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Appendix E-1: Assumption Checking for the Use of Cox Proportional Hazards Modeling

The proportionality assumption underlying the Cox model used in the present analysis was evaluated in several ways, with the focus on dislocation as the outcome of interest. The Kaplan-Meier nonparametric analysis provides one way to examine the empirical survival curve for the procedures. As shown in Figure E-1, the 2 survival lines are largely parallel, which lends support for the proportionality assumption in the subsequent Cox regression model. The "log-log" of the Kaplan-Meier survival function is another way to examine the proportionality assumption, with the "log-log" line showing parallelism if the assumption is valid. Figure E-2 shows this "log-log" plot, which demonstrates reasonable adherence to this assumption.

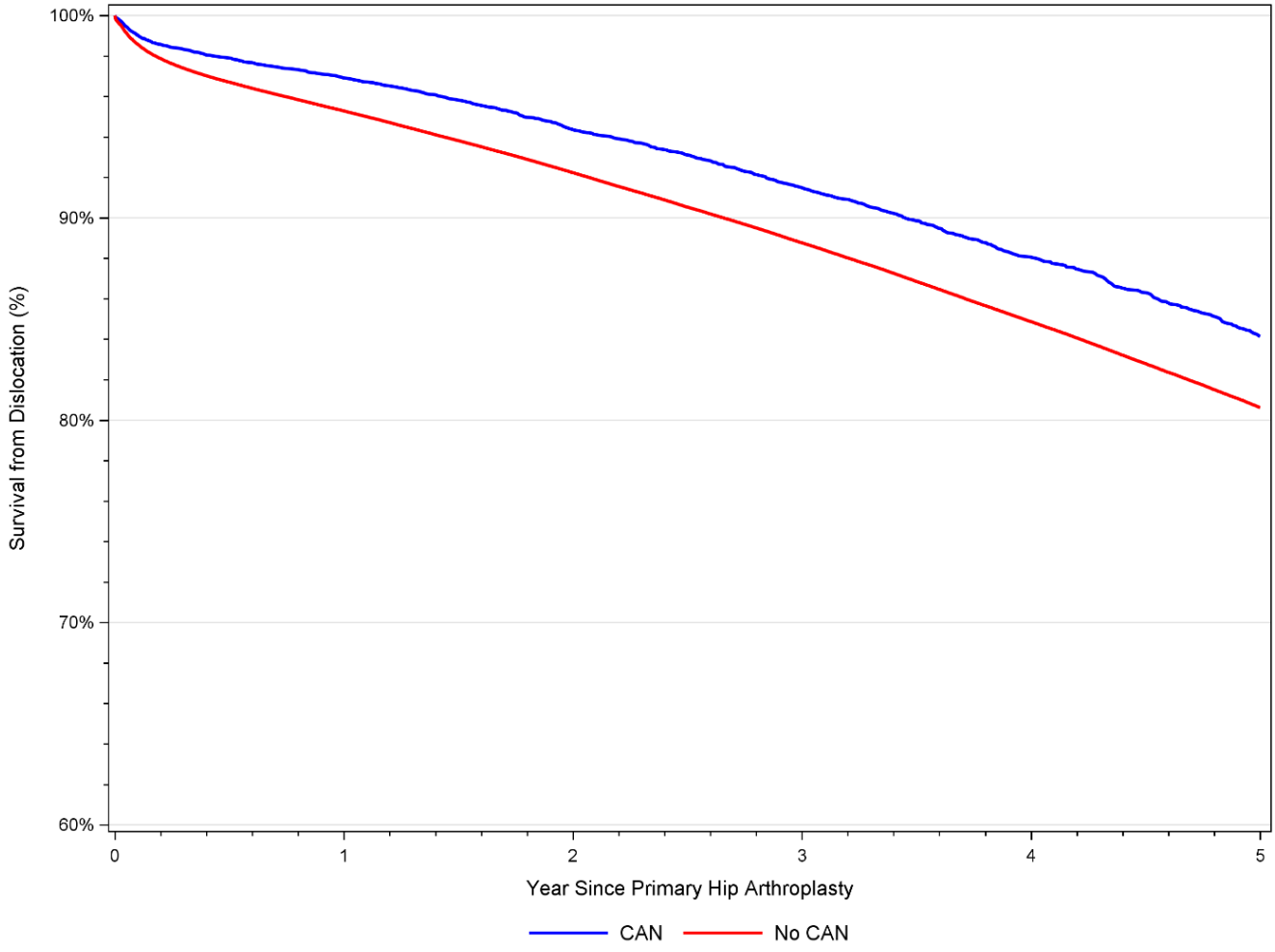

Figure E-1
Kaplan-Meier survival functions. CAN = computer-assisted navigation.

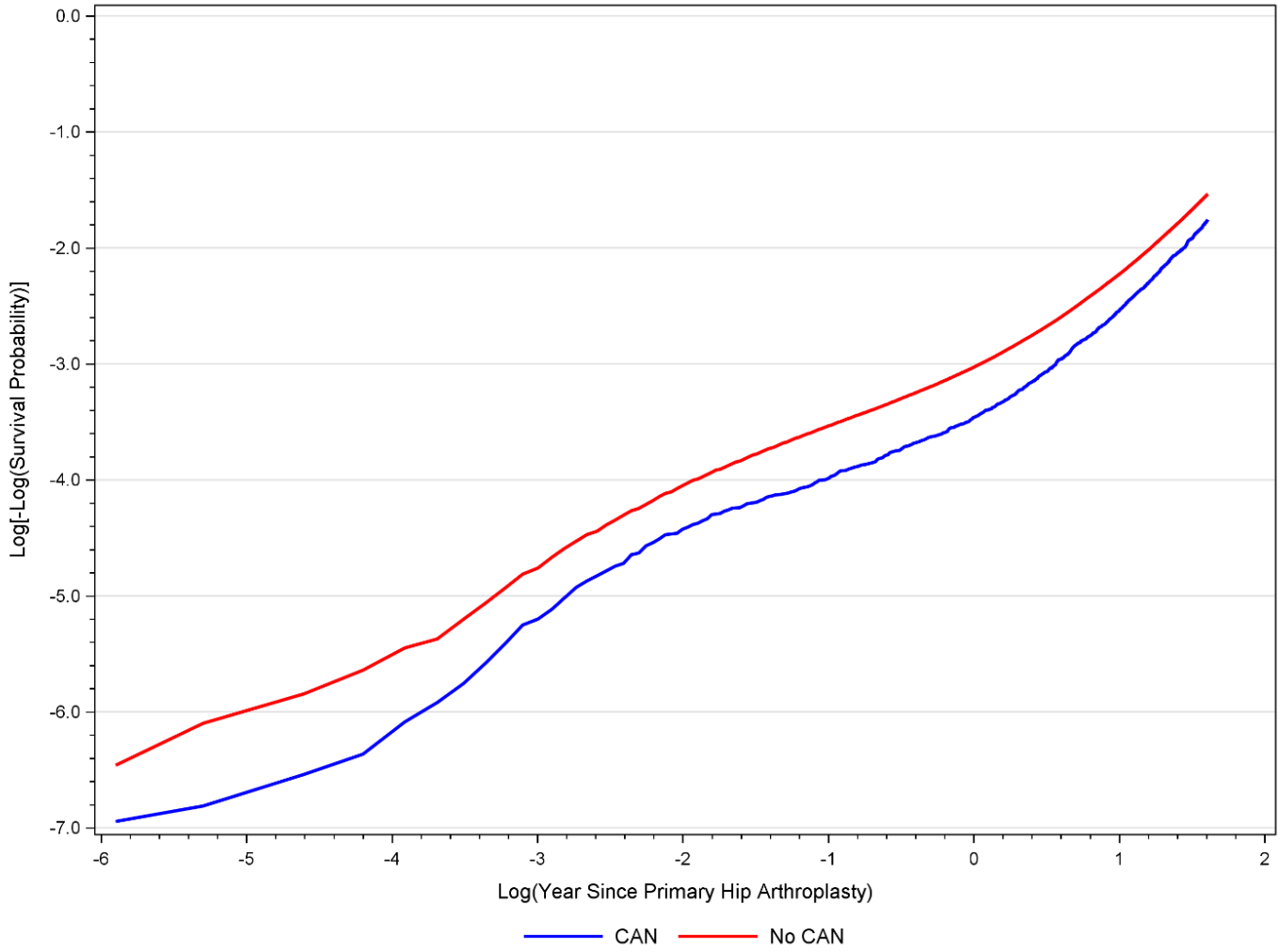

Figure E-2
Log [−Log S(t)] plot of Kaplan-Meier survival function. CAN = computer-assisted navigation.

After the model is fit, the SAS PHREG (proportional hazards regression) procedure also provides the ability to assess the proportionality of the hazards. One way to do that is with Schoenfeld residuals, which are computed for each subject and for each covariate. We examined the weighted Schoenfeld residuals associated with the navigation variable. Figure E-3 shows the weighted Schoenfeld residuals for the navigation and nonnavigation groups plotted against time. Residuals from both groups show a relatively flat pattern without a substantial increase or curvature over time. This suggests no departure from proportionality. Figure E-4 shows the same Schoenfeld residuals, but plotted against subject number. The 2 bands of values corresponding to the navigation and no-navigation groups can be seen, again with all of the observations falling within a narrow band throughout.

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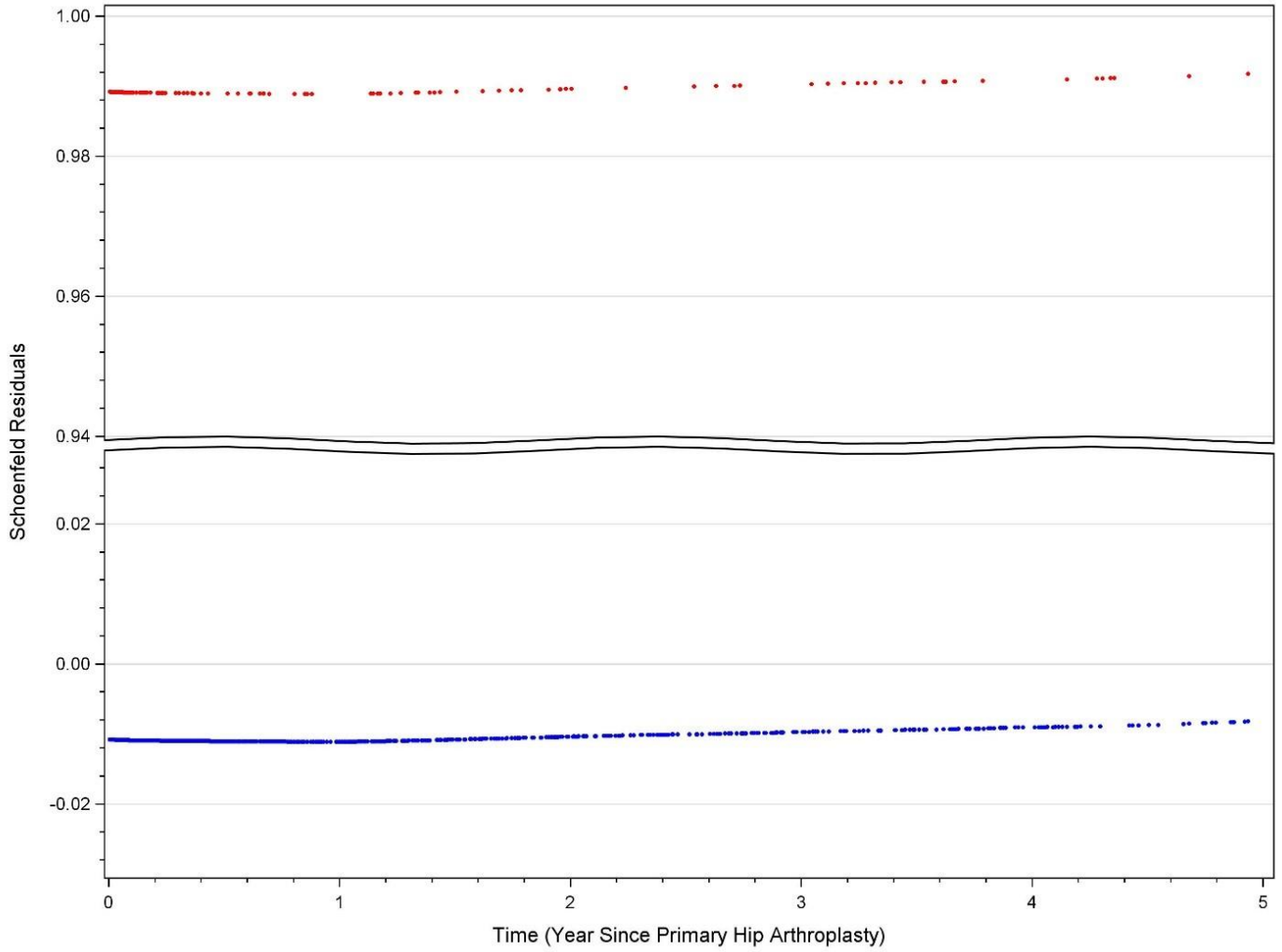

Figure E-3
Schoenfeld residuals for the navigation variable by time. Blue = computer-assisted navigation, and red = no computer-assisted navigation.

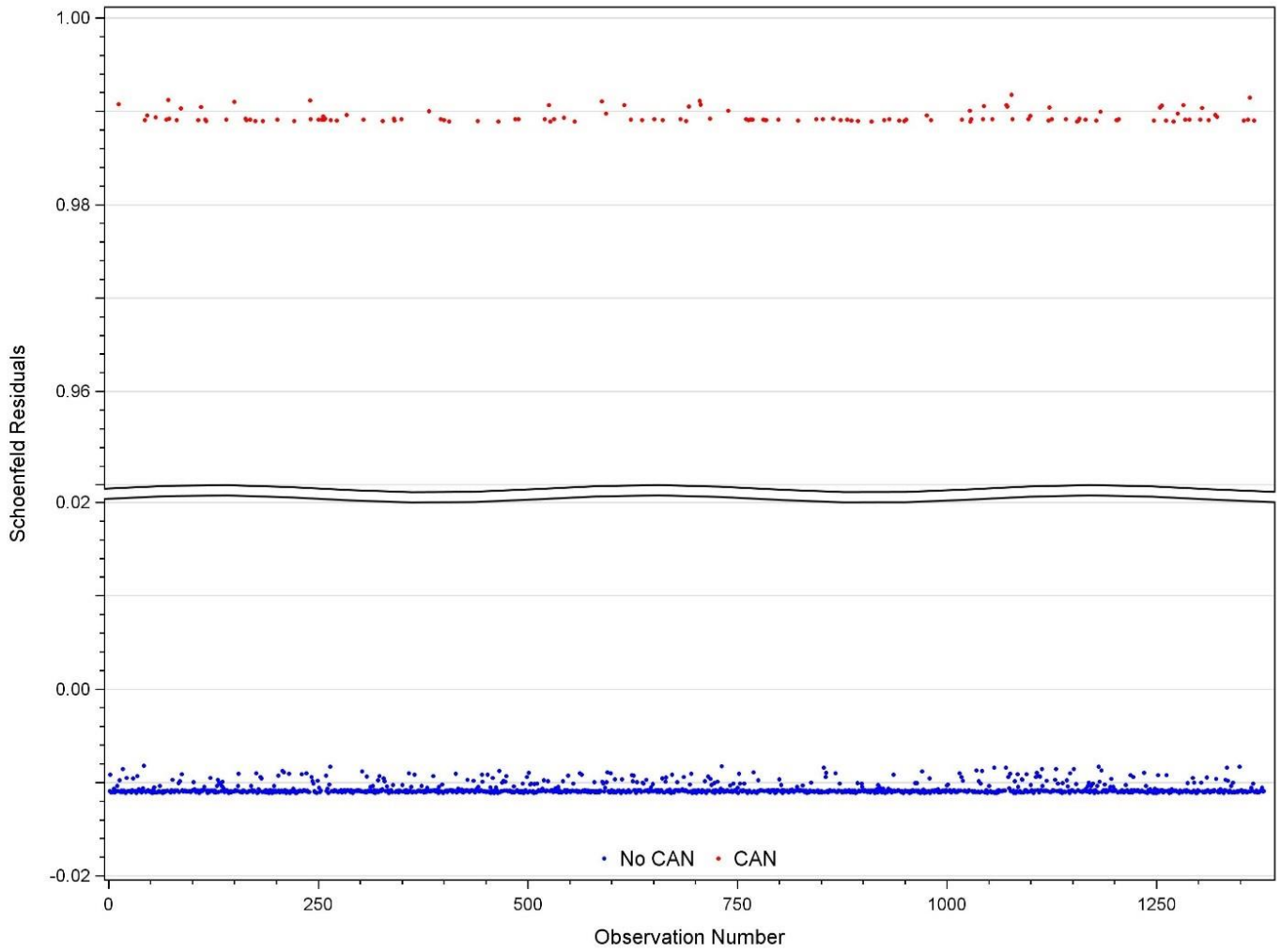

Figure E-4
Schoenfeld residuals for the navigation variable by observation number. CAN = computer-assisted navigation.

The ACCESS facility from the SAS PHREG (proportional hazards regression) procedure is yet another way to evaluate proportionality. The proportionality is evaluated by plots of the cumulative score residuals against time. Using a Brownian process, 30 random paths were generated under the proportional hazard condition and the path from the actual data was compared with these randomly generated paths under the proportional hazard assumption. If the actual path is within the general area traversed by other paths, the proportionality assumption is thought to be satisfied. Figure E-5 shows the plot of these random processes against the path from the actual data for the navigation variable. The path for the actual data is close to the lower end of the other paths during the middle range of the time. Although the path for the actual navigation variable is not right at the center of these paths, it is still largely within the range of the other paths over time.

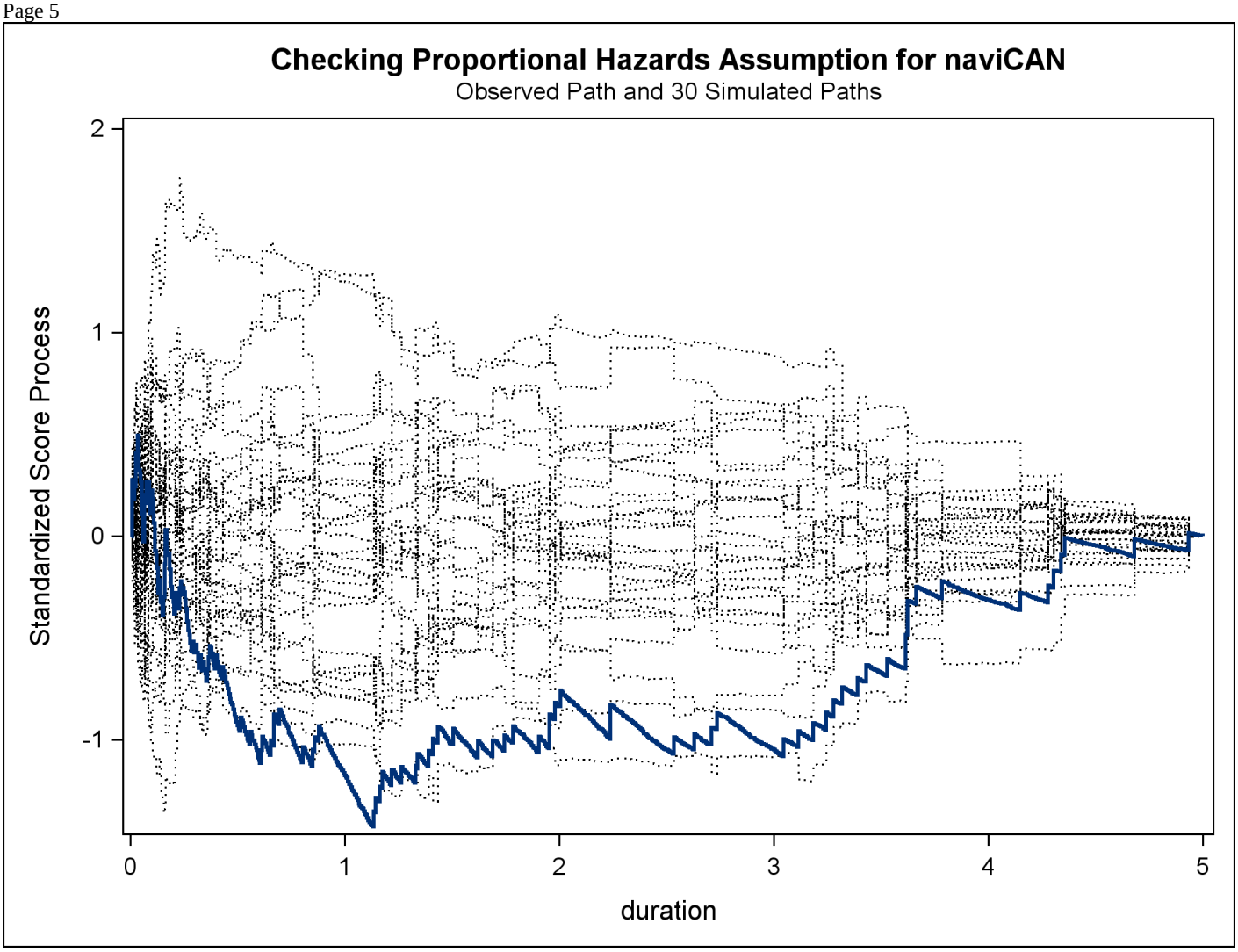

Figure E-5
Observed path and 30 simulated paths.

Based on these additional calculations, we believe there is no compelling evidence of gross violation of the proportionality assumption used in the Cox model, especially for the estimation of the effect associated with the use of computer-assisted navigation. In a large study such as this one using the Medicare file, it is unrealistic to expect every covariate to have a perfectly parallel or perfectly proportional relationship among levels of the covariate throughout the entire time range. We believe some departure in some covariate would not be a surprise. As long as the departure is not gross and extreme, the conventional Cox model still provides a valid vehicle for evaluating the relative risk of dislocation.