VALIDATION OF QYSCORE®'S FULLY AUTOMATED QUANTITATIVE IMAGE SEGMENTATION TOOLS AGAINST AN EXPERT MANUAL GOLD-STANDARD

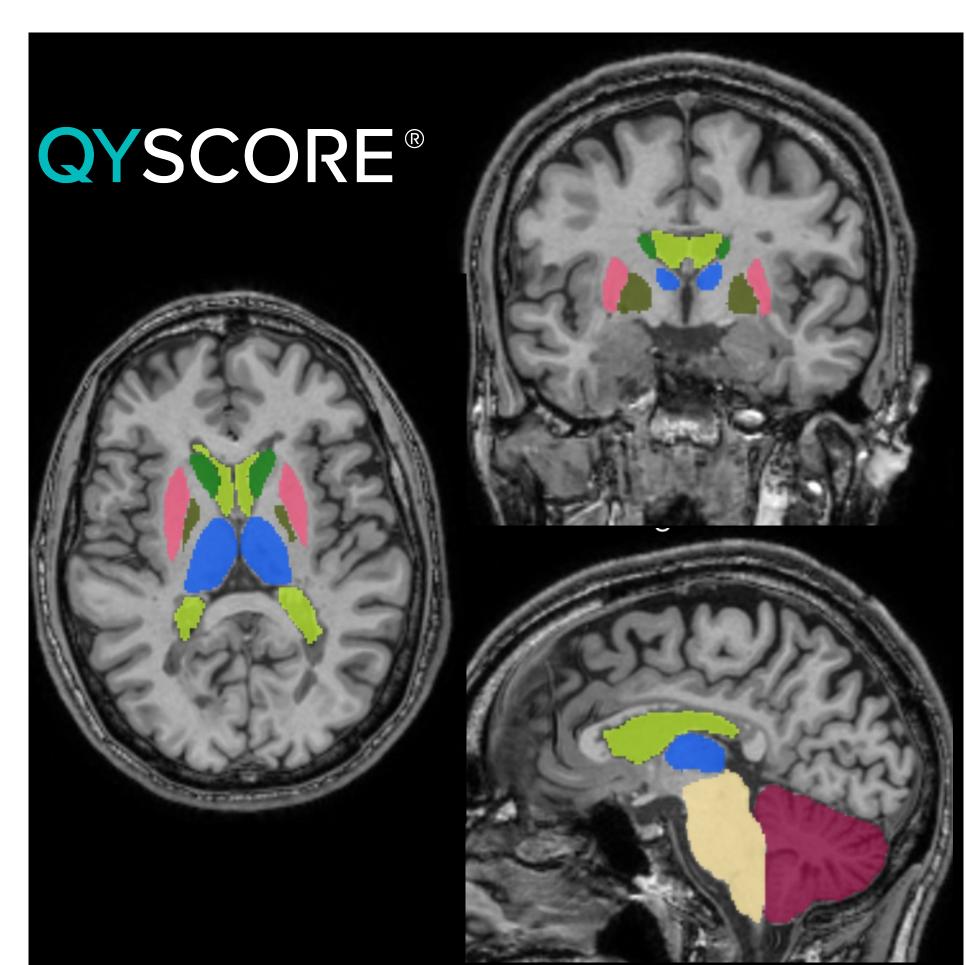
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BACKGROUND

- Quantitative imaging provides valuable information for early detection, improved confidence in diagnosis, disease progression and treatment response monitoring.
- Measurement of key subcortical regions have been shown to be particularly sensitive to early changes across the spectrum of neurodegenerative dementias
- Manual segmentation is the current gold-standard, but is prohibitively labour-intensive for large scale use, such as in clinical routine, and suffers from individual variability.
- Thus, there is a substantial unmet need for validation of automatic segmentation techniques that perform as accurately as this labour-intensive manual gold-standard and the certification of such algorithms to support patient assessment in clinical routine



RESULTS

- Results demonstrated a high degree of agreement between the consensus manual gold-standard and QyScore®'s automated segmentation as evidenced by uniformly high DSC score (0.81 0.95) (Table 1)
- A strong concordance between the volumes, expressed as a percentage of intracranial volume (%ICV), was obtained across all seven structures (Table 1: Figure 1).
- This agreement remained consistent following stratification by field strength, demonstrating generalizability to most clinical imaging centres.
- The DSC for all seven structural markers was equivalent to or higher than the currently reported state-of-the-art automated segmentation methods for each marker²

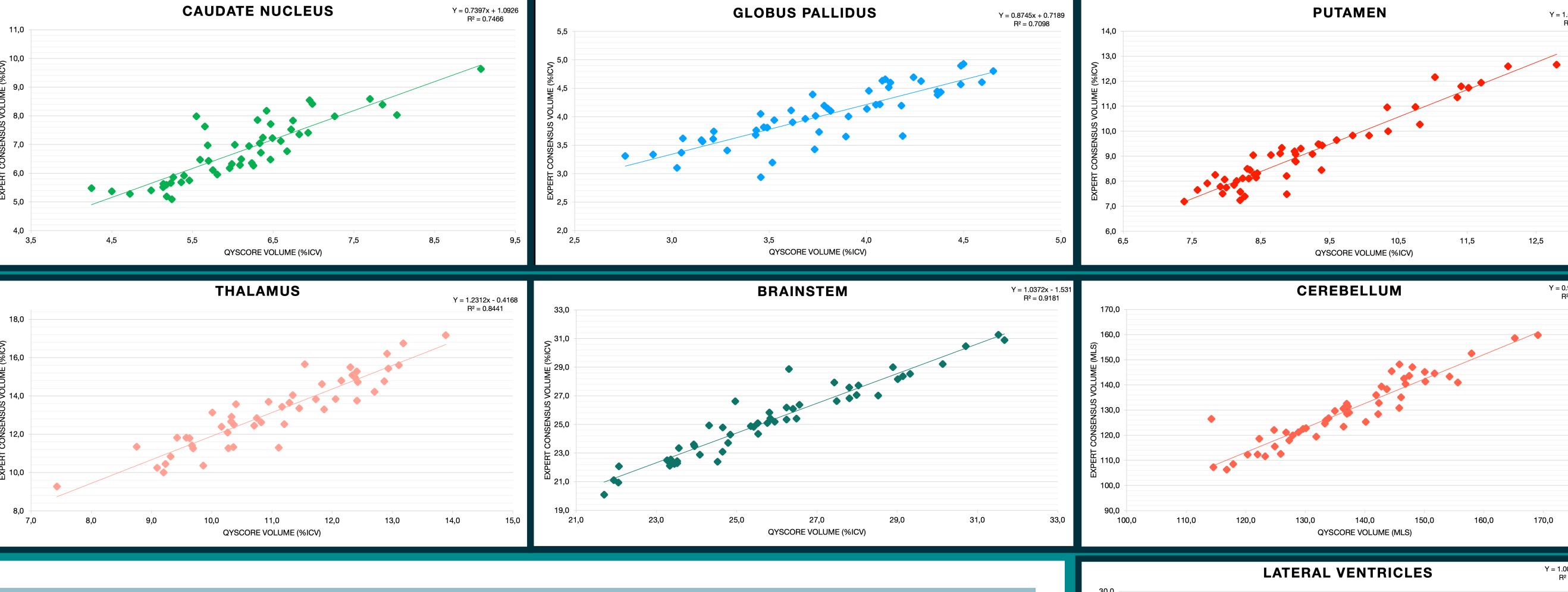


Table 1. Dice Similarity Coefficient and R2 for QyScore®'s fully automated segmentation structural segmentations compared with the gold-standard consensus of three expert neuroradiologists DSC Mean (standard deviation) Caudate 0.82 (0.03) 0.87, 0.89

	(standard deviation)		
Caudate	0.82 (0.03)	0.82, 0.84	0.75
Putamen	0.88 (0.03)	0.87, 0.89	0.91
Globus Pallidus	0.81 (0.06)	0.80, 0.83	0.71
Thalamus	0.86 (0.01)	0.86, 0.87	0.84
Cerebellum	0.95 (0.02)	0.94, 0.95	0.87
Brainstem	0.94 (0.02)	0.94, 0.94	0.92
Lateral Ventricles	0.91 (0.03)	0.92, 0.93	0.99

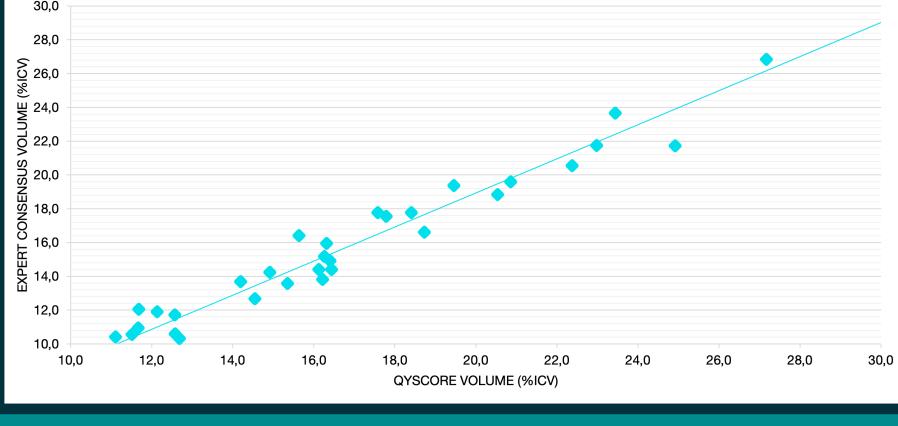


Figure 1. Regression analysis plotting volumes, expressed as a percentage of intracranial volume (%ICV), derived from the gold-standard consensus of three expert neuroradiologist' manual segmentations (y-axis), against QyScore®'s fully-automated U-Net based segmentation algorithm (x-axis) for each of the seven regional markers

References: [1] Warfield et al., (2004) IEEE Trans Med Imaging, 23(7):903-21 [2] Internal literature review: results available on request egordon@gvnapse.com

OBJECTIVES

To validate fully automated U-Net segmentation algorithms against expert manual gold-standard segmentations for inclusion into QyScore®, an FDA-approved and CE-marked neuroimaging medical device.

METHODS

The validation cohort consisted of 50 individuals (mean age: 50.39y \pm 21.01, range: 18y–86y, 48% female), with Alzheimer's Disease (n=4), Parkinson's Disease (n=3), Multiple Sclerosis (n=6), and Healthy Controls (n=37).

• Data were acquired across multiple scanners, with balanced magnetic field strength (48% 1.5T, 52% 3T)

Three expert neuroradiologists manually segmented the caudate, putamen, globus pallidus, thalamus, cerebellum, brainstem, and lateral ventricles on 3DT1 images using itk-SNAP software.

• Consensus expert segmentation was derived using the STAPLE (Simultaneous Truth and Performance Level Estimation) algorithm1 for each region and segmentations and volumes compared with the fully automated segmentations utilizing a U-Net convolutional neural network architecture within QyScore®

Performance was investigated using the Dice Similarity Coefficient (DSC) and concordance assessed with plotted linear regression.

CONCLUSIONS

QyScore® produces fast reliable automated segmentations with comparable accuracy to the consensus of expert neuroradiologists.

These findings support the implementation of QyScore® in clinical trials and clinical routine to provide fully automated quantitative image analysis in support of diagnosis and monitoring of disease progression and treatment response.