typ BF och CF).

Elektromedicinska jordfelsbrytaren skyddar också om en patient kommer i kontakt med spänningsförande del eller tar i apparathöljen med höga beröringsströmmar.

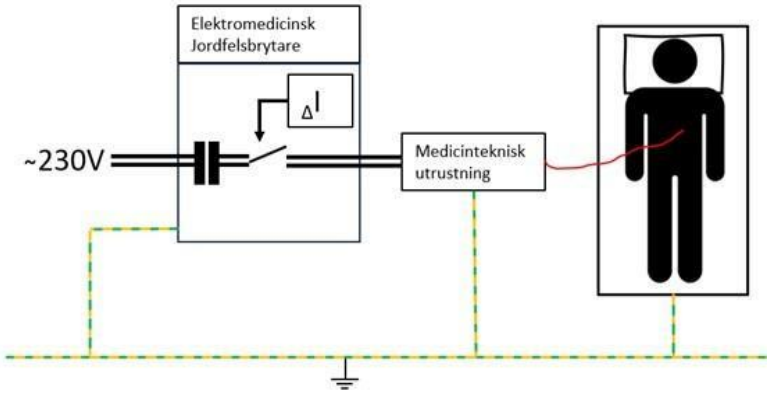
Den elektromedicinska jordfelsbrytaren mäter läckströmmen kontinuerligt och triggar frånkoppling om den överskrider ett inställt värde.

Resultat: Förutom att frånkoppla för höga läckströmmar begränsas även den absolut högsta läckström som kan förekomma i systemet, i prototypens fall till strax över **200 µA**.

Diskussion: Utöver de grundläggande säkerhetsfunktionerna kan man lägga till andra funktioner som lagring av händelser med tidsstämpling för att få spårbarhet bakåt vid misstanke om mikrochock eller om man endast önskar monitorering och larm vid för höga läckströmmar är detta också möjligt.

Slutsats: Konceptet visar att det är tekniskt möjligt att utveckla bättre skydd mot läckström.

Figuren visar den elektromedicinska jordfelsbrytarens användning. Förutom att jordfelsbrytaren reducerar läckströmmar vid normal drift varnar eller kopplar den ifrån matningen om läckströmmen blir för hög. Gränsvärdet för läckströmmen kan ställas in mellan 10 – 500 µA. Det är också möjligt att välja om jordfelsbrytaren endast ska larma eller både larma och koppla ifrån matningen när gränsvärdet uppnås.



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