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Deep Learning-enabled Ultrasound Imaging – Opportunities, Risks, and Challenges

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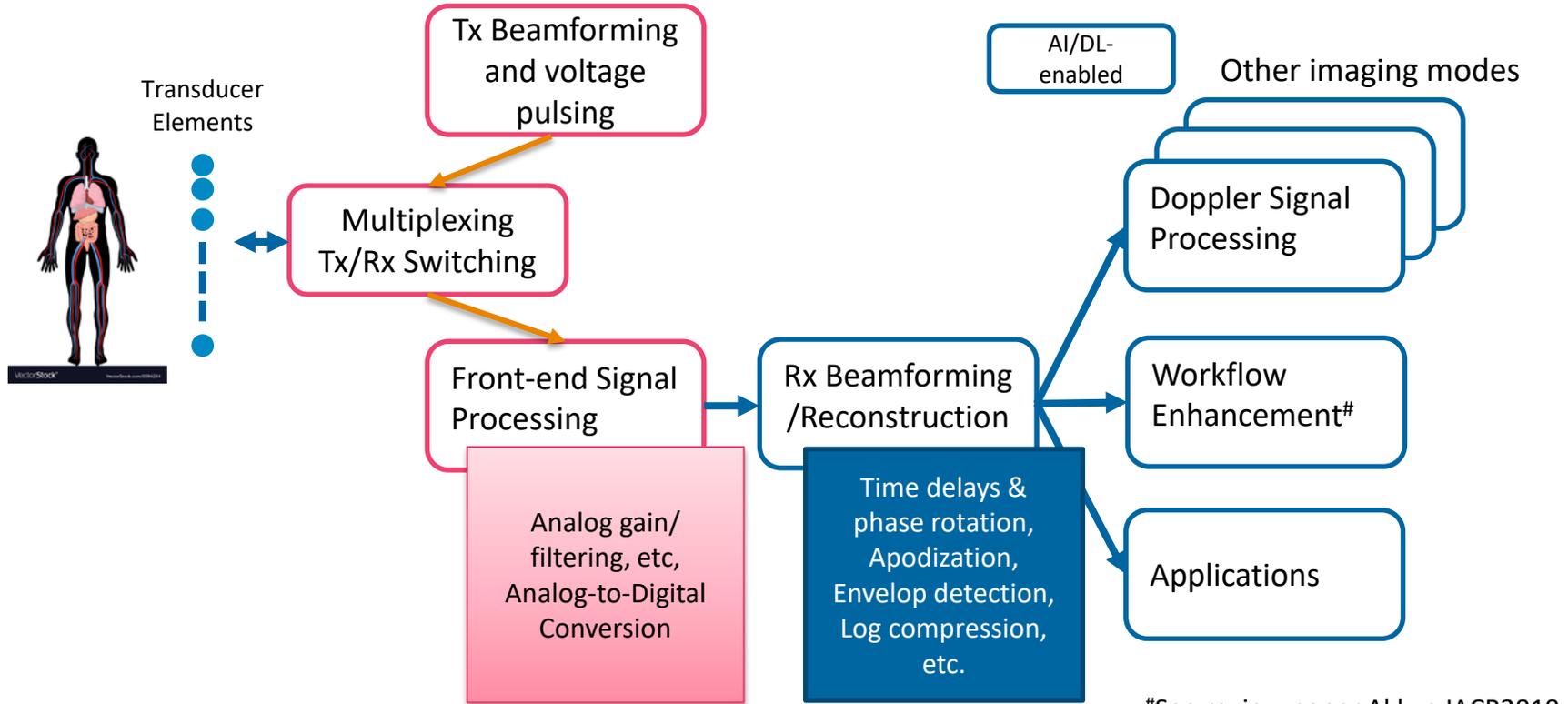
What ultrasound currently can offer and clinical users' demands



- Ultrasound imaging offers
 - Portable
 - Real-time and Interactive
 - Point-of-care diagnosis
 - Multi-functional
 - Cost-effective
 - No ionizing radiation
- Top clinical user demands (from Society of Radiologists in Ultrasound 2019)
 - Image quality (top priority)
 - Workflow
 - Applications (e.g. quantification, disease classification)
- How AI can satisfy some of these demands from image acquisition's perspective?



How Artificial Intelligence/Deep Learning has been used in ultrasound imaging?



#See review paper Akkus JACR2019
Tx: Transmit
Rx: Receive



Benefits of Using DL in Ultrasound Imaging

Engineering	Offer higher flexibility in development <ul style="list-style-type: none">• DL model can be used to develop one component of the imaging chain or end-to-end chain• DL model can operate on RF data, beamformed data, reconstructed images	More flexible, robust, and generalizable than classical image/signal processing methods
	More computationally efficient and robust <ul style="list-style-type: none">• Adaptive• Bypass complex mathematical model through learning by examples• Minimal manual parameter tuning• Intrinsically exploit hidden relationships in data	
	Replicate complex algorithm calculations in much shorter time	
	Minimal to none handcrafted feature extraction	
	Development can become more data efficient by leveraging existing knowledge on imaging physics and engineering (human intelligence)	
Clinical	<ul style="list-style-type: none">• Faster and easier image acquisition without sacrificing image quality• Emulate complex/expensive hardware with simpler/cheaper hardware• More streamlined workflow• More sophisticated applications	Better user experience for clinicians and quality of care for patients

Technological Challenges

	Technological challenges addressed/covered by existing regulatory frameworks:	Technological challenges that might require consideration with existing frameworks:
Data quality and governance	<ul style="list-style-type: none">• Validation dataset provenance, quality, and match to intended use	<ul style="list-style-type: none">• Training dataset provenance, quality, and match to intended use
Image quality evaluation	<ul style="list-style-type: none">• In validation and during ongoing clinical use	<ul style="list-style-type: none">• Adequacy of existing image quality evaluation method• Frequency of image quality check after release• Change in risk level w.r.t. intended use
Bias detection and correction	<ul style="list-style-type: none">• Check validation datasets and results for potential bias	<ul style="list-style-type: none">• Check training datasets and intermediate results for potential bias• Extrapolation of trained neural net to new data• Apply Good Machine Learning Practice



Regulatory Challenges

- Accelerated release of “retrained and refrozen” improvements within original intended use
- Regulatory submission preparation and review vs product development timeline
- Regulatory science development to align with the speed of technology advancement
- Balance between transparency and information overload

Outlook and Opportunities – for AI/DL-enabled radiological imaging devices



- Leverage and re-calibrate existing FDA's regulatory approaches and tools
 - Tools have already developed have set up a good foundation
 - How to make the best out of them?
- Agile quality evaluation and monitoring system
 - Combination of performance measures, monitoring, feedback, and mitigation mechanisms
 - Benefit-risk assessment framework adaptive to range of benefit and risk levels
 - Flexibility in Pre- and Post-market data to demonstrate TPLC safety and effectiveness
 - Real world performance
- Practice guide for data governance
 - Build trust on the data we used (and are going to use) in training and testing (representative, avoid bias, reflect clinical outcome)
- User education
 - User training, risk and benefit awareness, channels for reporting issues
- We share the responsibility to ensure patients' safety and well-being



Beamforming/Reconstruction



Purposes	Transform received ultrasound signals to images for diagnosis or for further processing		
Conventional methods and shortcomings	<ul style="list-style-type: none"> • Delay-and-Sum Beamforming - Low computational complexity and fast, but limited image quality • Minimum Variance (MV) Beamforming - Adaptive, but extremely computational complex, limit the application for real world (e.g. long reconstruction time for matrix-transducers) • Require full-sampling -> long acquisition time 		
How DL was used	<p>Estimate sub-sampled RF data by exploiting RF data redundancy in Rx-Tx and Rx-Scan Line domains through low rank Hankel matrix decomposition -> fast imaging</p>	<p>Increase reconstruction speed by 400 times by replacing the bottleneck (apodization weights calculation) in MV beamformer through mapping the weights for each pixel</p>	<p>Perform fast end-to-end reconstruction at MV beamformer quality with a medical ultrasound-specific loss function¹ through mapping time-delayed raw data to a minimum variance ground truth</p>
Training Input/target Data	Sub-sampled multi-line acquisition (MLA) data/original B-mode MLA data	Pre-delayed array response for a particular pixel/ corresponding array apodizations	Time-delayed channel data/ MV-beamformed data
References	Yoon IEEE TMI 2019	Luijten ICASSP 2019	Simson IEEE IUS 2018
DL offer	Improve beamforming/reconstruction speed and flexibility for better clinical workflow and expanded applications without sacrificing clinical image quality		

¹peak signal-to-noise-ratio (PSNR) loss, and the multi-scale structural similarity index (MS-SSIM) loss via a weighting factor

Doppler Signal Processing



Purposes	<u>Spectral Doppler</u>	<u>Tissue Doppler Echography Encoding</u>
	Estimation of blood and tissue velocity distributions from slow-time data sequences, i.e. a series of subsequent pulse-echo snapshots	Measure myocardial strain rate and tissue velocities for detecting epicardium-parietal pericardium border and quantification of stiffening of developing lesions
Conventional methods and shortcomings	<ul style="list-style-type: none"> Fourier-transform-based periodogram methods – fast but time-frequency resolution tradeoff Adaptive spectral estimators – better spectral estimate and resolution but computational complexity is high 	<ul style="list-style-type: none"> Phase estimate from pulse-to-pulse autocorrelation – noisy, limited accuracy, time-spatial resolution tradeoff
How DL was used	Solving for filter bank coefficients in adaptive spectral estimators to obtain spectral estimates	Learn Doppler measurements based on an encoder-decoder architecture w.r.t. Kasai autocorrelator
Training Input/ Target Data	Beamformed slow-time RF/ filter coefficients for each filter in the filter bank	IQ data ensemble/Kasai Doppler estimates (axial velocity)
References	van Sloun Proc IEEE 2019	van Sloun IEEE IUS 2018
DL offer	Provide computational efficient method while maintaining spectral estimate accuracy and resolution	Learn algorithm by example

Applications: Contrast-enhanced Imaging



Purposes	<p><u>Contrast-enhanced Ultrasound (CEUS)</u></p> <p>Image blood volume and flow at capillary level and provide quantitative information</p>	<p><u>Super-resolution Imaging/ Ultrasound Localization Microscopy</u></p> <p>Image deep vasculature at very high (mm) resolution</p>
Conventional methods and shortcomings	<ul style="list-style-type: none"> • Second harmonic imaging to separate non-linear response of microbubbles from tissue's – but tissue also exhibits nonlinear response • Spatio-temporal filtering (SVD) – threshold settings for tissue and blood signals depend on scans and subjects & require many iterations to converge 	<ul style="list-style-type: none"> • Identify centroid of PSF from sparse microbubbles and project over time – but sparse bubble paradigm significantly increases scan times (practically non-viable) • High-density microbubble paradigm leads to blurry image due to extensive microbubble PSF overlap
How DL was used	<p>Solve the convolution in PCA for the decomposition problem for tissue & blood signals through backpropagation</p>	<p>Locate PSF centroid based on simulation of an encoder-decoder architecture</p>
Training Input/ Target Data	<p>Beamformed images/Simulated and in-vivo decomposition of tissue and blood signals</p>	<p>Synthetic down-sampled RF CEUS signals/ super-resolved microbubble locations with varying density, intensity</p>
References	<p>Li ICASSP 2019, vanSloun ProcIEEE 2019</p>	<p>vanSloun ICASSP 2019, Errico Nature 2015</p>
DL offer	<p>Remove clutter signals from stationary or slowly moving tissues in a computationally efficient, robust, and adaptive way</p>	<p>Obtain super-resolution image in near real time from high-density microbubble paradigm</p>