Toward autonomous robotic-assisted interventions — the value of proximally placed audio-sensors for surface and event characterization

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This article combines a holistic look at needed developments toward autonomous robotic-assisted surgeries combined with a presentation on a novel sensor and analysis technology using vibroacoustic audio signals as a tool for guiding, sensing, and supporting technology.

Healthcare will experience many changes in the next 10 years. Intentional technology-based disruptions will have an effect on actual delivery but also come with novel health business models. This article will initially present some of the upcoming developments and subsequently focus on the use of artificial intelligence (AI) and intelligent sensing for application in robotic assisted surgery (RAS).

The combination of these technologies will lead to dedicated RASs in the near future with reduced cost and complexity and higher precision and prediction capabilities.

While the procedures have significant advantages for the patient, they also have problems, as the navigation/guidance of the devices to a target location is based on either preoperatively acquired images and then performed freehand or accompanied by intraoperative imaging, such as MRI or CT, which is expensive and complicated and can produce artifacts or video-based technologies that only allow direct visualization. Using robotic systems for moving and guiding these interventional and therapeutic devices adds additional issues, such as a lack of palpation sensation and/or tissue feedback. While it is possible to add sensors to the distal tip, this creates other obstacles concerning reduced functionality, need for cables, sterility issues and added complexity and cost.

We propose the use of a proximally attached audio sensor to record tissue tool interactions and provide real-time feedback to clinicians. This paper reports initial attempts to use this technology with robotic arms for surface characterization and interventional vascular procedures, which have recently gained increased attention in combination with robotic devices.

Advanced sensors and AI will be powerful combinations not only for guiding and supporting robotic procedures but also for enabling surgical outcome prediction, which could theoretically increase the safety of RASs.

Keywords:

Robotic assisted surgery (RAS), surgery sensors, artificial intelligence (AI), interdisciplinarity, exponential medicine, semiautonomous surgery, autonomous surgery, audio sensing, proximal sensor, audio feature extraction, signal processing, device guidance

What will you learn:

- Some upcoming developments and new concepts for the Future of Health
- Technological needs for autonomous Robotic Assisted Surgery
- An Introduction to Audio Sensors in combination with RAS
- Some examples on how Audio sensing can be employed and used with RAS

Introduction

Technological developments and their integration into medical devices, tools, and workflows should be based on real and validated unmet clinical needs, but they should also help to pave the way toward a new healthcare vision. The healthcare system and delivery are based mainly on the concepts and tasks of diagnosing a sick or injured individual and the subsequent follow-up therapy and recovery process. This will, of course, constitute a major part of what we expect from healthcare in the future. This can be described as an incremental goal:

The current quality of traditional medicine and the experience of clinicians and patients should be improved.

What we also should think about as innovators is how technological developments will lead to a new MEDICINE, a novel way of employing technology for PREVennization, PREDICTION, PERSONALISATION and an EMPOWERED and ENGAGED PATIENT. We need to occasionally dare to look into the future! This approach is especially valuable when certain technologies are emerging; however, these technologies are still disappointing in terms of their performance, cost, packaging, and size (e.g., Quantum Computing in 2022), but this could lead to future paradigm shifts (or DISRUPTIONS).

With a broad view of current developments (see [1] – a popular book from a celebrity with no science background, but because of that well written with the input of experts and great references), you can, for example, come up with a short 15-year future vision like the one presented here:

> *2037: Most cancers are detected early and treated before they cause significant damage and before major interventions are needed. A personalized treatment for neurodegenerative diseases has just been introduced, and most of your organs can be rejuvenated using a combination of stem cell therapy combined with 3D scaffold printing. Health monitoring and personalized recommendations (AI, ML, DL, etc.) have led to a significant reduction in health emergencies, which are typically resolved with minor interventions using autonomous surgical robotic systems. Healthy lifetimes now average 120!*

Is this absolutely far-fetched?

ANSWER: It is, at least, not totally unrealistic to look at what is currently being developed, whether already in preclinical trials or even in clinical trials. The past has shown that we are typically overestimating developments and their effects in the short term (3-5 years) and significantly underestimating them in the long term (10-15 years), which are exponential developments that we cannot grasp with our linear thinking capabilities [2,3].

It is a good exercise to regularly look at developments and see what kind of effect one can imagine or anticipate with respect to one's own work or domain. If you just use the abovementioned example, then think about some potential consequences for the future of healthcare [4, 5].

Implications

Can we actually afford – as individuals or as a society – an average life expectancy of 120 without major changes in how we live, how we work, how long we work …?

Who would benefit from these developments first? Likely the richer countries and the wealthier part of that population. What are the societal consequences?

What will happen to the role of the doctor, the capacities of the hospitals, the product offerings of the Siemens Healthineers, General Electrics, or Philips Medicals of the world?

Who will pay for what and when? And many, many more …

Why am I saying that? Because I believe that we need to start thinking more exponentially … we will need to develop an EXPONENTIALLY ADVANCED HEALTH MINDSET! And that will also have an effect on how we see current developments and with that understand the need for a significant change in the way we understand and perform medicine within a health care paradigm.

FUTURE HEALTH INNOVATIONS have to continue to improve traditional medicine, but they also need to create a new exceptional ADVANCE—and that is also needed to decrease the gap between low-income and high-income nations. Advanced medicine is currently far from being globally available.

And with that ask yourself on whether you believe THAT THE CURRENT DEVELOPMENTS AND THE GLOBAL HEALTHCARE SETUP WILL ADRESS THESE ISSUES?

It is quite likely that novel technologies—those disrupting existing health approaches—will lead to new business models.

Incentives that are currently almost exclusively based on fast and accurate diagnosis and a therapy response will need to include reimbursements that ensure that individuals stay healthy for as long as possible and that any detrimental health developments are recognized long before they trigger invasive and costly clinical responses.

Why are we talking about this, and what does it have to do with robotic surgery? … and what does that have to do with Audio Sensing for Tissue and Event Characterization?

1. These developments will affect all of us involved in either trying to innovate in the healthcare space or as a clinical/medical provider.
2. Plan for these developments and develop an exponentially open mindset and be open to ideas that seem impossible or infeasible.
3. The progress in the last 10 years has been dramatic, and progress will be significantly more dramatic in the next decade.
4. Semiautonomous and even autonomous surgical robotics are probably closer than you think.
5. Both of these are based on several exponentially advanced technologies that also require novel sensor approaches to actually reach the levels of true autonomy (see figure 1, [6-8]).

Having said all this: *The author has no idea how the future will develop and how things will develop. The point is that you maintain an open mindset and try to avoid linear thinking, which will not work anymore.*

In the following, I would like to only describe robotics and AI (here, together with all other machine learning technologies). In doing so, I will also discuss the current advantages and disadvantages, and I will list the next development steps to provide a basis for an outlook at the end. The whole thing is not explicitly related to a specific surgical discipline, as I cannot imagine that the spread and use of these technologies will be dramatically different for ENT or for visceral or orthopedic surgery.

Please think now for a moment about what could change for you in the future and how an adapted training and innovation generation could look like. No one knows how the future will actually unfold, but a plan and mindset can, at least, be adapted.

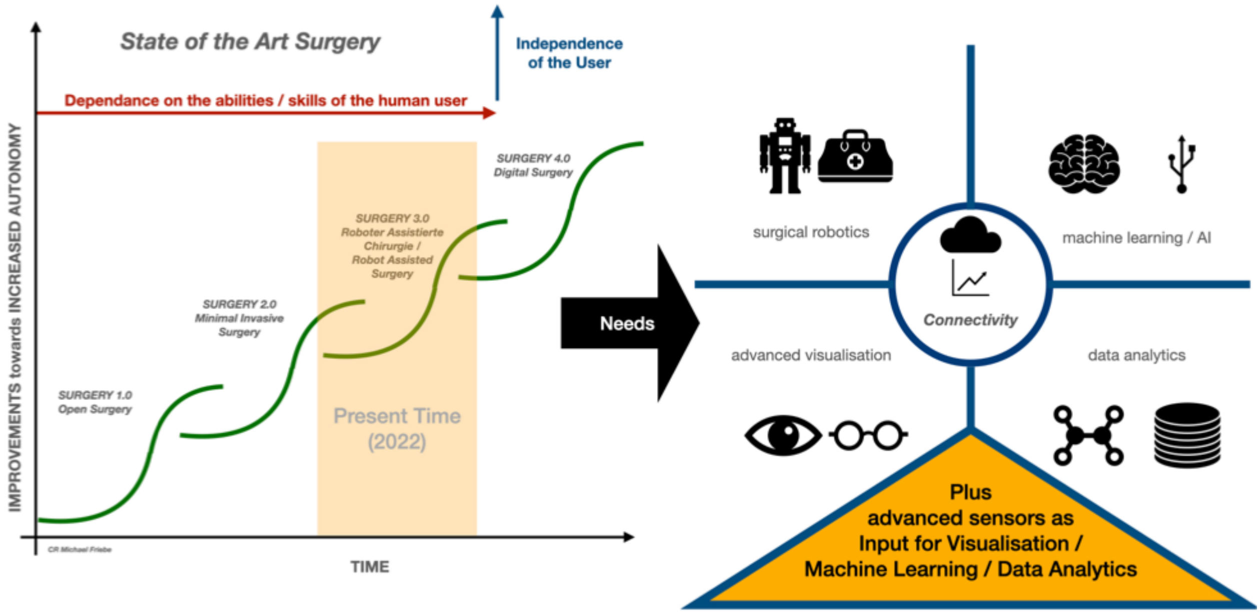
"*Any sufficiently advanced technology is indistinguishable from magic*"; third law of Sir Arthur Clarke (futurist, author, inventor) from 1973 fits quite well in this context!

SURGERY 3.0/4.0

Open surgery (SURGERY 1.0) has been significantly improved for patients in many areas in recent decades by keyhole technologies/minimally invasive surgery (SURGERY 2.0). Since 1995, there have been reports of robotic assisted surgery (RAS) and its evolution to AUTONOMOUS SURGERY 3.0 (see Figure 2).

However, there is a rather sobering record of RAS. The studies published to date and analyzed below have shown that whether patients are operated on with or without robotics actually makes no difference. The presence of a surgical robot was not decisive for success, but the experience of the surgeon remains paramount.

The surgeon bears a very great responsibility toward the patient. The smallest intervention performed on the patient's body can ameliorate irreparable damage and lead to an expected recovery. New digital technologies will expand surgeons' capabilities and improve their chances of success and will not replace them in the short term. However, patient empathy before and after the surgical procedure would definitely secure the position and value of the clinician in the long-term. Currently, this is not always a proven strength of surgeons [9,10].



<u>Figure 1:</u> *State of the Art Surgery. Moving toward the next level - DIGITAL SURGERY - requires a combination of several exponential technologies and eventually lead to a greater independence of the individual users capabilities. That in return will increase the number of systems being employed and reduce the associated costs.*

The nucleus of a hospital is surgery. On the one hand, the operating room is a profit center; on the other hand, it is often the place with the lowest efficiency. To deliver better and consistently good quality of care for every patient, machine learning (ML)/AI must be used, and the knowledge gained about "best practices" must be made globally available. However, fully digitized surgery is needed for this purpose [9].

Another breakthrough will certainly come with the introduction of more or less autonomous robotic systems. Although it will certainly take some time until then, these systems will get their place. First, digital surgery (SURGERY 4.0) has been developed by combining improved visualization (optical, integration of other diagnostic systems, image processing and display) with globally networked data analysis in advance (patient individualization) of a procedure, and the integration of AI will once again significantly expand the quality and possible applications of the procedure.

The dependence on the clinical user's ability will also be significantly reduced due to the higher level of computer-generated support and automation that will then be available and the lower learning curve (see Figure 2 for more details).

STATUS QUO ROBOTICS + ARTIFICIAL INTELLIGENCE (AI) IN SURGERY

Most of the nearly 10,000 RASs currently installed globally (60% of the USA, 20% of Europe, nearly 80% of the market share of INTUITIVE SURGICAL) are merely assistance systems directly controlled by clinicians or surgeons. New device sales amounted to € 4.5 billion in 2020, with an expected increase in sales to almost € 15 billion in 2030, with almost 40,000 installed systems, which will then also be able to provide autonomous decisions and, in certain areas, also autonomously decide or perform a surgical operation independently under the responsibility of a clinician [6, 9-11].

Although not yet clearly advantageous, robotics in surgery is undoubtedly highly important for attractiveness and external marketing. Because of the higher precision, there is theoretically a reduction in surgical and postoperative complications when using robotics. Due to the relaxed and less stressful position, there is also less physical strain. However, this is currently offset by the high cost of training, low utilization, and very high capital and variable costs. The technical complexity of these systems is also very high because of the many different fields of application, and the preparation time is therefore correspondingly

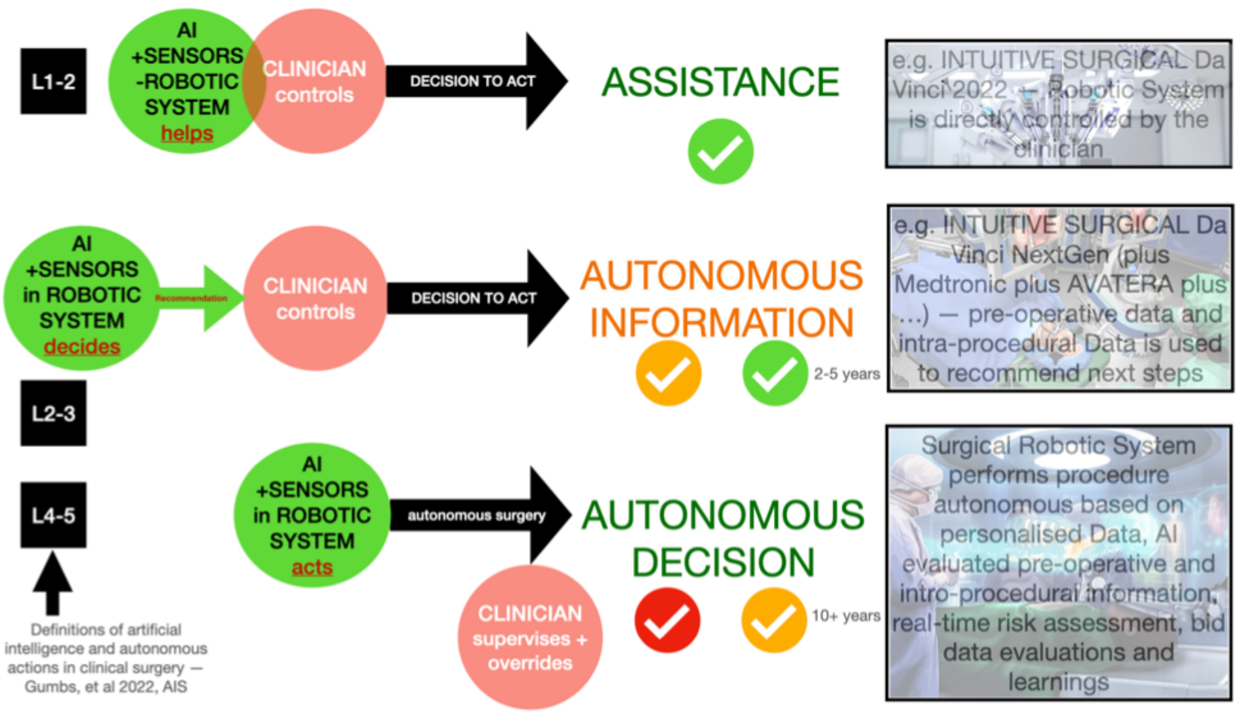


Figure 2: *The different autonomy levels that are associated with the different types of robotic surgical systems - ASSISTANCE (currently), AUTONOMOUS INFORMATION (uses Machine Learning and advanced sensors) and AUTONOMOUS DECISION (performs surgeries and predicts outcomes or events)*

long. In the meantime, there are almost 20 companies offering commercial products and a large number of startups in the segment. It is foreseeable that there will be more specialized, smaller and less complex systems, which will then also be significantly cheaper to purchase and maintain. All of these technologies will be equipped with increasing amounts of artificial intelligence (AI), provide autonomous information and solve the current disadvantages in the short term.

The current advantages and disadvantages of robotics and artificial intelligence are briefly summarized in Figure 2.

The advantages of networked data sharing for improving AI are obvious. Digitally captured information can be used globally to improve systems. For this to happen, however, there also needs to be advances in the area of data security and standardization of data formats. AI is able to combine many structured and unstructured data points and use them, for example, to make predictions about certain interventions or to detect even the smallest changes at an early stage during the intervention [12]. Of course, there are still too few data points and too few case studies.

Moreover, there is still not enough sensor input available to feed the AI and allow more autonomous operation of surgical robot systems.

Device Guidance Sensor Concepts and Issues

Touching sensation and haptic feedback provide important information for human clinicians. These findings will aid initial and procedural diagnostics and help guide therapeutic interventions. The interventional radiologist pushes the guide wire through the vascular system to the final destination and “listens” partly to the tissue feedback. For initial vascular access, the pulsating femoral artery was searched for using the sensing hands. Touching and feeling organs during an open surgery give additional information about where and how to perform a surgical intervention … just some examples of the importance of haptic and touching/feeling information in the clinical context (see Figure 3 left).

Most RASs cannot provide any of these materials; typically, they are complemented with a visual feedback system in some instances with external diagnostic imaging support.

In the past, researchers have attempted to add electronic and tactile sensors to robotic subsystems to simulate or provide alternative information about tissue response to pressure while simulating a palpation sensation. The state of the art is to add these sensors to the device tip, as that approach is the closest to the actual human tissue and is the only advantage and benefit of that location. These sensors take some physical space, and to reduce the actual performance of the tip device, they require mechanical wires or cables; additionally, they typically have high device costs and a complete new device design and require new regulatory approval (see Figure 3 right, including some examples of sensors attached to graspers and guide wires [13,14]).

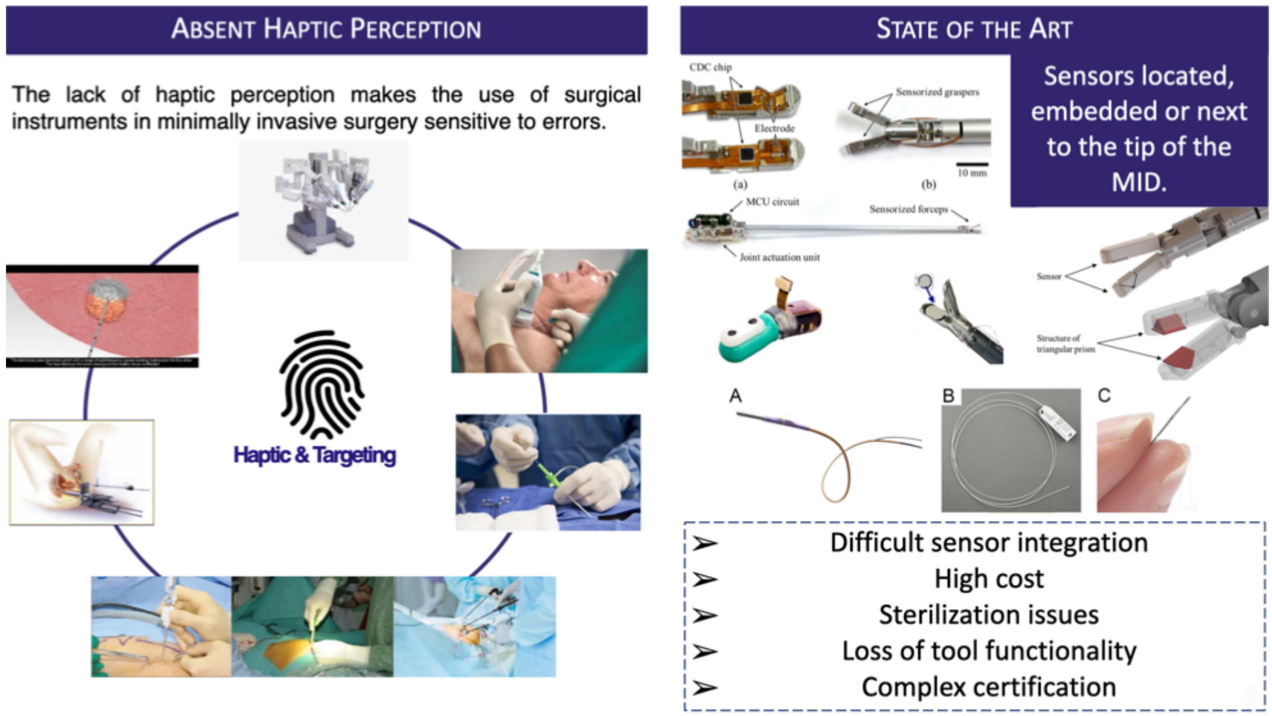


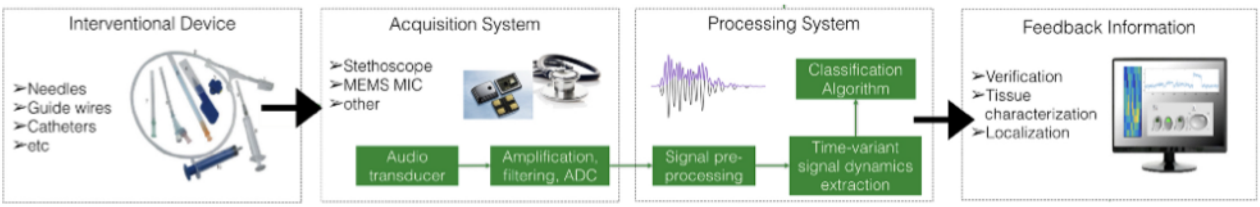
Figure 3: Haptic information is needed and helpful in clinical applications. For external therapeutic devices and/or robotic assisted systems a haptic feedback is either missing or significantly reduced compared to the human abilities. State of the art research to overcome that by using sensors added to the devices are shown on the right part. They are typically embedded or added to the tip of the device (e.g. Medical catheter products equipped with miniature tactile sensors. (A)(B)(C) [13] or Force Sensors integrated in Surgical Forceps for Minimally Invasive Robotic Surgery [14]) and come with significant problems with respect to complexity, regulatory approval, reduced functionality of the clinical use, and high device cost. It would be ideal to add inexpensive sensors to existing tools outside the treatment area and ideally outside the patient.

SUrgical Audio Guidance - SURAG

The audio guidance technology is based on very easy physical principles and acquisition methods (see Figure 4).

1. Direct interactions (e.g., touching or inserting) between two different materials will cause friction waves to travel through tissue or via an acoustic conductor.
2. These friction or vibroacoustic waves can use the interventional device shaft as a transport medium.
3. Since this signal is generated at the tip of the device gliding through tissue or over a tissue surface, it can be picked up at the other end of the shaft (papercup - principle) in a clinical setting now outside the patient.
4. The propagated audio signal can now be detected, “listened”, recorded and transferred to an evaluation unit with the help of a microphone.

5. An audio is not just a one-dimensional signal but can be processed using several algorithmic signal processing methods that allow for more in-depth characterization and feature extraction of the individual signal.
6. This approach allows for the assignment of certain features, dedicated frequencies and their distributions to a specific event or surface characteristic.



<u>Figure 4:</u> *The basic principle of the **SU**rgical **A**udio **G**uidance (SURAG) principle. An audio sensor is attached to the proximal end of an interventional device (e.g., guide-wire/catheter/robotic instruments/aspiration needle/veress needle/biopsy device) outside the body and without the need for a dedicated clinical device, wires or cables, and with greatly reduced sterilization efforts. The acquisition system preprocesses and filters the signal that is then sent to the processing unit. The user interface depends on the application and can range from a visual "traffic light" feedback to an amplification and magnification of specific sounds. [15]*

This means that, depending on the physical properties of the individual tissue (liquid content, roughness, material, etc.), different acoustic waves will be produced when a needle, for example, is pushed through that particular tissue or, in another example, when a device glides over a more or less rough and more or less watery surface.

Motion of a clinical device (endoscope, needle, guide-wire, robotic arm, etc.) device through or over tissue will create a vibroacoustic response that travels over the device connection/shaft and can be picked up at the proximal end and subsequently processed to identify and display an event or provide audio-derived tissue characteristics.

In the following sections, more technical details, especially with respect to the signal processing section, and example applications will be presented.

How does it work? Technical principles

If there is no motion between the device and the tissue, then there is little motion (possibly due to arterial or respiratory sounds propagating through the tissue layers to the shaft), or no audio signal is received. Motion is therefore essential. The audio information is collected using microphones.

For that purpose, we initially used conventional stethoscope membranes that were attached to the shaft of the medical interventional device or guide wire (see Figures 8-10) and subsequently replaced with custom-made and more dedicated microelectromechanical system (MEMS) sensors. However, the general principle is the same, and the stethoscope

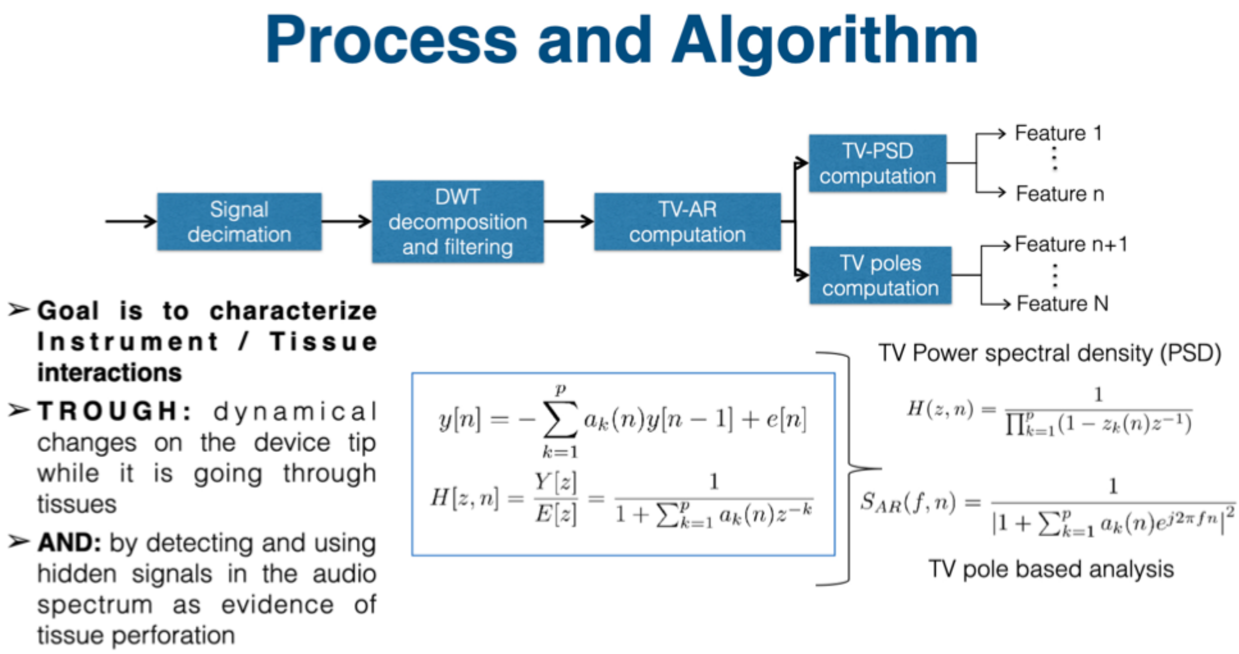


Figure 5: The audio sensing and analysis process has the goal to characterize vibroacoustic instrument - tissue interactions, for example crossing layers or to identify tissue features for classification. Several signal processing methods are used starting with a reduction of the obtained audio signal followed by Discrete Wavelet Transformation (DWT) algorithms and a subsequent Time Variant Autoregressive computation method that leads to Time Variant Power Spectral Densities (TV-PSD) and Time Variant (TV) Pole computations. With that large feature set dominant ones can be selected and used to describe actions, events or tissue characteristics [15].

results were actually quite good; however, the device itself was too bulky, heavy, and partly even too sensitive but had a very narrow frequency band in the audible range of up to 2.000 Hz (with extended diaphragms).

The audio sensing and analysis process has several clinical goals, among which are to characterize vibroacoustic instrument–tissue interactions, for example, crossing layers or identifying tissue features for classification. These events trigger a dynamic event that the employed signal processing methods are looking for.

The whole algorithmic process starts with a reduction in the obtained audio signal followed by a discrete wavelet transformation (DWT) and a subsequent time variant autoregressive computation. The result is an individual display of spectral density (TV-PSD) and time-variant pole computations. With that, large feature sets that are dominant can be selected and used to describe actions, events or tissue characteristics [15].

These calculations have shown that certain device events and different surfaces all have a very distinct frequency and power distribution that allows us to extract meaningful characterizing features that can be used for future classification using audio signals for many different applications, as presented in the following paragraphs.

Sensing Opportunities using Audio

Audio is often associated with hearing. With hearing, we typically refer to the human listener.

In our case, we use audio to extract information that cannot be heard by a human if it is not specifically filtered and amplified. This is the process that can be employed with needle applications, where it is important to have real-time feedback to the user when entering or leaving certain tissues or crossing tissue layers. To accomplish this, the signal is preprocessed and filtered, and only the relevant frequency bands for these events (which are known) are amplified and communicated via a speaker to the user. This is an extremely powerful response; specifically, when you move the needle through apparent homogeneous tissue without any "feeling" response and then hear a loud noise indicating that you just entered a different tissue layer. This has been attempted 100's of times using a darkened gelatin phantom with embedded strawberries or other very soft objects. The user was not able to feel any crossing, but the audio was able to indicate entering the object, which was additionally verified by external ultrasound guidance.

Other possible sensing applications (see Figure 6) include the detection of blood pulsation with directional and crude distance information (the closer the louder), event detection that occurs during the insertion of guide wires or catheters (e.g., bumping the vessel call, penetrating the vessel wall, moving along the vessel wall), surface characteristics of organs and internal tissues or even individual characterization (and diagnosis) of tissue status, as shown in some initial experiments on knee joints for

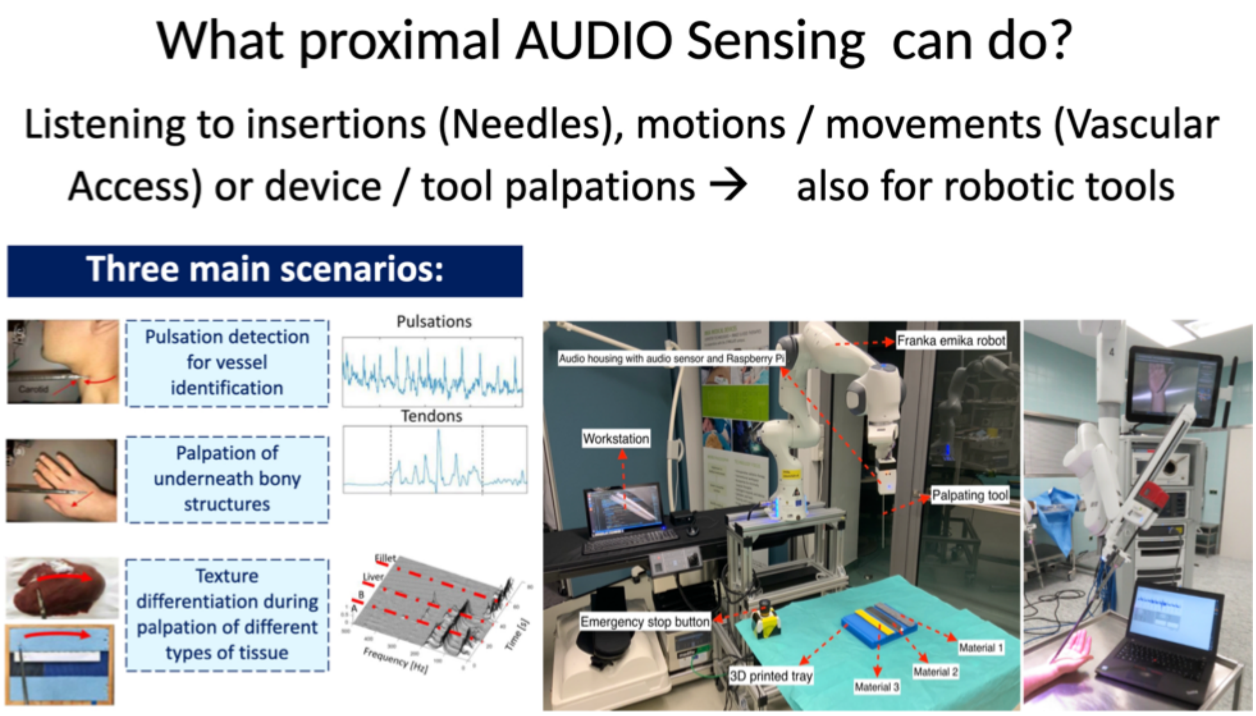


Figure 6: In Robotic Assisted Surgery applications toward semiautonomous operation the SURAG sensing concept can be used for example for pulsation detection or for obtaining palpation information or for texture differentiations or … or in a future development stage even for an audio based histopathology [15].

determining cartilage quality. Additionally, as previously mentioned, advanced sensor input is needed for AI subsystems to move RAS applications toward semiautonomous and eventually autonomous decision-making and actual robotic surgery.

Data on events and the prediction of future events require data points, and audio input could be one of these data generators. In a future development stage, we could even envision that we arrive at an audio-based histopathology that would allow some generic characterization of tissues without requiring a physical probe. This approach requires many more data points and a considerable development effort from several international research teams.

Example Results: Needle Guidance

Figure 7 shows the original and filtered signals, TV-AR spectrum and maximum pole energy for the constant-speed/force needle insertion experiments performed with PERSIMMON, GRAPE, CHICKEN BREAST, and CHICKEN LIVER.

These objects were embedded in a gelatin phantom, and the needles were pushed at different but constant speeds using a machine setup. In separate experiments, different human users performed the same experiment.

The speed of the insertion had no significant effect on the quality of the audio signal or the accuracy of the event characterization (entering the object and leaving the object with the needle). Additionally, the different users produced similar audio responses.

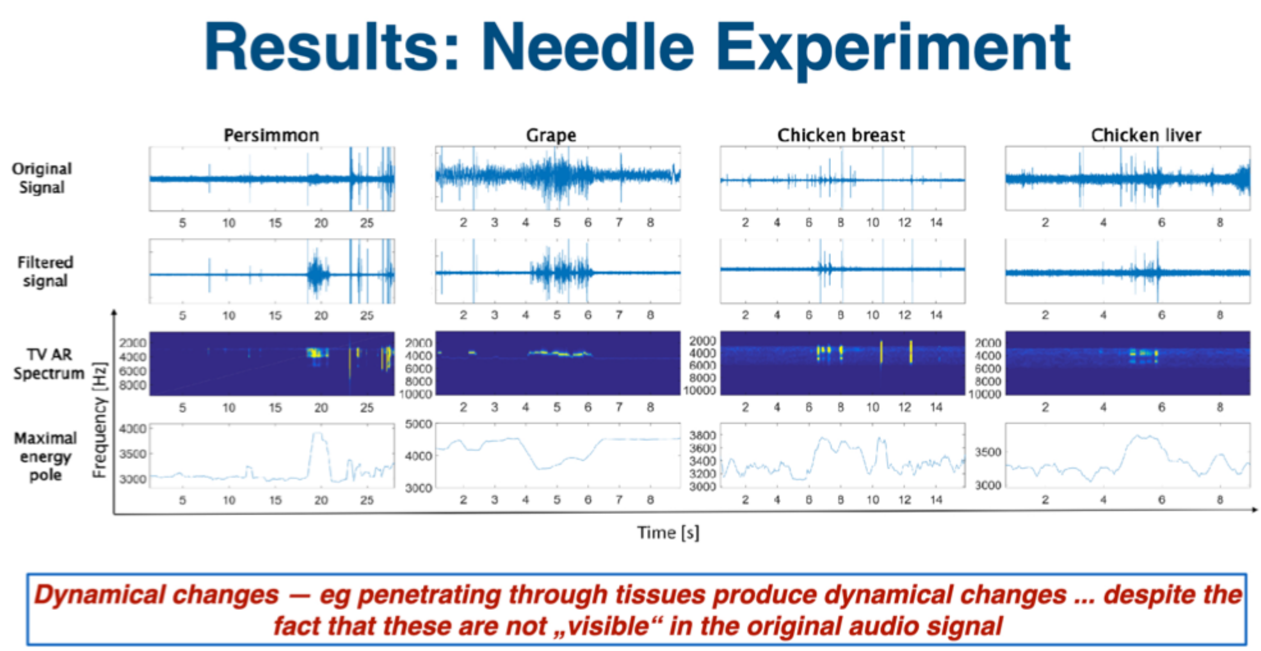


Figure 7: The displayed results show the original and filtered signal, TV-AR spectrum and the maximum pole energy for a constant speed/force needle insertion experiment entering PERSIMMON, GRAPE, CHICKEN BREAST, and CHICKEN LIVER that were embedded in a gelatin phantom. It is quite obvious that all of them have a very unique audio profile particularly the frequency spectrum and the pole energy [15, 16].

It is quite obvious from the results that all of them have a very unique audio profile, particularly with respect to the frequency spectrum and the pole energy [15, 16]

Additionally, the original signal obtained without preprocessing or filtering was not able to display the event details.

For certain easy and straightforward interventions and clinical applications (e.g., veress needle insertion or vascular access), it may be sufficient to limit the signal processing to filtering and amplification, which would significantly simplify the entire setup and still work with an audio signal for the user. In other applications, this approach is not possible or feasible because the raw and processed signal intensities are too low.

Example Results Guide-Wire Event Sensing

Guidewire applications are currently being proposed for use by robotic/telemanipulated systems that allow the interventionalist to stay outside the area of X-ray radiation exposure. This, however, comes with the loss of haptic feedback that the performing clinician receives by moving the guide wire or catheter forward through the vessel system to the therapy location.

We wanted to check whether it is possible to use the audio sensing approach that we described in combination with guide wires and develop a 3D-printed coupling adaptor to

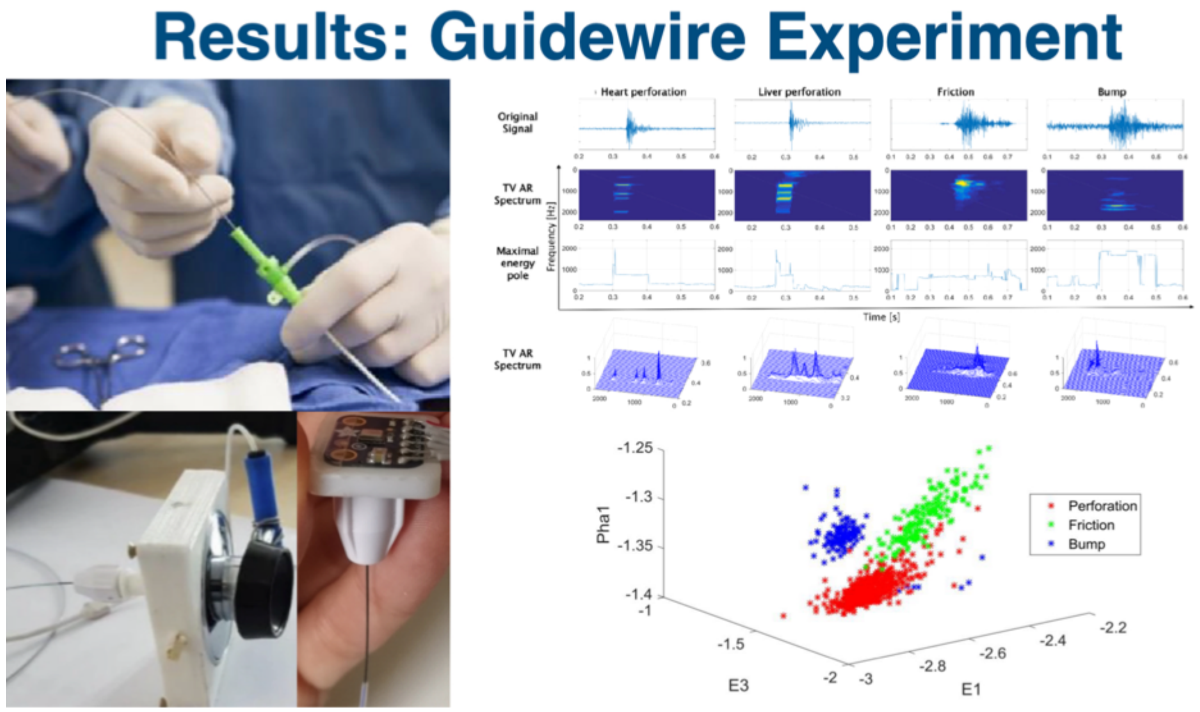


Figure 8: Guide-wire experiment using pigs hearts and arteries. Initially, we just created a coupling adaptor for a conventional stethoscope (bottom left), that was eventually replaced with an electronic MEMS sensor. We performed several hundred events: (1) vessel/heart perforation, (2) liver perforation, (3) moving the guide-wire along the vessel wall to create a friction, and (4) tapping/bumping with the guide-wire on vessels or organ tissue. The analysis shows clear clustering of these events using the obtained and processed audio data with support of feature extraction and machine learning [17, 18].

connect a conventional stethoscope (see Figure 8 bottom left), which was eventually replaced with an electronic MEMS sensor.

Several hundred “interventions” using pig hearts and vessels were performed, and the data were recorded for the following event categories: (1) vessel/heart perforation, (2) liver perforation, (3) movement of the guide wire along the vessel wall to create friction, and (4) tapping/bumping with the guide wire on vessels or organ tissue.

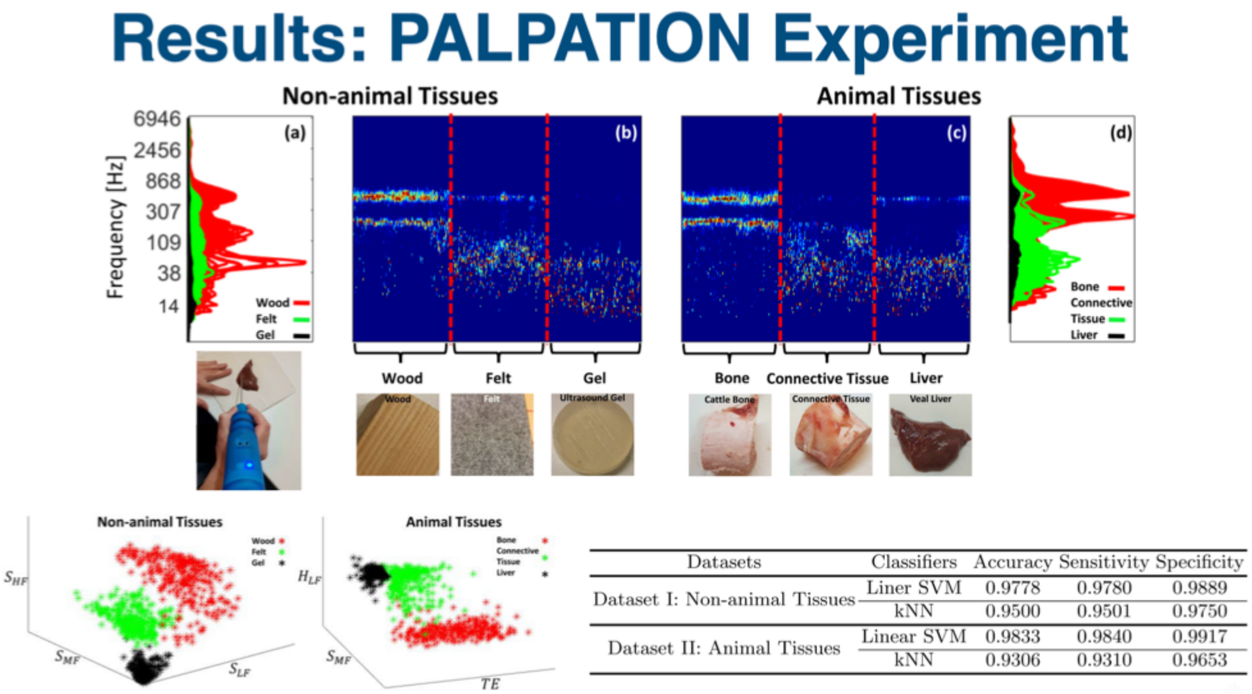
The analysis, as shown in Figure 8, revealed that we were able to clearly cluster the events after feature extraction with the help of dedicated machine learning algorithms [17, 18].

The use of audio event detection could improve procedure accuracy and patient safety when an unintended perforation is detected in real time.

Another application that we have already presented involves simulated palpation for detecting and characterizing surfaces.

Example Manual Device Palpation

The experiments, as shown in Figure 9, used a special audio system that was added to a palpation device. The hypothesis was that we would be able to detect characterizing vibroacoustic features when moving a dedicated palpation device over different surfaces to be able to actually classify the surfaces. As in previous experiments, we combined



Datasets	Classifiers	Accuracy	Sensitivity	Specificity
Dataset I: Non-animal Tissues	Liner SVM	0.9778	0.9780	0.9889
	kNN	0.9500	0.9501	0.9750
Dataset II: Animal Tissues	Linear SVM	0.9833	0.9840	0.9917
	kNN	0.9306	0.9310	0.9653

Figure 9: In this experiment a palpator with the SURAG technology was used and moved over different nonanimal (Wood, Felt, Gel) and animal (Bone, Cartilage, Liver) textures. Every one of them showed a very distinct frequency profile that lead to a clear identification and classification as shown in the clustering charts and very high classification accuracies [19, 20].

time-variant signal processing and frequency analysis with machine learning for tissue clustering.

Three different nonanimal (wood, felt, or gel) and animal (bone, cartilage, or liver) tissues were used, and each of these tissues exhibited a very distinct frequency profile that led to clear identification and classification, as shown in the clustering charts and very high accuracy [19, 20].

This experiment was the basis for the cartilage classification in the last example that was presented but also led us to try this approach for robotic graspers.

Example Robotic Grasper Surface Palpation

The problem is that in RAS, the sensor cannot be directly attached to the grasper or tool shaft touching the human tissue. We therefore added the SURAG sensor to the grasper housing of the Da Vinci tool, as shown in Figure 10, and measured the indirect vibroacoustic signals that traveled over the shaft and onto the housing.

This setup was later tested using a real operational robot system (that produces additional noise, wire motion, etc.) installed in a dedicated real clinical/surgical environment. Even then, it produced similarly useful and indicative results.

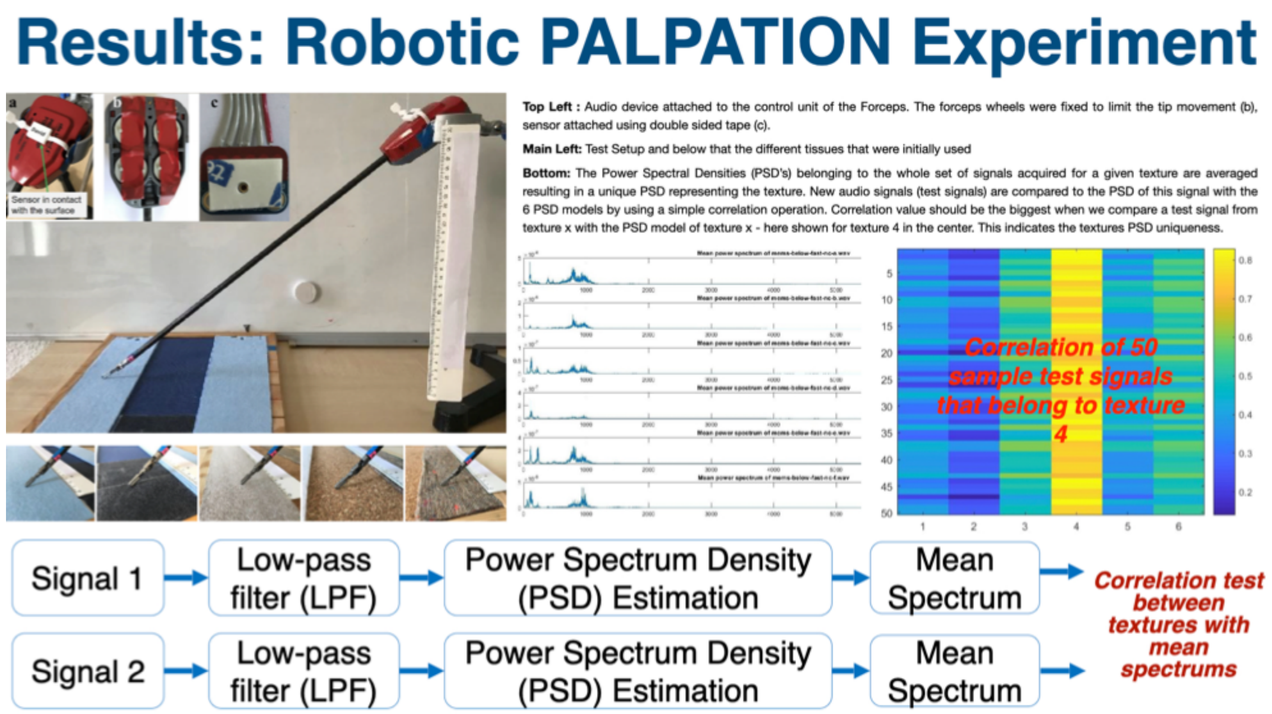


Figure 10: In robotic assisted surgery the sensor cannot be directly attached to the component that touches the human tissue. In the above case we added the SURAG sensor to the housing of a Da Vinci tool and measured the indirect vibroacoustic signal that travels over the shaft, and the housing. This setup was subsequently tested in a real operational robot with similar results. Several different surfaces were used and the grasper was moved over them. As in previous experiments every surface showed a distinct signal and frequency profile and lead to high confidence of tissue identification [19, 20]

Several different surfaces were used to test the technology, and the grasper was repeatedly moved over them. As in previous experiments, every surface showed a distinct signal and frequency profile, which led to high confidence in tissue identification [19, 20].

Figure 8 also shows the verification tests that were performed. The mean frequent spectrum results of one surface that were calculated for every signal using low-pass filtering and a power spectrum density estimation were compared to the spectrum results of other surfaces. Using texture 4 as an example, the 50 results were compared to each other with a very high correlation. This means that the signals do not differ much from each other, as hoped for. On the other hand, if these 50 texture 4 results are compared with 50 results for another texture, then the results indicate a very low correlation, which means that the results from one texture to another are distinctively different and should therefore be able to characterize textures and/or surface characteristics.

Additionally, our last example was used for an experiment on real knee joints with the goal of determining the Osteoarthritis Research International (OARSI) score, which is a numbering scheme that is used to determine whether a knee implant should be implanted.

Example Cartilage Palpation Knee Joint

This experiment is shown in Figure 11. A palpator was used to touch different areas of a knee joint, and the audio data were analyzed as described in the previous examples, with the goal of identifying some audio-extracted features that could be used to classify cartilage quality.

If that would work, then the device could be attached to an arthroscopy device and actually be used to obtain a more objective score in combination with additional (or maybe even without) external diagnostic imaging (such as MRI). The OARSI scores obtained have large interrater variability and may lead to unnecessary surgeries and total knee replacements.

The obtained signals were compared to the OARSI scores determined by clinical experts. The less cartilage and/or the less homogenous the surface was, the greater the OARSI score was. A good correlation was found between certain audio signal responses and frequencies and a particular OARSI score, as indicated in the frequency chart in Figure 11.

For example, audio sensing technology could also be used as a diagnostic tool or to obtain a more objective assessment of the functionality of a particular tissue [21].

SUMMARY AND OUTLOOK

Complex technical systems without AI will likely not exist in the future, and via very fast networked "learning", these systems will also be able to prove their advantages in future

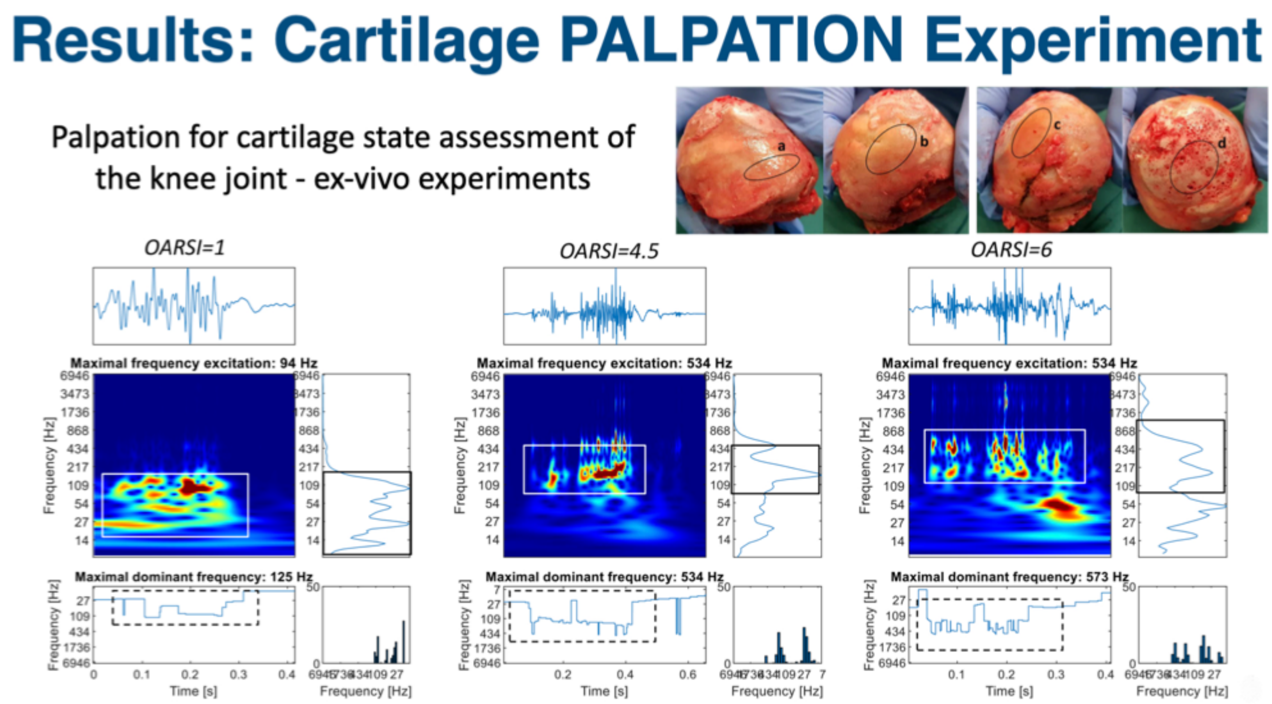


Figure 11: This experiment shows a potential application of the SURAG sensing approach. A palpator was used to touch different areas of a knee joint with the goal to classify the cartilage quality. The signals were compared to the OARSI scores as determined by the clinical experts. The obtained results showed a nice correlation between certain audio signal responses and frequencies [21].

studies. In this respect, we can assume that the use of robotics in combination with AI for surgery will shape the future.

In this context, I would also like to briefly discuss current clinical and medical technology education. We talk about SURGERY 4.0 or INDUSTRY 4.0, but we are still educating at level 2.5. We do not teach future foresight in innovation. The current generation is ignorant of likely changes in business models and is educated in siloes. The engineer has little contact with clinical staff, and clinical disciplines often have little or no input into the development of new systems. There needs to be an EDUCATION 4.0, which is much more interdisciplinary and teaches clinicians the technical basics; on the other hand, it teaches engineers how to work clinically and teaches everyone more empathy and enhances future innovation methodology [5, 22, 23].

Surgeons are in a key position in the introduction of AI in the clinical setting. AI could revolutionize education and significantly improve the quality of patient care in the future. In the future, surgeons, in particular, need to work closely with data scientists to achieve this goal [6-10].

Innovation will be interdisciplinary, and for this to happen, there needs to be much more interdisciplinary research and development. Innovation is actually only innovation when it actually reaches the patient and generates significant added value, which is very often generated by a significant reduction in treatment costs.

In the future, we will record digital data in all areas of healthcare, link them together, and then make risk predictions and plan and implement appropriate interventions. This will then open up completely new business models, and healthcare will then also revolve more around the health of the patient. Data usage and handling will be an issue, but I am also certain that there will be pragmatic solutions to that [12].

Upheavals always come with new opportunities. Exciting and thrilling developments are ahead of us. We also see this when we look at the partnerships between clinical product developers and digital companies and think about what could happen when APPLE teams up with Siemens or GE with GOOGLE or MEDTRONIC with AMAZON or INTUITIVE SURGICAL with ALIBABA or...

And with respect to Robotic Surgery: all just said above applies. AI will quickly move the current autonomy level toward semiautonomy and—also quicker than we would expect or predict at the moment—to a more fully autonomous level of operation [7].

This approach, however, will be possible not only with advanced sensors that are visual or diagnostic imaging related but also by measuring, observing and detecting changes or events that a human operator has no developed senses for or is simply incapable of detecting. In combination with AI, it will then also be possible to predict outcomes or clinical developments and initially warn surgeons of any upcoming event.

Audio-sensing, which is currently still in its technological infancy, has already been shown to detect and display surgically relevant events and is also able to classify tissue properties. We are convinced that additional research and data points will help to improve the use of this sensor technology as an important guidance support and information generator combined with its small size, regulatory and compliance advantages, and low cost.

Additional possible applications include combinations with robotic systems and audio-based histopathological characterizations.

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The main contributors to the presented research content are Alfredo Illanes PhD, Axel Boese PhD, Thomas Sühn, Moritz Spiller, Nazila Esmaeili and many other students.

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Key Learnings:

- Upcoming exponential developments will happen faster and cause more changes than you can imagine.
- Autonomous robot assisted surgery may be closer than you think.
- And more specifically that audio sensing could be a powerful tool for device guidance, event and surface characterization and that it additionally is a technology that will increase procedure safety and outcome
- The SURAG audio sensing can be used in many different clinical applications for device monitoring, tissue characterization and even for diagnostic evaluations.

References

[1] Robbins T, Diamandis P (2022). Life Force How New Breakthroughs in Precision Medicine Can Transform the Quality of Your Life & Those You Love. Simon & Schuster Ltd. ISN 978-1-4711-8837-4

[2] Diamandis P (2016). Disrupting today's healthcare system. http://www.diamandis.com/blog/disruptingtodays-healthcare-system (2016).

[3] Diamandis P (2016). The D's https://www.diamandis.com/blog/the-6ds

[4] Friebe M (2020). Healthcare in need of innovation: exponential technology and biomedical entrepreneurship as solution providers (Keynote Paper). Proc. SPIE 11315, Medical Imaging 2020: Image-Guided Procedures, Robotic Interventions, and Modeling, 113150T https://doi.org/10.1117/12.2556776

[5] Friebe M (Editor) (2022). Novel Innovation Design for the Future of Health. SPRINGER Nature, Chapters 1-5. ISBN 13: 978-3031081903

[6] Hasimoto et al (2018). Artificial Intelligence in Surgery: Promises and Perils https://dx.doi.org/10.1097%2FSLA.0000000000002693

[7] Gumbs AA, Frigerio I, Spolverato G, Croner R, Illanes A, Chouillard E, Elyan E. Artificial Intelligence Surgery: How Do We Get to Autonomous Actions in Surgery? Sensors (Basel). 2021 Aug 17;21(16):5526. doi: 10.3390/s21165526. PMID: 34450976; PMCID: PMC8400539.

[8] Vilsmeier S (2021). Leveraging AI and Digital Technologies for Healthcare in 2021 and beyond. https://www.brainlab.com/de/journal/leveraging-ai-and-digital-technologies-for-healthcare/

[9] Smith R (2019). How Robots and AI are Creating the 21st-Century Surgeon. https://www.roboticsbusinessreview.com/health-medical/how-robots-and-ai-are-creating-the-21st-century-surgeon/

[10] Mesko B (2021). The Technological Future Of Surgery. https://medicalfuturist.com/the-technological-future-of-surgery/

[11] Nakanishi T, Lee S-H (2021). Global Surgical Robots Market. BIS Research. https://bisresearch.com/industry-report/global-surgical-robotics-market-2025.html

[12] O'Sullivan S, et al (2019). Operational framework and training standard requirements for AI-empowered robotic surgery. The International Journal of Medical Robotics and Computer Assisted Surgery V0l 16, Issue 5, pages 1-13, https://doi.org/10.1002/rcs.2020

[13] Li Y, Wang P, Meng C, Chen W, Zhang L, Guo S. A brief review of miniature flexible and soft tactile sensors for interventional catheter applications. *Soft Sci* 2022;2:6. http://dx.doi.org/10.20517/ss.2022.05

[14] Zhao Z, Jordan S, Tse ZTH. Devices for image-guided lung interventions: State-of-the-art review. Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine. 2019;233(4):444-463. doi:10.1177/0954411919832042

[15] Illanes A, Boese A, Maldonado I, Pashazadeh A, Schaufler A, Navab N, and Friebe M (2018). Novel Clinical Device Tracking and Tissue Characterization Using Proximally Placed Audio Signal Acquisition and Processing. *Scientific Reports*, 2018. DOI: 10.1038/s41598-018-30641-0

[16] Sabieleish, M., Heryan, K., Boese, A. et al. Study of needle punctures into soft tissue through audio and force sensing: can audio be a simple alternative for needle guidance?. *Int J CARS* **16**, 1683–1697 (2021). https://doi.org/10.1007/s11548-021-02479-x

[17] Illanes A, Schauffler A, Maldonado I, Boese A, and Friebe M (2017). Time-varying Acoustic Emission Characterization for Guidewire Coronary Artery Perforation Identification. *Computing in Cardiology* 44 (2017): 1. doi: 10.22489/CinC.2017.135-113

[18] Mahmoodian N, Schaufler A, Pashazadeh A, Boese A, Friebe M, and Illanes A (2019). Proximal detection of guide wire perforation using feature extraction from bispectral audio signal analysis combined with machine learning. *Computers in biology and medicine* 107 (2019): 10-17. doi: 10.1016/j.compbiomed.2019.02.001

[19] Chen C, Sühn T, Kalmar M, Maldonado I, Wex C, Croner R, Boese A, Friebe M and A. Illanes (2019). Texture differentiation using audio signal analysis with robotic interventional instruments. *Computers in biology and medicine* (2019): 103370. doi: 10.1016/j.compbiomed.2019.103370

[20] Friebe M, Boese A, Heryan K, Spiller M, Sühn T, Esmaeili N, and Illanes A (2022). Surface and Event Characterization - Proximal Audio Sensing to improve Manual and Robotic Device Interventions. *Current Directions in Biomedical Engineering* 2022;8(1): 1-4. doi: 10.1515/cdmbe-2022-0001

[21] Schaufler, Anna, Fritzsche, Holger, Bertrand, Jessica, Lohmann, Christoph, Boese, Axel and Friebe, Michael. "Sensor-based measurement for advanced monitoring and early detection of PE wear in total knee arthroplasties" Current Directions in Biomedical Engineering, vol. 7, no. 2, 2021, pp. 283-286. https://doi.org/10.1515/cdbme-2021-2072

[22] Fritzsche H, Barbazzeni B, Mahmeen M, Haider S and Friebe M (2021). A Structured Pathway Toward Disruption: A Novel HealthTec Innovation Design Curriculum With Entrepreneurship in Mind. Front. Public Health 9:715768. doi: https://doi.org/10.3389/fpubh.2021.715768

[23] Friebe M (2022). Biomedical Engineering Innovation Toolset – Exploration, Evaluation, and impact Generation: Using the HEALTH Purpose Launchpad. Workshop IEEE EMBC 2022, https://embc.embs.org/2022/sessions-and-workshops-information/theme-11/#11-1