U.S. FOOD & DRUG ADMINISTRATION

Appendix: Strategy to Estimate Low to High Cycle Fatigue Transition of Nitinol for Fatigue to Fracture Test Planning

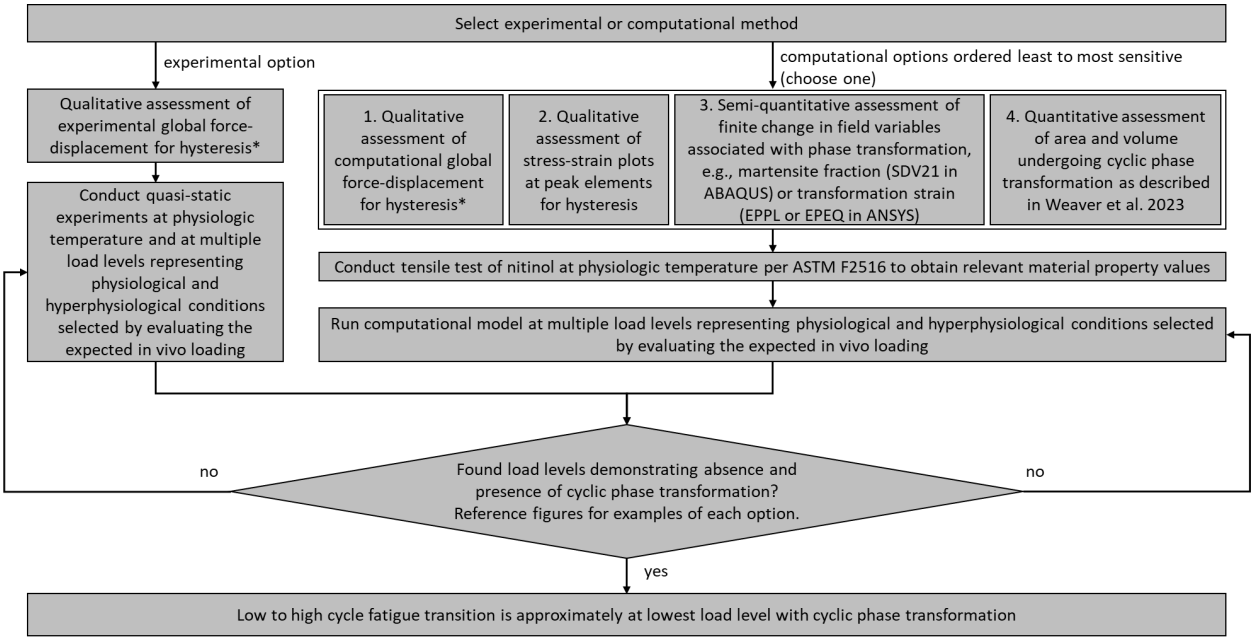

Figure 1: Flowchart to estimate low to high cycle fatigue transition.

*Note: When the volume of material undergoing phase transformation is small relative to the full device, the influence of local phase transformation on the global force-displacement observations will be similarly small. Accordingly, when using 'global' methods, the presence or absence of hysteresis in the force-displacement results should be interrogated carefully.

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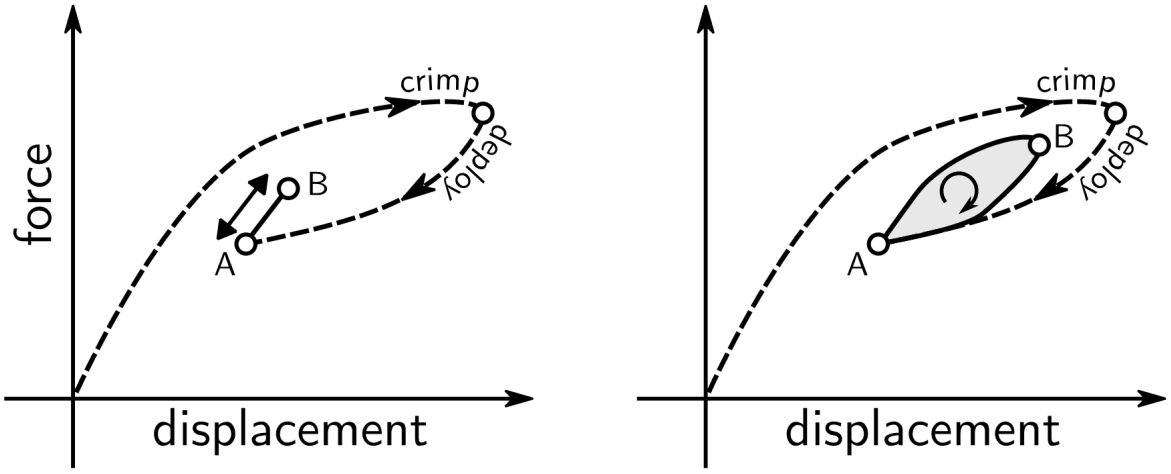

Figure 2: Experimental Option and Computational Option 1: Examples illustrating absence (left) or presence (right) of hysteresis when cycling between two loading points A and B.

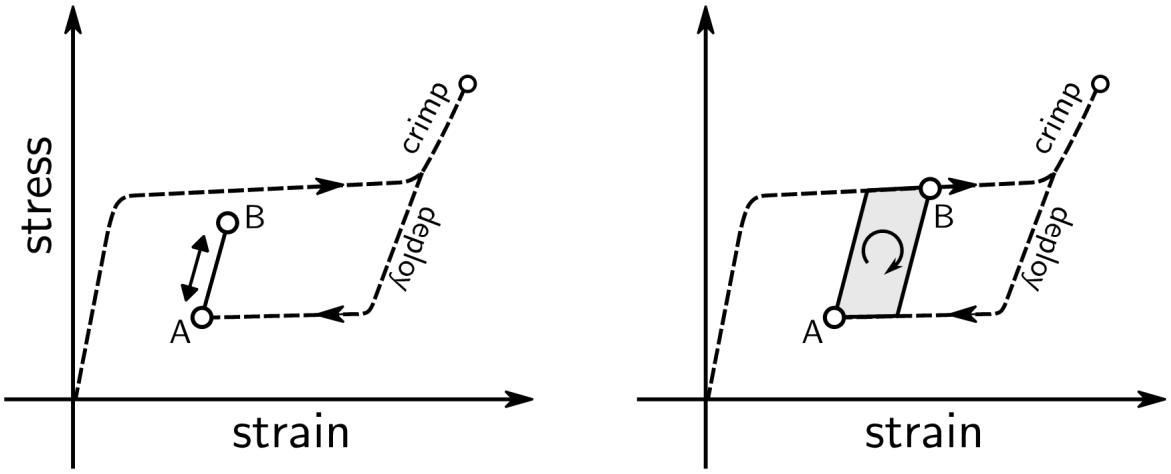

Figure 3: Computational Option 2: Examples illustrating absence (left) or presence (right) of hysteresis when cycling between two loading points A and B.

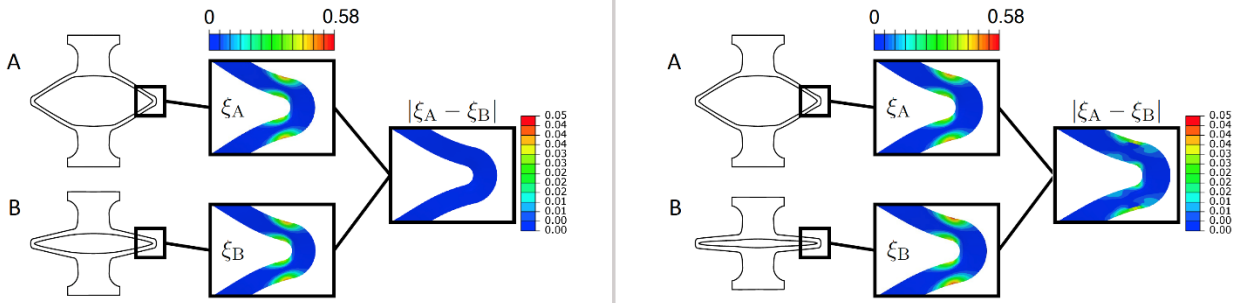

Figure 4: Computational Option 3: Examples illustrating semi-quantitative assessment of finite change in field variables associated with cyclic phase transformation between

two loading points A and B. The left shows an absence of cyclic phase transformation whereas the right shows the presence of cyclic phase transformation.

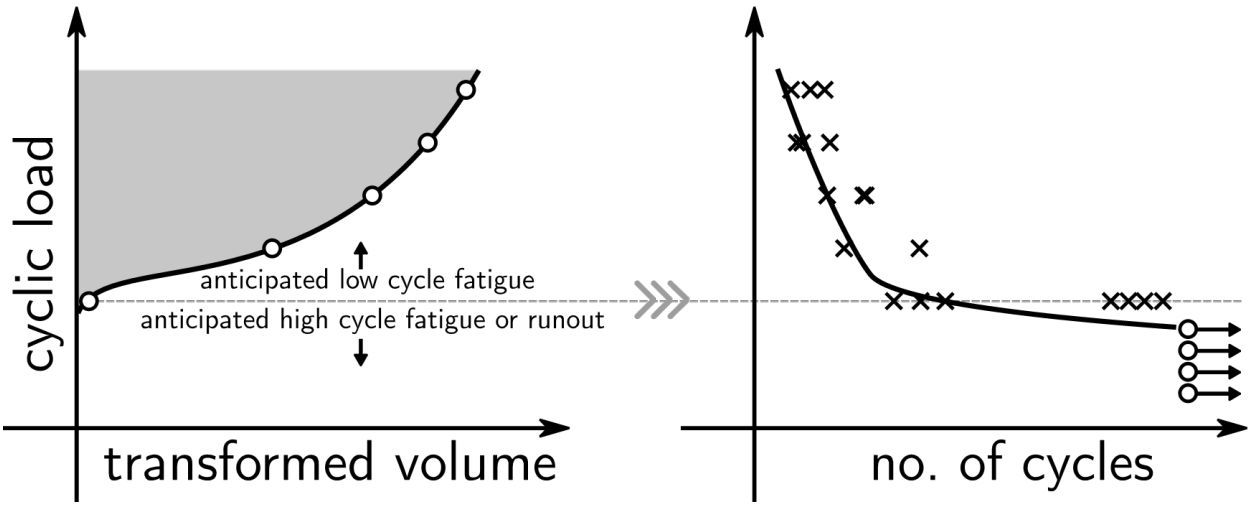

Figure 5: Computational Option 4: As described in Weaver et al. 2023, quantitative assessment of area and volume undergoing cyclic phase transformation may be calculated. A non-zero cyclic phase transformation (area or volume) suggests that low cycle fatigue may be anticipated. Refer to the publication for further detail.