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Modeling and testing treated tumor growth using cubic smoothing splines

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Human tumor xenograft models are often used in preclinical study to evaluate the therapeutic efficacy of a certain compound or a combination of certain compounds. In a typical human tumor xenograft model, human carcinoma cells are implanted to subjects such as severe combined immunodeficient (SCID) mice. Treatment with test compounds is initiated after tumor nodule has appeared, and continued for a certain time period. Tumor volumes are measured over the duration of the experiment. It is well known that untreated tumor growth may follow certain patterns, which can be described by certain mathematical models. However, the growth patterns of the treated tumors with multiple treatment episodes are quite complex, and the usage of parametric models is limited. We propose using cubic smoothing splines to describe tumor growth for each treatment group and for each subject, respectively. The proposed smoothing splines are quite flexible in modeling different growth patterns. In addition, using this procedure, we can obtain tumor growth and growth rate over time for each treatment group and for each subject, and examine whether tumor growth follows certain growth pattern. To examine the overall treatment effect and group differences, the scaled chi-squared test statistics based on the fitted group-level growth curves are proposed. A case study is provided to illustrate the application of this method, and simulations are carried out to examine the performances of the scaled chi-squared tests.