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Development of statistical tools to test the equivalence between two measurement methods

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Abstract.

The needs of the industries to quickly assess the quality of products and the performance of the manufacturing methods leads to the development and improvement of alternative analytical methods sometimes faster, easier to handle, less expensive or even more accurate than the method corresponding reference. These so-called alternative methods should ideally lead to results comparable to those obtained by a standard method known as a reference.

To test statistically the equivalence between two measurement methods, a certain characteristic of a sample can be measured by the two methods in the experimental domain of interest. Pairs of points (X_i, Y_i) , representing the measures taken by the reference method and the alternative one can be modelled by a linear regression (a straight line). The estimated parameters are very useful to test the equivalence. Indeed, an intercept significantly different from zero indicates a systematic analytical bias between the two methods of measurement and a slope significantly different from one indicates a proportional bias. The estimated parameters and their confidence intervals are then used to test the equivalence of the two measurement methods. To achieve this correctly, it is essential to take into account the errors in both axes and heteroscedasticity in both axes. Different types of regression exist to handle these cases and a lot of confusion still exists in the literature. We review therefore the equations for estimating the regression by these different techniques and standardize the notations. Then, we focus on the most suitable equivalence techniques tests and we propose a new methodology to test the proportional bias and the analytical bias at the same time with a simultaneous confidence interval and a confidence band for an errors-in-variables regression with heteroscedasticity in both axes.