OLYMPUS

Quantitative CT Analysis

Patient Selection with SeleCT

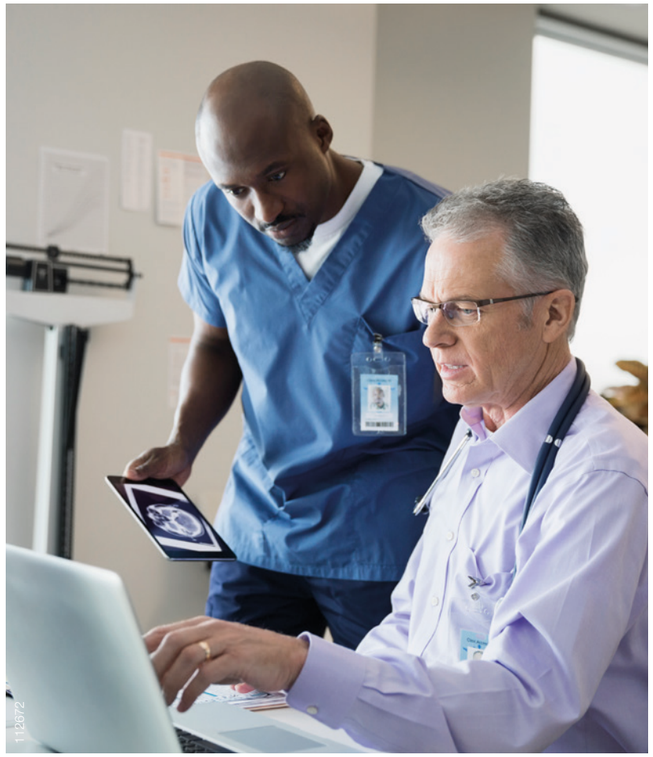
For the Treatment of Severe Emphysema

112677

Patient Selection

The Key to Successful Patient Outcomes

SeleCT is a completely non-invasive patient screening solution that provides key measures of emphysema severity, heterogeneity. These measures are provided in an easy-to-read report to assist physicians with selecting qualified patients and potential target lobes for improved outcomes using bronchoscopic lung volume reduction (BLVR). SeleCT is a quantitative CT service that offers rapid results and includes a qualified overread by a trained medical professional.



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SeleCT

SeleCT provides a method for clinicians to submit high-resolution computed tomography (HRCT) scans and receive quantitative measurements to support visual readings of lung structures. This process is known as quantitative CT (QCT) analysis.

This helps confirm patient eligibility and identify the correct target lobe for endobronchial valve treatment.

QCT is reproducible and concordant with visual CT analysis.[1]

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Patient Selection

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Proper patient selection is crucial for the success of endobronchial valve treatment, not only to achieve a good response to therapy but also to reduce risks and complications.

Criteria to determine eligible patients for the treatment are based upon findings from clinical studies, specifically established by the EMPROVE clinical trial.[2] These recommendations are not meant to replace patient-specific clinical judgement.

Patient Evaluation

The inclusion and exclusion criteria used in the EMPROVE clinical trial serves as a guide to determine patient eligibility.[2]

Inclusion Criteria	
Medical History and Physical Exam	• ≥40 years of age • Diagnosed with severe emphysema • Considered to be "stable" COPD as defined by the ATS/ERS Guidelines for Management of stable COPD[3] • ≥6 weeks without exacerbation • Able to tolerate a bronchoscopic procedure
Radiographic	• Severe emphysema defined as target lobe with ≥40% emphysema involvement • High heterogeneity defined as ≥10 point disease severity difference with the ipsilateral lobe • Fissure integrity defined as ≥90% completeness of the fissure(s) separating the target lobe
Pulmonary and Exercise Evaluation	
FEV_1	≤45% predicted
Residual Volume (RV)	>150% predicted
Total Lung Capacity (TLC)	>100% predicted
6MWD	>140 meters

Patient selection for endobronchial valve treatment involves a thorough patent evaluation.

Exclusion Criteria
Patient is an active smoker
Patient has a severe gas exchange abnormality in either PCO_2 or PO_2 as defined by PCO_2 >55 mm Hg, or PO_2 <45 mm Hg on room air
Patient has a BMI <15 kg/m^2
Patient had a hospitalization for COPD exacerbation or respiratory infections in the past 3 months prior to baseline testing
Patient has bronchitis with sputum production > 4 tablespoons per 60 ml per day
Patient has an active asthma component to their disease or requires more than 15 mg of prednisone daily
Patient has giant bulla considered to be >1/3 volume in either lung
Patient has severe pulmonary hypertension based upon clinical evaluation
Patient has had prior lung volume reduction surgery or major lung procedures (lobectomy or greater)
Patient has a diffuse emphysema pattern
Patient is classified as ASA Class greater than P4 including presence of co-morbidity that could significantly increase the risk of a bronchoscopy procedure[4]

Criteria to determine eligible patients for the treatment are based upon findings established by the EMPROVE clinical trial. These recommendations are not meant to replace patient-specific clinical judgement.

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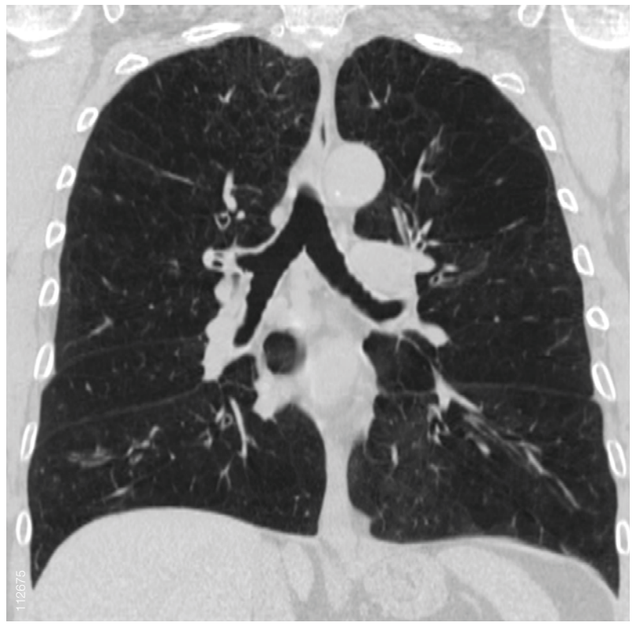
Patient selection for bronchoscopic lung volume reduction (BLVR) involves a thorough patient evaluation, examination for any comorbidities, as well as analysis of the patient's high-resolution computed tomography (HRCT).

In addition to HRCT, automated software solutions that are available for quantifying measurements are a powerful tool in emphysema disease evaluation, and provide a reliable assessment of emphysema distribution (heterogeneity), the severity of lung tissue destruction and quantifying fissure integrity. Fissure integrity itself can be utilized as a surrogate indicator for collateral ventilation.[5]

The selection of patients with low to no collateral ventilation prior to treatment is critical for procedural success.

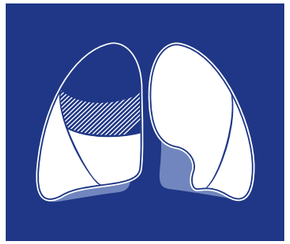
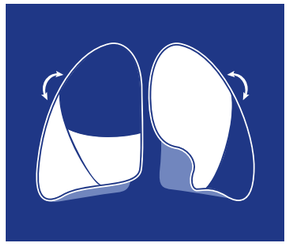
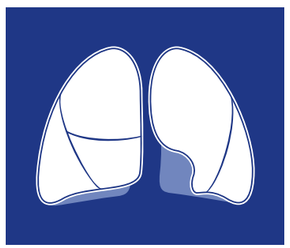


HRCT Scanning

An HRCT scan is used to estimate the extent and distribution of emphysema and to identify whether there is a suitable treatment lobe that may respond favorably to Spiration Valve treatment.

The three key parameters used to determine whether the patient has a lobe suitable for valve treatment include:

- Emphysema Severity
- High Heterogeneity
- Fissure Integrity

HRCT Evaluation		Quantitative Analysis Strategies
Emphysema Severity		
	The lobe with the greatest amount of emphysema involvement should be evaluated first. If that lobe does not meet subsequent criteria, consider the second most diseased lobe.[2,6]	Target lobe has ≥40% emphysema severity, assessed quantitatively with HRCT at -920 HU.[2]
High Heterogeneity		
	A high heterogeneity difference between ipsilateral lobes may be useful to verify that the non-target lobes that will expand are healthier than the lobe targeted for treatment and volume reduction.[2,7,8]	Target lobe has emphysema involvement ≥10 percent greater than the healthier ipsilateral lobe, assessed quantitatively with HRCT.[5] Perfusion scintigraphy may also be conducted to confirm heterogeneity and verify perfusion of the target lobe region.[2,8,9]
Fissure Integrity		
	The selected lobe must have an intact fissure separation with the ipsilateral lobe.[2,8]	Fissures may be visually estimated to be intact if they are >90% complete after viewing the HRCT in three dimensions (sagittal, axial, and coronal).[8,10] Automated methods to provide exact quantifications and support visual readings are recommended.[8]

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Quantitative Analysis Process

SeleCT provides rapid results and metrics on key indicators of valve success. There are flexible options for using SeleCT. The following SeleCT services are offered, regardless of which option you select to best support your practice:

- SeleCT provides quantitative measures to identify potential responders for treatment
- Trained medical professionals perform a QA overread on the QCT results before releasing the report to users
- Secure access and protection of patient health information

Option 1: SeleCT Online Portal

With a secure online platform, treating facilities can submit image series for quantitative CT analysis.

1. Clinicians select HRCTs to submit for QCT analysis.

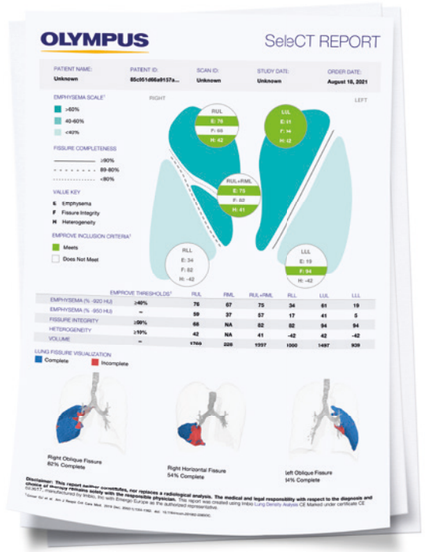
2. HRCTs are uploaded through a secure, web-based portal to a platform that runs automated QCT analysis.

4. Users download the final reports from the same portal.

3. Trained medical professionals will perform a QA overread of the QCT results and then upload the report back into the portal.

Quantitative Measurements

Each quantitative report contains lung parenchymal measurements at -920 HU.



Key quantitative measures to identify responders for the Spiration Valve System:

EMPHYSEMA SEVERITY
Allows physician to quickly identify the most diseased lobe

HETEROGENEITY
Differentiates target and ipsilateral lobe emphysema to facilitate redirection of ventilation to healthier tissue[8,11]

FISSURE INTEGRITY
EMPROVE trial results confirmed radiographic assessment of fissure completeness to be a reliable surrogate for collateral ventilation

Quantitative Measurement Advantages

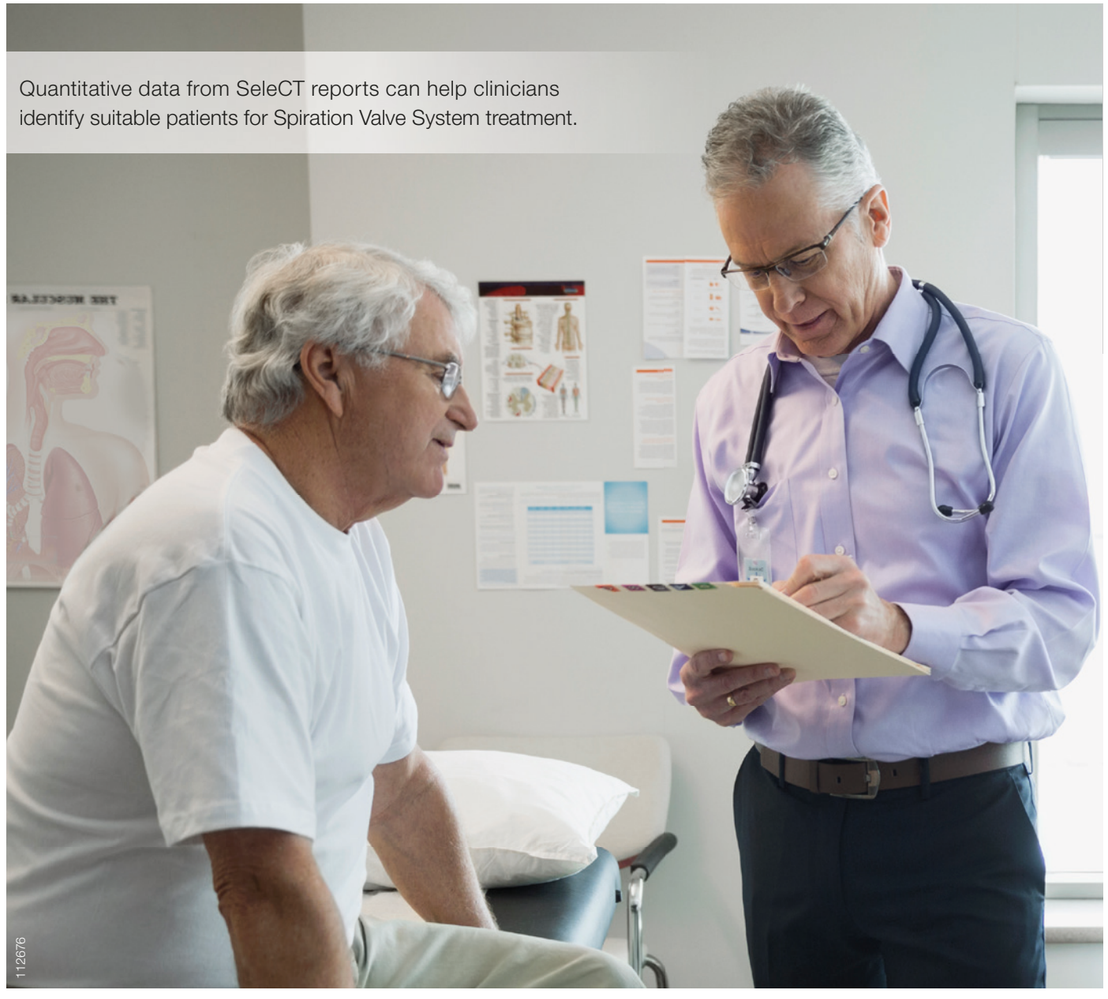
Quantitative measured reports are more accurate and reproducible than visual CT analysis[11]

- Comparable accuracy to more invasive patient selection tools[11]
- Avoid an invasive procedure just to confirm collateral ventilation[11]
- Not dependent on anatomy, coughing or mucus where direct bronchoscopic measure may be unreliable or not possible[8]
- Provides useful measures beyond complete fissures such as emphysema severity, heterogeneity and lobar volume that may improve the prediction of lung volume reduction[11]

SeleCT

The Key to Successful Patient Outcomes

By integrating QCT analysis from SeleCT into clinical routine, the measures of of emphysema severity, heterogeneity and fissure integrity can assist clinicians and hospitals by providing more objective measures for patient evaluation, and procedure planning for Spiration Valve System treatment.



References

1. Van Rikxoort EM, Goldin JG, Galperin-Aizenberg M, et al. A method for the automatic quantification of the completeness of pulmonary fissures: evaluation in a database of subjects with severe emphysema. Eur Radiol. 2011;22(2):302-9.

2. Criner GJ, Delage A, Voelker K. Late Breaking Abstract - Endobronchial Valves for Severe Emphysema – 12-month Results of the EMPROVE Trial. Eur Respir J. 2018;52(suppl 62). doi:10.1183/13993003.congress-2018.OA4928

3. ACP/ACCP/ATS/ERS Guidelines for Management of Stable COPD. http://www.thoracic.org/statements/resources/respiratory-disease-adults/179full.pdf. Accessed 2018.

4. The American Society of Anesthesiologists Physical Classification System, 1999. http://www.asahq.org/Home/ For-Members/Clinical-Information/ASA-Physical-Status-Classification-System. Accessed 2018.

5. Eberhardt R, Gompelmann D, Herth FJ, Schuhmann M. Endoscopic bronchial valve treatment: patient selection and special considerations. Int J Chron Obstruct Pulmon Dis. 2015 Oct 8;10:2147-57.

6. Supplement to: Scuriba F, Ernst A, Herth FJF, et al. A randomized study of endobronchial valves for advanced emphysema. NEJM 2010; 363:1233-1244.

7. Eberhardt R, Gompelmann D, Schuhmann M, et al. Complete unilateral versus partial bilateral endoscopic lung volume reduction in patients with bilateral lung emphysema. Chest. 2012;142(4):900-908. doi:10.1378/chest.11-2886.

8. Slebos DJ, Shah PL, Herth FJ, et al. Endobronchial Valves for Endoscopic Lung Volume Reduction: Best Practice Recommendations from Expert Panel on Endoscopic Lung Volume Reduction. Respiration. 2017;93(2):138-150

9. Thurnheer R, Engel H, Weder W, et al. Role of lung perfusion scintigraphy in relation to chest computed tomography and pulmonary function in the evaluation of candidates for lung volume reduction surgery. Am J Respir Crit Care Med 1999;159(1):301-10.

10. Gompelmann D, Eberhardt R, Slebos DJ, et al. Diagnostic performance comparison of the chartis system and high-resolution computerized tomography fissure analysis for planning endoscopic lung volume reduction. Respirology 2014; doi:10.111/resp.12253.

11. Schuhmann M, Raffy P, Yi Y, et al. CT Predictors of Response to Endobronchial Valve Lung Reduction Treatment: Comparison with Chartis. Am J Respir Crit Care Med 2015; 191(7):767-774; doi:10.1164/rccm.201407-1205OC.

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