

Empowering Quantitative Imaging Challenges and Lessons Learned

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Objective

Small Business Viewpoint for Commercialization and Routine Clinical Use of Quantitative Imaging

- Hurdles and Lessons Learned
- Progress
- Path to Clinical Use



1. Clinical Validation

- Moving Medical Imaging from Visual to Quantitative Practice
 - Standard protocols for examination, relative measures
 - Correcting variability in scanner acquisition, quantitative output
 - Phantom Analysis
- Validation studies (Academic, Industry)
 - Imaging control of study
 - Training CROs



Airway Segmentation



04/26/11

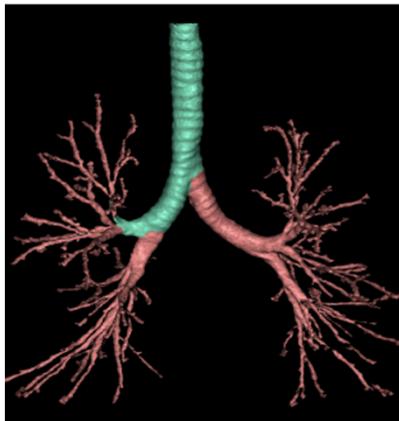
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DIAGNOSTICS
The Leader in Pulmonary Image Analysis and Therapy Planning

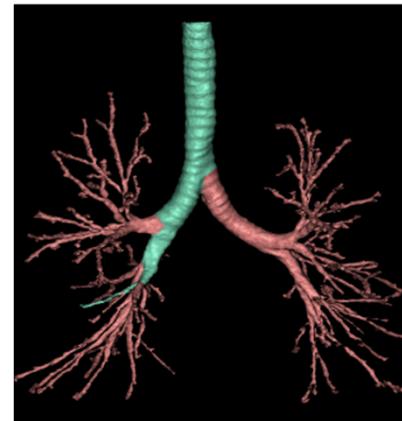


Automatic 6-Path Measurement

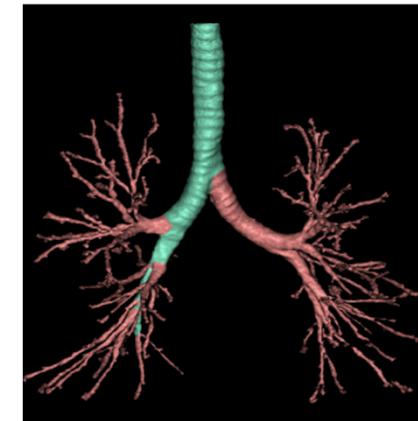
RB1



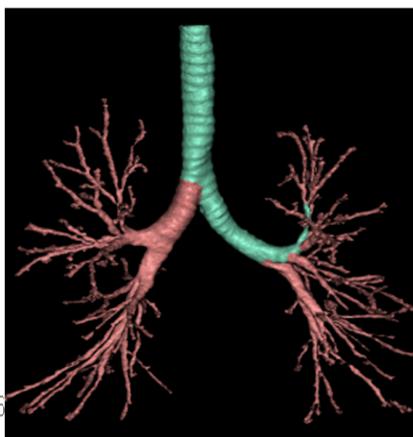
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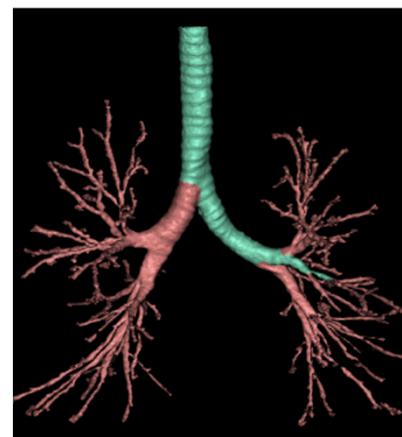
RB10



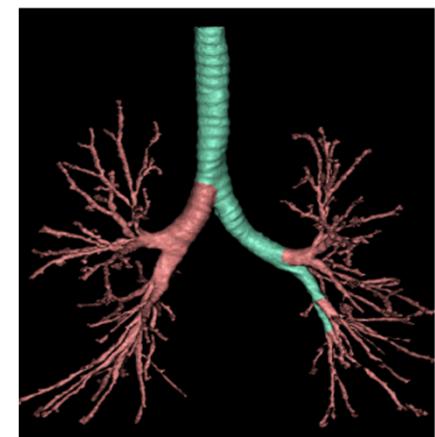
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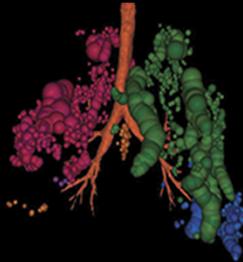


LB4



LB10



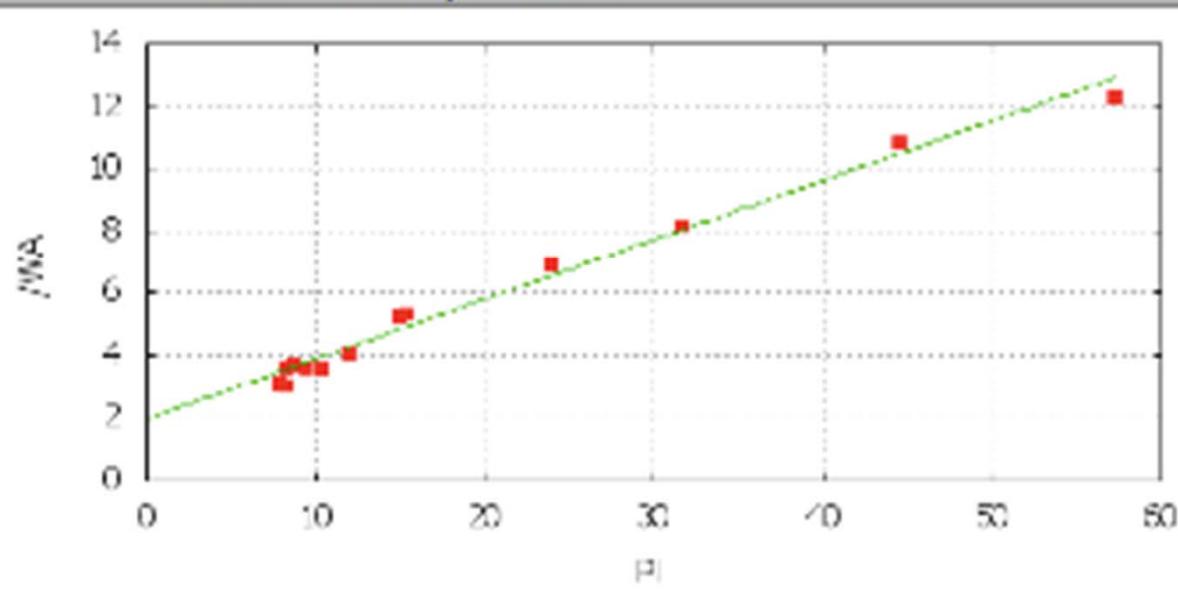


Automatic 6-Path Measurement

	Average Inner Area (mm ²)	Average Inner Perimeter (mm)	Luminal Eccentricity	Average Wall Thickness (mm)	Wall Area (mm ²)	Wall Area %
Trachea	254.84	57.25	0.86	2.27	151.6	37.36
RMB	148.07	44.48	0.85	2.15	117.88	44.32
BronInt	70.74	31.62	0.57	1.8	67.11	48.69
RLL7	41.52	23.98	0.68	1.65	47.27	53.27
RB10	16.75	15.36	0.62	1.42	28.5	62.99

Global Pathway Measures

SQRT(WA)@Pi10 = 3.58mm





2. Regulation

Opportunities

- Working with FDA for reasonable guidance
- Entering the FDA discussion early with collaboration
- Reenergizing the QI innovative process

Successes

- Requirement for validation for QI and automation
- Turnover
- Some QI Approvals (iCAD, HOLX)



3. EU Exodus

- Innovation commercializing in EU first
 - Clearly defined regulatory path
 - More immediate revenues
 - Less financial/investment risk
- Business plan adjustments



4. Changing Consumers, Changing Requirements

- Consumers of QI information are expanding
 - Referring physician, patient
 - Consumability requirements differ (e.g., vol v. planar)
 - Structured, quantitative, interactive reporting
 - Dataflow changes
 - Consultative radiology, reach out to referring



4. Changing Consumers, Changing Requirements





4. Changing Consumers, Changing Requirements

- Market/sell to referring physicians and pull through to radiology
- Does the reimbursement change
- Do the budgets change
- Value proposition to radiology/pulmonology/patient with better accuracy and efficiency in collaboration

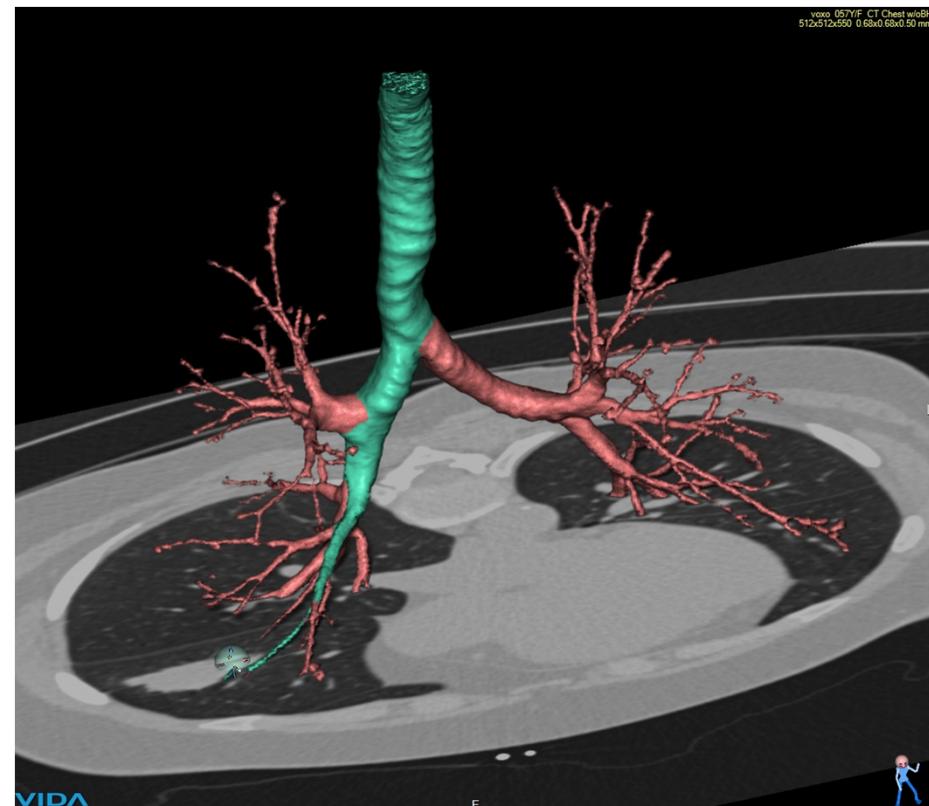


5. Reimbursement

- Therapy – More easily reimbursed
- Diagnosis – Automated measurement and follow up, incorporated in scan
- Screening – Automation, reimbursement (?)



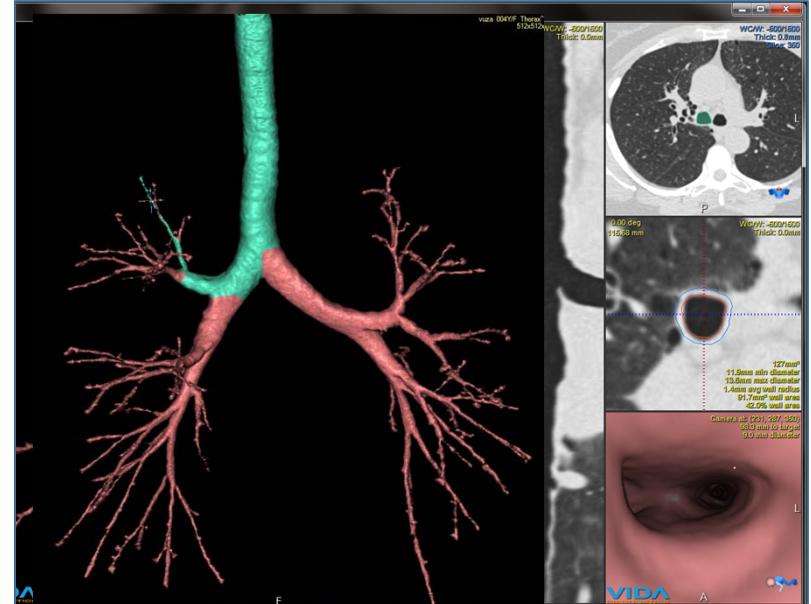
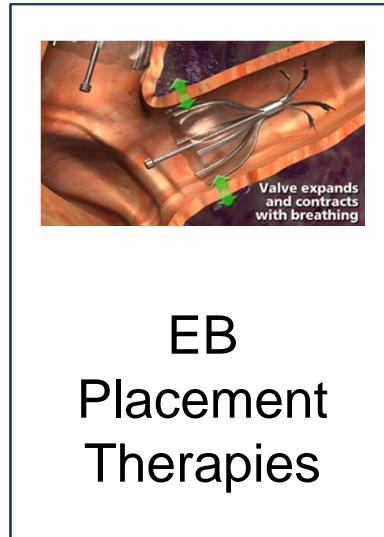
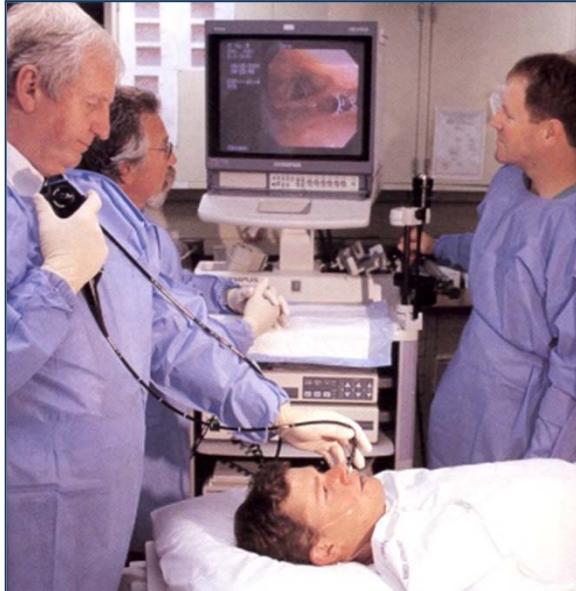
Navigationally-guided peripheral lung access





Guided Interventional Therapies

Targeting Personalized Therapies





6. Building Markets and Financing

- Difficult if aiding a device
- Regulation
- Funding (near-term revenue)
- Collaboration v. Infighting