This paper will review the use of the receiver operating characteristic (ROC) analysis for the clinical evaluation of imaging systems. Clinical evaluation is necessary because at the present time, the evaluation of imaging systems by model observers is limited to basic discrimination tasks using well characterized signals and backgrounds that can be described statistically. Real medical images require the reader to perform multiple tasks including discrimination and classification. In addition the signals are frequently ill characterized and are embedded in complex pictorial backgrounds that may compete with the signal for the readers attention.

The ROC methodology is preferred because it allows the investigator the separate the ability of the readers to discriminate between diseased and disease-free cases from the criteria that they use to make the decision. Applying the ROC analysis to real images poses some problems for the clinical investigator. The images must be representative of some clinical population and at the same time must fit the ROC paradigm. For example, the images must be divided into two categories, diseased and disease-free on the basis of an independent standard. The disease-free cases must be sufficiently difficult to produce a measurable false positive fraction. The readers need to report results using a rating scale rather than a more familiar free-form text report.

Clinical investigators have overcome these problems by devising stress tests using a single lesion that represents some class of abnormalities with definable physical properties. Nodules represent low frequency objects and interstitial fibrosis represents high frequency objects This establishes a link, albeit a tenuous one to model observers. This approach has been very successful in the evaluation of digital chest radiography and of soft copy displays.

The results of stress tests may not apply to the general diagnostic population and ultimately field trials are necessary. Development of new approaches to ROC analysis such as the DROC of Chakraborty and of alternatives to ROC analysis such as mixture distribution analysis may enable the performance of field trials.

Educational Objectives

1. Understand the sources of bias in evaluating clinical imaging systems using ROC analysis.
2. Understand the methodological tradeoffs required when doing a clinical ROC analysis.
3. Be aware of some of the enhancements and alternatives to the ROC methodology