

ONSUScan: Noninvasive ICP Monitoring with Ultrasound and AI

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Abstract:

Intracranial pressure (ICP) monitoring is critical in neurological care, but current invasive methods carry inherent risks. Optic Nerve Sheath Ultrasonography (ONSUS) offers a noninvasive alternative by measuring optic nerve sheath diameter (ONSD), which correlates with ICP. This paper introduces ONSUScan, a novel device integrating high-frequency ultrasound (US) and advanced AI algorithms for real-time image processing and precise ICP estimation. The device's design, clinical applications, and future prospects are discussed, emphasizing its potential to enhance patient safety and clinical outcomes in ICP monitoring.

Keywords: *Intracranial Pressure (ICP), Optic Nerve Sheath Diameter (ONSD), Optic Nerve Sheath Ultrasonography (ONSUS), Non-invasive, Ultrasound imaging, Convolutional Neural Networks (CNNs), Wavelet-based denoising, Auto-segmentation, Transfer learning*

Introduction:

Elevated intracranial pressure (ICP) constitutes a critical determinant of patient outcomes across various neurological conditions, including traumatic brain injuries (TBI), hydrocephalus, and intracranial hemorrhages (ICH) (Lee & Kim, 2020). Effective monitoring of ICP is imperative for the management of these conditions, as timely detection and intervention are essential to mitigate risks such as brain herniation and mortality. However, conventional methods for monitoring ICP, despite their accuracy, are associated with significant invasiveness and potential complications, including infection, hemorrhage, and brain tissue damage (Paganini & Hutchinson, 2016). Optic Nerve Sheath Ultrasonography (ONSUS) presents a promising non-invasive alternative by exploring the anatomical relationship between the optic nerve sheath (ONS) and ICP.

This paper focuses on the development of ONSUScan, a novel device designed to capture ultrasonography (US) images of the ONS. ONSUScan integrates advanced artificial intelligence (AI) algorithms tailored for image denoising and analysis, facilitating precise estimation of ICP. The device's innovative approach aims to enhance clinical practice by offering accurate and non-invasive ICP monitoring capabilities, potentially transforming the management of neurological conditions associated with elevated ICP.

Background:

Traditional methods for monitoring ICP, such as intraventricular catheters (IVC) and lumbar punctures (LP), while accurate, are highly invasive procedures associated with significant risks.

IVC are inserted through a burr hole into the ventricles of the brain, allowing direct measurement of cerebrospinal fluid (CSF) pressure. This invasive procedure carries risks of infection, hemorrhage, and damage to brain tissue due to the surgical insertion and subsequent presence of the catheter. Lumbar punctures involve inserting a needle into the subarachnoid space in the lumbar region to measure CSF pressure. This procedure is prone to complications such as post-dural puncture headaches, infection, and nerve damage (Paganini & Hutchinson, 2016). Furthermore, both IVC and LP require skilled medical personnel and specialized equipment, making them impractical in resource-limited settings where neurosurgical expertise and infrastructure are scarce.

The ONS envelops the optic nerve and communicates with the subarachnoid space, facilitating the flow of CSF between the brain and the optic nerve (Figure 1). Elevated ICP causes the ONS to expand, a phenomenon quantified as ONSD, which correlates with increased ICP (Lee & Kim, 2020; Zhang et al., 2019). This relationship is grounded in the Monro-Kellie doctrine, which posits that the cranial vault maintains a fixed volume, necessitating compensation for changes in brain tissue, blood, or CSF volume to sustain ICP (Mokri, 2001.)

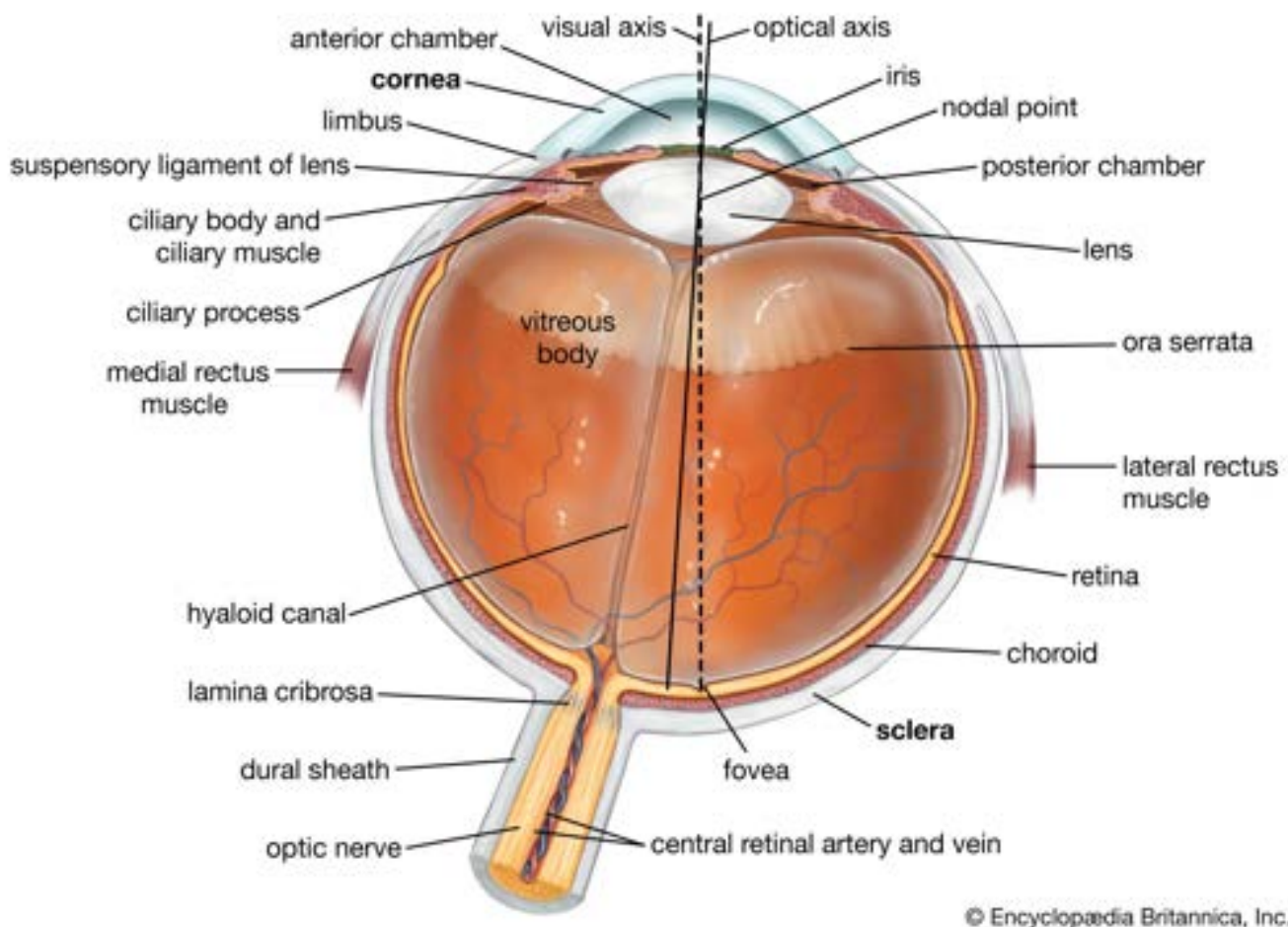


Figure 1: *Anatomy of the ONS, Britannica*

ONSUS involves placing a high-frequency US probe on the closed eyelid, emitting sound waves that penetrate ocular tissues and generate an image of the ONS on a screen (Appia et al.,

2019). The diameter of the ONS is measured from this image, providing an indirect assessment of ICP.

Inspired by real-world challenges with military conflict and resource-limited countries where neurosurgical care is limited, ONSUScan aims to provide a safer and more accessible alternative for ICP monitoring by leveraging existing US technology and integrating advanced AI algorithms.

Protocol:

The ONSUScan protocol enhances the functionality of existing US equipment available in clinical settings for non-invasive ICP monitoring. Central to this protocol is a high-frequency US probe operating within the frequency range of 7.5 to 10 MHz, which emits sound waves penetrating ocular tissues to generate detailed images of the ONS. Complementing this, a high-resolution digital camera captures these US images with precision, ensuring clarity for optic nerve sheath diameter measurements.

Component	Specification
Ultrasound Probe	Frequency: 7.5-10 MHz
Camera	High-resolution digital camera
Processing Unit	High-performance GPU for real-time processing
AI Framework	TensorFlow/PyTorch

Table 1: *ONSUScan Device Specifications*

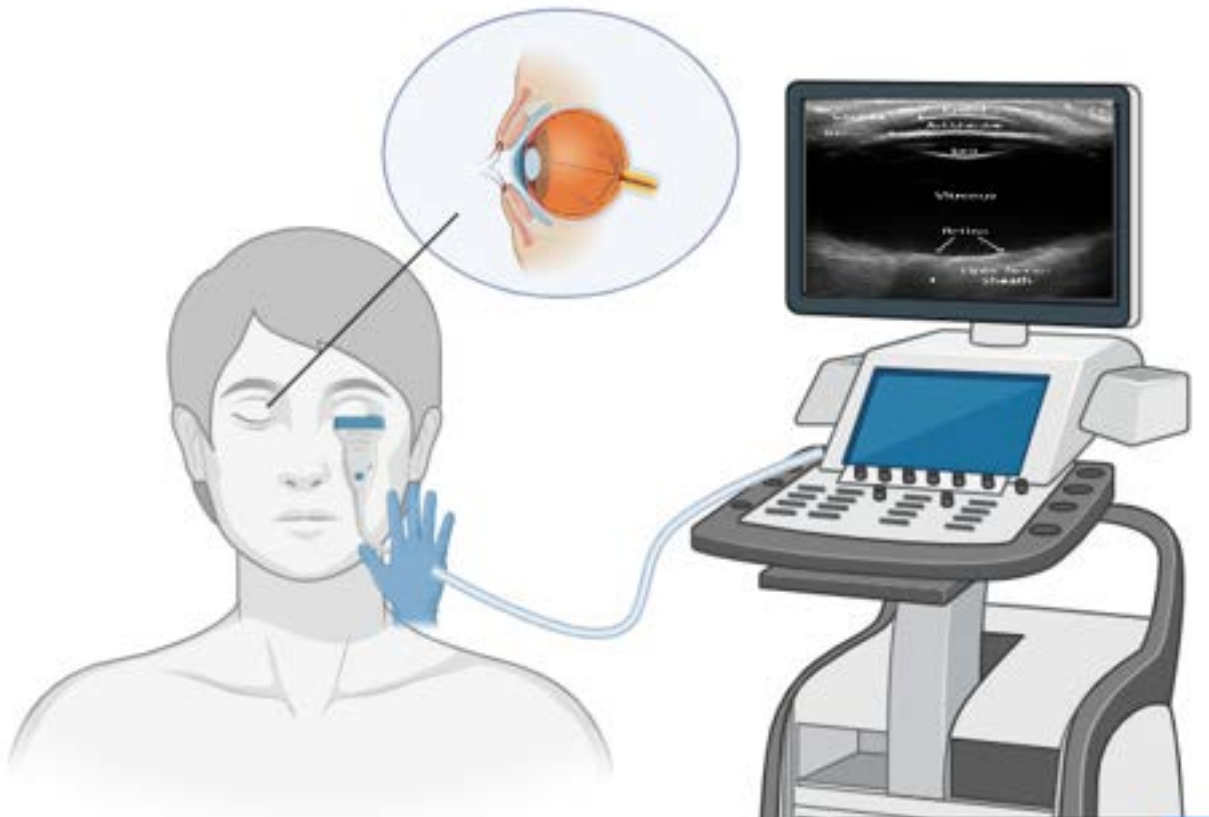


Figure 2: *ONSUScan Device Imagined*

Designed to integrate seamlessly with existing US systems, the ONSUScan protocol includes an intuitive user interface that guides healthcare providers through the monitoring procedure. Real-time feedback on image quality ensures optimal probe placement and image acquisition, crucial for accurate ONSD measurements. Automatic ONSD measurements reduce operator variability, enhancing measurement consistency and reliability in clinical settings (Zhang et al., 2019). The protocol also features a historical data display for trend analysis, enabling healthcare providers to monitor ICP dynamics over time and tailor treatment strategies accordingly.

The ONSUScan procedure begins with positioning the patient supine and slightly elevating the head for optimal US probe placement. The healthcare provider then gently positions the US probe on the closed eyelid to initiate image acquisition. Sound waves emitted by the US probe penetrate ocular tissues and reflect off the boundaries of the ONS, generating real-time images on the device's screen. These images undergo AI-driven denoising algorithms to remove artifacts and enhance clarity, preparing them for subsequent analysis. The integrated AI system analyzes the denoised images to measure the ONSD, which is then matched to a trained algorithm estimating the ICP value. The estimated ICP value is promptly displayed on the device's screen, providing immediate insights for clinical decision-making

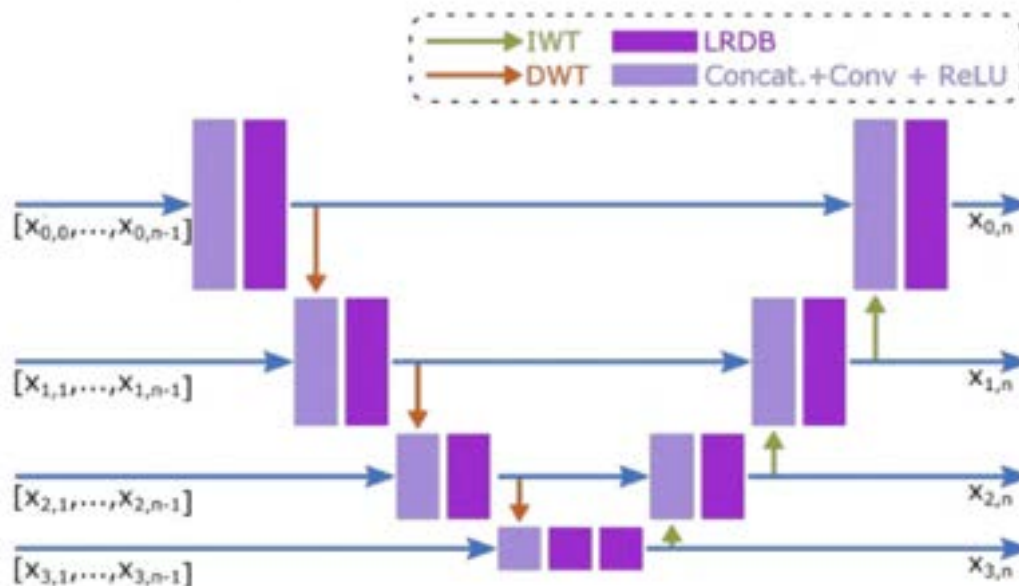
Algorithm:

Noise and Artifact Reduction

US images are susceptible to various types of noise and artifacts such as speckle noise, shadowing, and reverberation (Singh & Awasthi, 2019). Addressing these challenges, the ONSUScan protocol employs AI algorithms for image denoising and analysis.

Convolutional Neural Networks (CNNs) excel at feature extraction from noisy images. By passing the image through multiple convolutional layers, CNNs can learn to identify meaningful patterns despite the presence of noise (Lv et al., 2019). Open-source frameworks like TensorFlow provide pre-trained CNN models for image-denoising tasks, which can be leveraged as a starting point for fine-tuning specific to ONSUScan (Abadi et al., 2016; Paszke et al., 2019)

Architectures like autoencoders and U-Nets, such as DDUNet (Jia, Wong, and Zeng, 2021) are specifically tailored to enhance image quality by learning compressed representations and reconstructing denoised images (Ronnenberger et al., 2015; Lv et al., 2019). Autoencoders learn a compressed representation of the image, effectively encoding the underlying structure. The decoder then reconstructs the image from this compressed representation, removing noise in the process. U-Nets, a variation of autoencoders, incorporate skip connections that preserve spatial information, leading to superior image-denoising performance (Ronneberger et al., 2015).



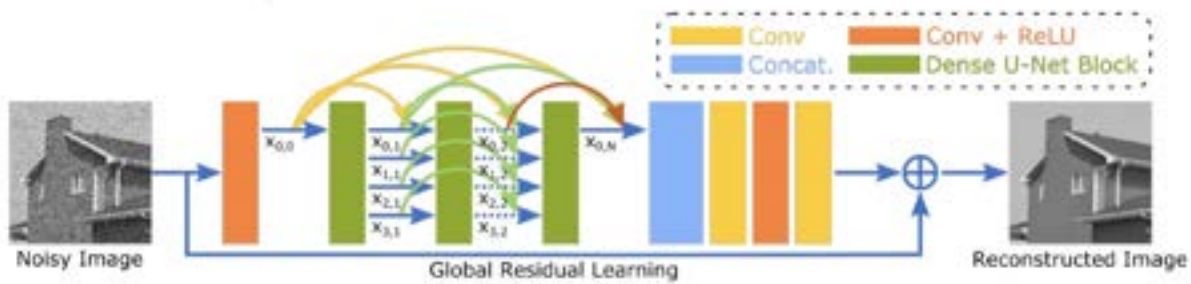


Figure 3: Example U-net Diagram for Image Denoising, (Jia, Wong, and Zeng, 2021)

Generative Adversarial Networks (GANs) further augment image quality by employing a dual-network framework, effectively pitting two neural networks against each other: the generator creates denoised images, while the discriminator distinguishes between real and generated images, enhancing the realism and accuracy of the denoising process (Goodfellow et al., 2014; Zhang et al., 2018). This adversarial training results in refined, noise-free images suitable for precise measurement of ONSD.

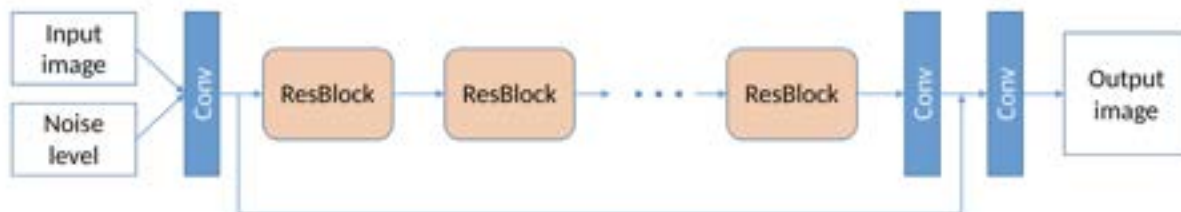


Figure 4: Example GAN Generator Architecture (Linh, Tran Duy et al, 2020)



Figure 5: Example GAN Discriminator Architecture (Linh, Tran Duy et al, 2020)

Furthermore, Wavelet-based denoising can transform an image from the spatial domain to the wavelet domain, where noise and signal components can be distinctly separated due to their different characteristics. In the wavelet domain, noise typically appears as high-frequency components, whereas the actual signal manifests as low-frequency components. This distinct separation allows for the selective removal of noise by thresholding or attenuating the high-frequency coefficients while preserving the low-frequency coefficients that represent the true image details (Mallat, 2009; Singh & Kaur, 2013). The process involves decomposing the image into multiple scales using wavelet transforms, applying denoising techniques at each

scale, and then reconstructing the image from the modified wavelet coefficients. Open-source libraries such as SciPy in Python provide robust and efficient wavelet transform functionalities, which can be seamlessly integrated into the ONSUScan application to enhance its performance by effectively reducing speckle noise in US images (Virtanen et al., 2020).

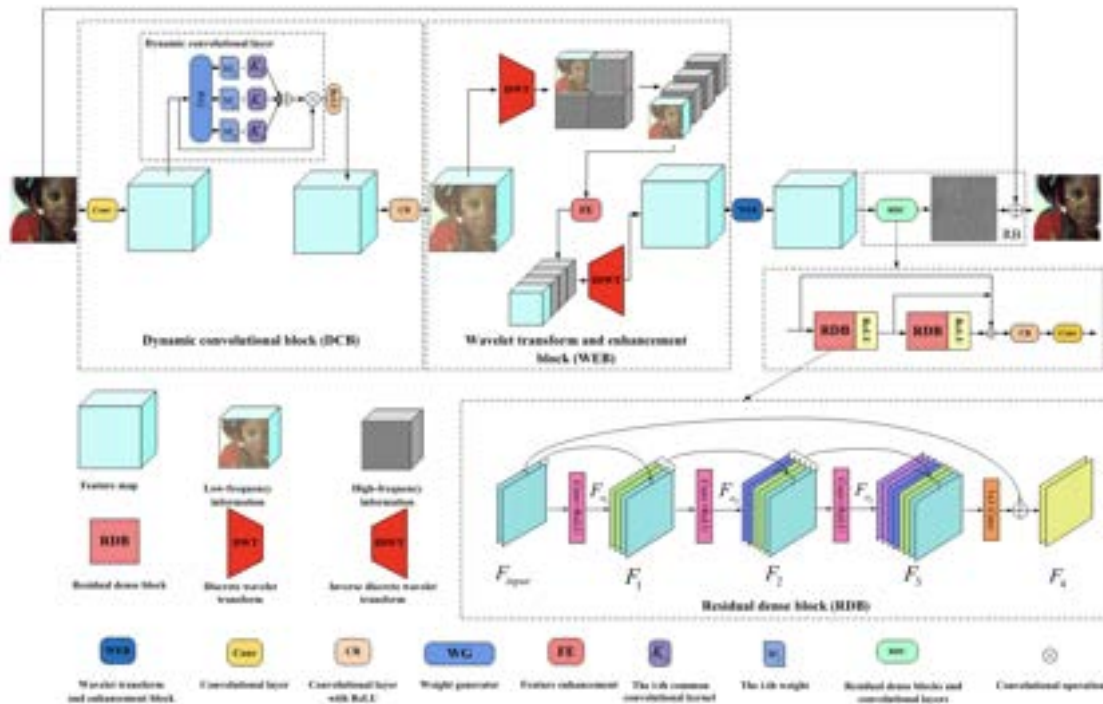


Figure 6: Example Architecture for Wavelet-Based De-Noising (Chunwei et al, 2023)

Image Analysis and ICP Estimation

Following denoising, the AI system proceeds with image analysis to estimate ICP through accurate measurement of ONSD. This involves auto segmentation techniques where a dataset of segmented ONSD images is prepared using tools such as ITK-Snap, facilitating automated segmentation in new images. Initially, a threshold-based classification approach identifies ONSD values indicative of elevated ICP, typically above 5 mm in adults, corresponding to pressures exceeding 20 mmHg (Lee & Kim, 2020). Currently, technology exists for measuring the ONSD through image enhancement algorithms that can produce a relative measurement in ~60 seconds, (Stevens, et al., 2021) but new technologies have yet to be developed using threshold-based auto-segmentation algorithms.

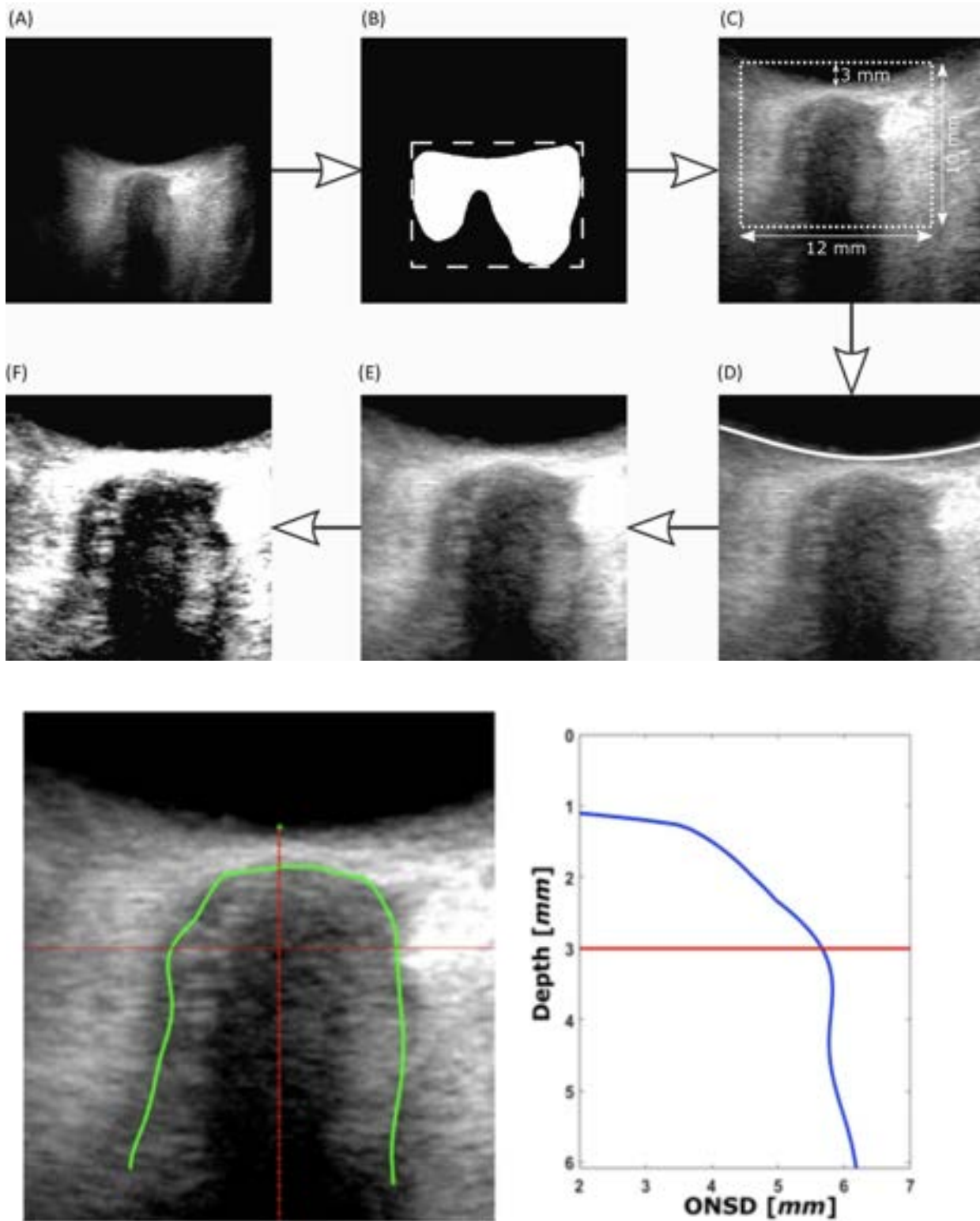


Figure 6: Image-Enhancement-Based ONSD Measurement (Stevens et al., 2021)

Advanced regression models using Gradient Boosting Machines (GBMs) are concurrently developed to predict precise ICP values based on ONSD measurements and extracted image features. GBMs involve sequentially building an ensemble of models. However, unlike random forests, each new model in the ensemble learns to correct the errors of the previous models, leading to potentially more accurate predictions (James et al., 2013). XGBoost, a popular GBM implementation, is known for its efficiency and scalability, making it a strong candidate for ICP prediction in ONSUScan. Open-source libraries like scikit-learn and XGBoost themselves provide functionalities for building and training GBM models (Pedregosa et al., 2011; Chen & Guestrin, 2016).

Transfer learning techniques are employed to leverage pre-trained models on extensive image datasets, accelerating training and enhancing overall system performance (Pan & Yang, 2010). Instead of developing the AI algorithms from scratch, ONSUScan integrates established models and frameworks available in the market. For instance, frameworks like TensorFlow and PyTorch provide access to pre-trained convolutional neural networks (CNNs), autoencoders, and U-Nets, which have been fine-tuned on large-scale image datasets (Abadi et al., 2016; Paszke et al., 2019). These models are adapted and optimized specifically for ONSUScan to ensure robust noise reduction, accurate segmentation, and reliable ICP estimation steps, resulting in consistent and clinically relevant outcomes.

Preprocessing/Training:

Preprocessing and training the AI algorithms for ONSUScan involves several critical steps to ensure robust performance and generalizability across diverse patient populations. Initially, a comprehensive dataset of ultrasound images is collected, encompassing variations in noise levels and artifacts commonly encountered in clinical settings (Litjens et al., 2019). These images are meticulously annotated with ground truth measurements of ONSD using ITK-Snap and corresponding ICP values to facilitate supervised learning (Litjens et al., 2019).

To enhance the model's robustness and ability to generalize, data augmentation techniques are employed. These techniques involve applying transformations such as random flips, rotations, and scaling to augment the dataset (Shorten & Khoshgoftaar, 2019). By introducing diverse variations into the training data, ONSUScan becomes more adept at handling unseen scenarios, thereby reducing the risk of overfitting and improving its ability to accurately estimate ICP (Baxter, 2000).

Once the dataset is prepared and augmented, it is partitioned into training, validation, and testing sets. The training set is used to train the AI model, while the validation set is crucial for fine-tuning hyperparameters and optimizing the model's architecture (James et al., 2013). Cross-validation techniques are applied to ensure the model's robustness and to mitigate overfitting by validating its performance across different subsets of the data (Kohavi, 1995). Evaluation metrics such as mean squared error (MSE) and R-squared are employed to quantitatively assess the model's accuracy in predicting ICP values from denoised US images (Chai & Draxler, 2014). This rigorous preprocessing and training regimen forms the foundation

for ONSUScan's AI algorithms, ensuring reliable and clinically relevant outcomes in ICP estimation.

Limitations/Considerations:

ONSUScan faces several technical limitations that must be addressed for its effective deployment in clinical settings. US image quality is susceptible to various factors such as patient movement, eyelid thickness variations, and operator-dependent variability, all of which can impact the accuracy and consistency of ONSD measurements. Standardized training protocols are essential to mitigate these issues and ensure uniformity across operators. Additionally, the performance of AI algorithms embedded within ONSUScan may suffer when confronted with highly noisy or low-quality images, necessitating ongoing algorithmic refinement to enhance robustness and reliability.

Clinical validation studies are imperative to validate ONSUScan's accuracy and reliability across diverse patient demographics and clinical environments. Variations in the correlation between ONSD measurements and actual ICP levels based on patient age, underlying pathologies, and treatment modalities necessitate comprehensive research to establish diagnostic efficacy.

Ethical considerations surrounding ONSUScan's use include securing patient consent for image acquisition and data storage, as well as safeguarding patient confidentiality and data security. Addressing legal aspects such as liability issues in case of device malfunction or misinterpretation further underscores the need for meticulous regulatory adherence and operational transparency.

Operator dependence remains a pivotal concern despite ONSUScan's intuitive interface. The accurate placement of the US probe and precise image acquisition heavily rely on the skill and experience of healthcare providers. Therefore, implementing standardized training programs is essential to ensure consistent and reliable results across different clinical settings. Moreover, challenges such as US window limitations due to anatomical variations or injuries near the eye can hinder image acquisition, potentially compromising the accuracy of ONSD measurements. While ONSD measurements often serve as indicators of elevated ICP, their specificity as a standalone diagnostic tool may be limited by factors such as variations in intracranial blood volume, necessitating complementary clinical evaluations for comprehensive patient assessment. Integrating ONSD data with other physiological parameters through multimodal approaches promises to provide a more comprehensive assessment of ICP dynamics and distinguish between different etiologies of ONSD enlargement. Furthermore, achieving FDA regulatory approval is pivotal for advancing ONSUScan toward widespread clinical adoption, ensuring adherence to stringent medical device regulations, and mitigating potential legal complexities.

Conclusion:

ONSUScan represents a significant advancement in non-invasive ICP monitoring technology, poised to transform neurological care. Despite existing challenges and the need for ongoing

refinement, the device holds immense potential for improving patient outcomes and healthcare efficiency. By leveraging advanced AI algorithms and existing US technology, ONSUScan offers a safe and accessible alternative to invasive procedures, enhancing diagnostic accuracy and patient comfort. This innovation not only promises to reduce healthcare costs associated with traditional monitoring methods but also opens doors to telemedicine applications and global health equity by expanding access to specialized neurological care. As research and development efforts continue, ONSUScan stands at the forefront of innovation, heralding a future where precise, real-time ICP monitoring becomes integral to the management of neurological conditions worldwide.

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