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Approximate Tolerance Limits Under Log-Location-Scale Regression Models in the Presence of Censoring

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For a product manufactured in large quantities, tolerance limits play a fundamental role in setting limits on the process capability. Existing methodologies for setting tolerance limits in life test experiments focus primarily on one-sample problems. In this study, we extend tolerance limits in the presence of covariates in life test experiments. A method constructing approximate tolerance limits is proposed under log-location-scale regression models, a class of models used widely in reliability and life test experiments. The method is based on an application of the large sample theory of maximum likelihood estimators, which is modified by a bias-adjustment technique to enhance small sample accuracy. The proposed approximate tolerance limits are shown asymptotically to have nominal coverage probability under the assumption of "independent censoring." This includes Type I and Type II censoring schemes. Simulation studies are conducted to assess finite sample properties under the log-location-scale regression models. The method is illustrated with two datasets. R codes for implementing the proposed method are available online on the *Technometrics* web site, as supplemental materials.

KEY WORDS: Jackknife; Life tests; Maximum likelihood; Regression analysis.

1. INTRODUCTION

In the process of quality control in mass production, one of the most important quantitative measurements is the tolerance limit calculated from a controlled experiment. For example, a manufacturer may need to construct a lower tolerance limit for a battery that can be expected, with 95% confidence, to contain 90% of its lifespan after 1 year of operation. Other applications can be found in Hahn and Meeker (1991).

Since the pioneering work of Wilks (1941), many researchers derived tolerance limits under parametric models (see sections 3 and 4 of Patel 1986), which sometimes require special tables. Asymptotic approximations are commonly used as a convenient alternative to the exact approach when exact limits are difficult to obtain or do not exist. Other recent developments in the area of tolerance limits appear in Wang and Iyer (1994), Hamada et al. (2004), Fernholz and Gillespie (2001), Wang and Tsung (2009), Cai and Wang (2009), and Krishnamoorthy and Mathew (2004).

Tolerance limits under censoring were discussed frequently in engineering contexts. Goodman and Madansky (1962) described several guidelines for the optimality of tolerance limits and showed that the exact tolerance limit derived under exponential distribution with Type II censoring satisfies these optimality criteria. Bain (1978) gave the exact tolerance limit under the Weibull distribution with Type II censoring. Bain's approach requires special tables. The approach proposed by Lawless (2003) is to construct tolerance limits based on pivotal quantities. This approach can be applied to a wider class of distributions, such as the so-called log-location-scale families. Tolerance limits under Type I censored data are less tractable than those under Type II censored data. Exact tolerance limits under Type I censoring have not been derived and studies usually rely on the asymptotic approximation. Tolerance limits under the Weibull distribution with censoring can also be obtained as the confidence limits for the quantile (Bryan 2006).

The generalization of tolerance limits which incorporates covariates is useful in engineering, medical, and other contexts. In a real data example, shown in Section 6.2, lifetimes of motorettes are measured under various temperatures. In this kind of experiment, we are interested in calculating the lower tolerance limit at a given temperature. However, the construction of tolerance limits in the presence of covariates has rarely been discussed in previous studies. Most existing results on tolerance limits have dealt with one-sample problems. Jones et al. (1985) formulated their tolerance limits using log-location-scale regression models. However, their methods are not applicable if there is censoring. Justification of their approach is conducted by simulations only in the absence of covariates. In this study, we present explicit formulas for calculating tolerance limits under log-location-scale regression models. The method can handle a class of right-censoring schemes, including Type I and Type II censoring. We utilize large sample approximations to derive tolerance limits and establish their asymptotic validity. The method presented utilizes the standard approach for normal approximation and a bias-adjustment technique to obtain approximate tolerance limits.

This article is organized as follows. The regression models and estimation procedures are introduced in Section 2. Sec-

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tion 3 presents the proposed method of obtaining the approximate tolerance limits and establishes asymptotic validity. In Section 4, we compare existing tolerance limits with the proposed method. Section 5 investigates the performance of the proposed method and the competitors by simulations. Section 6 presents the results from data analysis. Finally, a conclusion is provided in Section 7.

2. REGRESSION ANALYSES UNDER CENSORING

2.1 Log-Location-Scale Models Under Censoring

The most commonly used parametric models for censored failure time data are log-location-scale regression models (Kalbfleisch and Prentice 2002; Lawless 2003). For $j = 1, \dots, n$, let T_j be the failure time and $\mathbf{Z}_j = (1, \mathbf{z}_j')'$, where $\mathbf{z}_j = (z_{1j}, \dots, z_{pj})'$ is the vector of observed characteristics. A class of models considered here is log-location-scale regression models

$$\log(T_j) = \mathbf{Z}_j'\boldsymbol{\beta} + \sigma W_j, \tag{1}$$

where $\boldsymbol{\beta} = (\beta_0, \beta_1, \dots, \beta_p)'$ and $\sigma > 0$ are unknown parameters and $W_1, \dots, W_n$ are independent random variables with a known density function $f(\cdot)$. The model in Equation (1) includes many common regression models in reliability and life test experiments. For example, Weibull and log-normal regression models for T_j correspond to $f(w) = \exp\{w - e^w\}$ and $f(w) = e^{-w^2/2}/\sqrt{2\pi}$, respectively. Under Equation (1), the distribution function for T_j is

$$G(t|\mathbf{Z}_j) = F\{(\log(t) - \mathbf{Z}_j'\boldsymbol{\beta})/\sigma\},$$

where $F(t) = \int_{(-\infty,t]} f(u)\,du$ and the hazard function for T_j is $h(t|\mathbf{Z}_j) = \{dG(t|\mathbf{Z}_j)/dt\}/\{1 - G(t|\mathbf{Z}_j)\}$.

For right-censored data, we observe $X_j = \min(T_j, C_j)$, $\delta_j = I(T_j \le C_j)$, and $\mathbf{Z}_j$, where C_j is a random censoring time. We impose the following assumption:

Assumption A (Independent right-censoring). Let $R(t) = \{j; T_j \ge t, C_j \ge t\}$ be a "risk set" that identifies those subjects that are at risk of failure at time t. Then, the instantaneous failure rates at time t can be expressed as the product of the hazard ratios at risk, that is,

$$\Pr(t \le T_j < t + dt, \delta_j = 1; j = 1, \dots, n | R(t), \mathbf{Z}_j) = \prod_{j \in R(t)} \{h(t|\mathbf{Z}_j)\,dt\}.$$

Remark 1. Assumption A is commonly employed in recent textbooks on failure time data analysis (see chapter 6 of Kalbfleisch and Prentice 2002 and section 2.2 of Lawless 2003). It encompasses a variety of commonly used censoring schemes. The independent right-censoring includes cases such as Type I censoring, Type II censoring, and progressive Type II censoring (see section 2.2 of Lawless 2003). Our proposal for the tolerance limits can handle censoring schemes that satisfy Assumption A.

2.2 Maximum Likelihood Estimator

Under Equation (1) and Assumption A, the likelihood of the observed data $\{(X_j, \delta_j, \mathbf{Z}_j); j = 1, \dots, n\}$ can be written as

$$L(\boldsymbol{\beta}, \sigma) = \prod_j \left\{ \frac{1}{\sigma} f\left(\frac{\log(X_j) - \mathbf{Z}_j'\boldsymbol{\beta}}{\sigma} \right) \right\}^{\delta_j} \times \left\{ 1 - F\left(\frac{\log(X_j) - \mathbf{Z}_j'\boldsymbol{\beta}}{\sigma} \right) \right\}^{1-\delta_j}.$$

The maximum likelihood estimator (MLE) maximizes $L(\boldsymbol{\beta}, \sigma)$, and is denoted by $(\hat{\boldsymbol{\beta}}, \hat{\sigma})$. The joint distribution of $(\hat{\boldsymbol{\beta}}, \hat{\sigma})$ can be approximated by the normal distribution with mean $(\boldsymbol{\beta}, \sigma)$ and covariance matrix $\mathbf{i}_n(\hat{\boldsymbol{\beta}}, \hat{\sigma})^{-1}$, where $\mathbf{i}_n(\hat{\boldsymbol{\beta}}, \hat{\sigma})$ is the observed Fisher information matrix. The justification for the normal approximation follows from the counting process and martingale theory (Andersen et al. 1993). The classical theory of MLE for iid random variables is not enough for our use, since under Assumption A, $\{(X_j, \delta_j, \mathbf{Z}_j); j = 1, \dots, n\}$ may not be a collection of n independent samples. Regularity conditions for the normal approximation are provided in Appendix A.1.

3. APPROXIMATE TOLERANCE LIMITS

Lower tolerance limits provide $(1-\alpha)100\%$ confidence of including $(1-\kappa)100\%$ of lifetimes drawn conditioning on $\mathbf{Z}$. Let $\boldsymbol{\chi} = \{(X_j, \delta_j, \mathbf{Z}_j); j = 1, \dots, n\}$ be a set of observed data. Formally, we define the statistic $L_Z(\boldsymbol{\chi})$ to be a $(1-\kappa)$-content, $(1-\alpha)100\%$-confidence lower tolerance limit under the covariate $\mathbf{Z}$ if

$$\Pr\big(1 - G(L_Z(\boldsymbol{\chi})|\mathbf{Z}) \ge 1 - \kappa\big) = 1 - \alpha, \tag{2}$$

where the probability statement is made on the sampling distribution of $\boldsymbol{\chi}$.

We focus on the lower tolerance limit under Equation (1) and Assumption A. Lower tolerance limits are of interest in many engineering or reliability applications. For instance, a manufacturer may have a desire to obtain the limit before which few failure events occur. Extension of the proposed method to upper tolerance limits and tolerance intervals is discussed in Section 3.3.

3.1 The Motivation for the Proposed Formulas

Before presenting the proposed formulas for $L_Z(\boldsymbol{\chi})$, we give outlines of our derivations. To illustrate the main idea, we temporarily ignore censoring by letting $C_j = \infty$. Following Goodman and Madansky (1962), the exact lower tolerance limit has the form

$$L_Z(\boldsymbol{\chi}) = \{2n/\chi^2_{1-\alpha}(2n)\} \cdot \{-\log(1-\kappa)\} \exp(\hat{\beta}_0) \tag{3}$$

for a simple model when $\mathbf{Z}_j' = 1$, $\boldsymbol{\beta} = \beta_0 \in R^1$, $f(w) = \exp\{w - e^w\}$, and $\sigma = 1$, where $\chi^2_{1-\alpha}(f)$ denotes the lower $(1-\alpha)$th quantile of the chi-squared distribution with the degrees of freedom f and $\hat{\beta}_0 = \log\{\sum_j T_j/n\}$.

Note that the formula $\{-\log(1-\kappa)\}\exp(\beta_0)$ is the κth quantile of T_j. Let $G^{-1}_{\exp}(\kappa) = \{-\log(1-\kappa)\}\exp(\beta_0)$. Consequently,

$\hat{G}^{-1}_{\exp}(\kappa) = \{-\log(1-\kappa)\}\exp(\hat{\beta}_0)$ is an estimator of $G^{-1}_{\exp}(\kappa)$ and Equation (3) can be rewritten as

$$L_Z(\boldsymbol{\chi}) = K_{\alpha,n} \cdot \hat{G}^{-1}_{\exp}(\kappa), \tag{4}$$

where $K_{\alpha,n} = 2n/\chi^2_{1-\alpha}(2n)$. In fact, if we check Bain (1978), the tolerance limits for the Weibull distribution also take a similar form. However, it is more difficult to obtain the corresponding coefficient for $K_{\alpha,n}$, which may require specific tables.

To extend the result to the general model in Equation (1), we can obtain the κth quantile of T_j as $G^{-1}(\kappa|\mathbf{Z}_j) = \exp\{\mathbf{Z}_j'\boldsymbol{\beta} + \sigma F^{-1}(\kappa)\}$ under Equation (1) and set a functional form for $L_Z(\boldsymbol{\chi})$ as

$$K^Z_{\alpha,n} \cdot \hat{G}^{-1}(\kappa|\mathbf{Z}),$$

where $\hat{G}^{-1}(\kappa|\mathbf{Z}) = \exp\{\mathbf{Z}'\hat{\boldsymbol{\beta}} + \hat{\sigma}F^{-1}(\kappa)\}$ is the MLE of $G^{-1}(\kappa|\mathbf{Z})$ and $K^Z_{\alpha,n}$ is an appropriate value depending on $\mathbf{Z}$, α, and n. Note that $\hat{G}^{-1}_{\exp}(\kappa)$ in Equation (4) is an unbiased estimator of $G^{-1}_{\exp}(\kappa)$. However, $\hat{G}^{-1}(\kappa|\mathbf{Z}) = \exp\{\mathbf{Z}'\hat{\boldsymbol{\beta}} + \hat{\sigma}F^{-1}(\kappa)\}$ may be a biased estimator for $G^{-1}(\kappa|\mathbf{Z})$ with the bias $B^Z_n = E\{\hat{G}^{-1}(\kappa|\mathbf{Z}) - G^{-1}(\kappa|\mathbf{Z})\}$. To seek a better lower tolerance limit by eliminating the bias, we consider the limit with the form

$$L_Z(\boldsymbol{\chi}) = K^Z_{\alpha,n} \cdot \{\hat{G}^{-1}(\kappa|\mathbf{Z}) - B^Z_n\}. \tag{5}$$

In the simple example mentioned earlier, we have $K^Z_{\alpha,n} = 2n/\chi^2_{1-\alpha}(2n)$ and $B^Z_n = 0$ given $\mathbf{Z} = 1$. However, the formula of B^Z_n was not derived under Equation (1) and it is fairly difficult to find the number $K^Z_{\alpha,n}$ which satisfies Equations (2) and (5) given the value of B^Z_n. In fact, in many specific models of Equation (1), B^Z_n and $K^Z_{\alpha,n}$ depend on unknown parameters and censoring patterns.

3.2 Proposed Tolerance Limit

We propose the lower tolerance limit in Equation (5) with $K^Z_{\alpha,n}$ and B^Z_n obtained by asymptotic approximation. A convenient way to approximate B^Z_n is to use the jackknife estimator

$$\hat{B}^Z_n = (n-1)\left\{\frac{1}{n}\sum_i \hat{G}^{-1}_{(-i)}(\kappa|\mathbf{Z}) - \hat{G}^{-1}(\kappa|\mathbf{Z})\right\},$$

where $\hat{G}^{-1}_{(-i)}(\kappa|\mathbf{Z})$ is the estimator $\hat{G}^{-1}(\kappa|\mathbf{Z})$ with the ith observation being deleted. If we find that $B^Z_n = 0$ by analytical calculation, using jackknife is redundant and we can re-define $\hat{B}^Z_n = 0$. Applying a Taylor series expansion to Equations (2) and (5), as shown in Appendix A.2, an appropriate choice becomes

$$\hat{K}^Z_{\alpha,n} = \exp\bigl[-z_{1-\alpha}\{\mathbf{A}'\mathbf{i}_n(\hat{\boldsymbol{\beta}},\hat{\sigma})^{-1}\mathbf{A}\}^{1/2}\bigr],$$

where $\mathbf{A}' = (\mathbf{Z}', F^{-1}(\kappa))$. Thus, the proposed tolerance limits have the form

$$L_Z(\boldsymbol{\chi}) = \hat{K}^Z_{\alpha,n} \cdot \{\hat{G}^{-1}(\kappa|\mathbf{Z}) - \hat{B}^Z_n\}. \tag{6}$$

Even when $B^Z_n \neq 0$, we can set $\hat{B}^Z_n = 0$ in Equation (6) and set $L^0_Z(\boldsymbol{\chi}) = \hat{K}^Z_{\alpha,n} \cdot \hat{G}^{-1}(\kappa|\mathbf{Z})$. In this case, we have

$$\log(L^0_Z(\boldsymbol{\chi})) = \mathbf{Z}'\hat{\boldsymbol{\beta}} + \hat{\sigma}F^{-1}(\kappa) - z_{1-\alpha}\{\mathbf{A}'\mathbf{i}_n(\hat{\boldsymbol{\beta}},\hat{\sigma})^{-1}\mathbf{A}\}^{1/2}.$$

The above expression is equivalent to the Wald-type lower confidence limits for $\mathbf{Z}'\boldsymbol{\beta} + \sigma F^{-1}(\kappa)$, which is the kth quantile of $\log(T_j)$ given $\mathbf{Z}$ (Lawless 2003, p. 295). However, it is known that the coverage probability of the Wald-type confidence limit for a quantile is not very accurate unless the sample is very large. For instance, at least $n = 200$ is necessary under simulation settings of Section 5. In Section 5, we compare the finite sample performance of $L_Z(\boldsymbol{\chi})$ and $L^0_Z(\boldsymbol{\chi})$ by simulations.

The tolerance limit in Equation (6) is an approximate tolerance limit in that it may not satisfy Equation (2) in a strict sense. Rather, Equation (2) holds as $n \to \infty$. The validity of the approximation is formally stated in the following theorem:

Theorem 1. Assume that conditions (A) through (E) in Appendix A.1 hold, and that $B_n = O(n^{-1})$ as $n \to 0$. Under Equation (1) and Assumption A,

$$\lim_{n\to\infty} \Pr\bigl(1 - G(L_Z(\boldsymbol{\chi})|\mathbf{Z}) \geq 1-k\bigr) = 1-\alpha$$

for any $0 < \kappa < 1$ and $0 \leq \alpha \leq 1$.

Conditions (A) through (E) and the proof of Theorem 1 can be found in Appendix A.1 and A.2, respectively. The condition $B_n = O(n^{-1})$ is a sufficient condition for the jackknife method to have second-order correctness (Lehmann and Casella 1998, p. 84). Now we provide examples of the proposed tolerance limits.

Example 1 (Weibull and exponential regressions). If one assumes $f(w) = \exp\{w - e^w\}$ in Equation (1), then T_j follows a Weibull regression model $G(t|\mathbf{Z}_j) = 1 - \exp\{-(t/e^{\mathbf{Z}_j'\boldsymbol{\beta}})^{1/\sigma}\}$. The lower tolerance limit is

$$L_Z(\boldsymbol{\chi}) = \exp\bigl[-z_{1-\alpha}\{\mathbf{A}'\mathbf{i}_n(\hat{\boldsymbol{\beta}},\hat{\sigma})^{-1}\mathbf{A}\}^{1/2}\bigr] \times \bigl[\exp(\mathbf{Z}'\hat{\boldsymbol{\beta}})\{-\log(1-\kappa)\}^{\hat{\sigma}} - \hat{B}_n\bigr],$$

where $\mathbf{A}' = (\mathbf{Z}', \log\{-\log(1-\kappa)\})$,

$$\mathbf{i}_n(\hat{\boldsymbol{\beta}},\hat{\sigma}) = \sum_j \begin{bmatrix} \mathbf{i}_{j,\beta}(\hat{\boldsymbol{\beta}},\hat{\sigma}) & \mathbf{i}_{j,\beta\sigma}(\hat{\boldsymbol{\beta}},\hat{\sigma}) \\ \mathbf{i}'_{j,\beta\sigma}(\hat{\boldsymbol{\beta}},\hat{\sigma}) & i_{j,\sigma}(\hat{\boldsymbol{\beta}},\hat{\sigma}) \end{bmatrix},$$

$$\mathbf{i}_{j,\beta}(\hat{\boldsymbol{\beta}},\hat{\sigma}) = \frac{1}{\hat{\sigma}^2}\mathbf{Z}_j\mathbf{Z}_j'\left(\frac{X_j}{e^{\mathbf{Z}_j'\hat{\boldsymbol{\beta}}}}\right)^{1/\hat{\sigma}},$$

$$\mathbf{i}_{j,\beta\sigma}(\hat{\boldsymbol{\beta}},\hat{\sigma}) = \frac{1}{\hat{\sigma}^2}\mathbf{Z}_j\frac{\log X_j - \mathbf{Z}_j'\hat{\boldsymbol{\beta}}}{\hat{\sigma}}\left(\frac{X_j}{e^{\mathbf{Z}_j'\hat{\boldsymbol{\beta}}}}\right)^{1/\hat{\sigma}},$$

and

$$i_{j,\sigma}(\hat{\boldsymbol{\beta}},\hat{\sigma}) = \frac{1}{\hat{\sigma}^2}\left\{\left(\frac{\log X_j - \mathbf{Z}_j'\hat{\boldsymbol{\beta}}}{\hat{\sigma}}\right)^2\left(\frac{X_j}{e^{\mathbf{Z}_j'\hat{\boldsymbol{\beta}}}}\right)^{1/\hat{\sigma}} + \delta_j\right\}.$$

In exponential regression models, $\sigma = 1$ is known a priori and the parameters to be estimated are $\boldsymbol{\beta}$ only. Accordingly, the lower tolerance limit is given by

$$L_Z(\boldsymbol{\chi}) = \exp\bigl[-z_{1-\alpha}\{\mathbf{Z}'\mathbf{i}^{\sigma=1}_n(\hat{\boldsymbol{\beta}}^{\sigma=1})^{-1}\mathbf{Z}\}^{1/2}\bigr] \times \bigl[\exp(\mathbf{Z}'\hat{\boldsymbol{\beta}}^{\sigma=1})\{-\log(1-\kappa)\} - \hat{B}_n\bigr],$$

where $\hat{\boldsymbol{\beta}}^{\sigma=1}$ is the MLE given $\sigma = 1$ and

$$\mathbf{i}^{\sigma=1}_n(\hat{\boldsymbol{\beta}}^{\sigma=1}) = \sum_j \mathbf{Z}_j\mathbf{Z}_j'\frac{X_j}{e^{\mathbf{Z}_j'\hat{\boldsymbol{\beta}}^{\sigma=1}}}.$$

Example 2 (Log-normal regression). If one assumes $f(w) = 1/\sqrt{2\pi}\exp(-w^2/2)$ in Equation (1), T_j follows a log-normal regression model $G(t|\mathbf{Z}_j) = \Phi\{(\log(t) - \mathbf{Z}_j'\boldsymbol{\beta})/\sigma\}$, where $\Phi(x)$ is the cumulative distribution function of the standard normal distribution. The lower tolerance limit is

$$L_Z(\boldsymbol{\chi}) = \exp\big[-z_{1-\alpha}\{\mathbf{A}'\mathbf{i}_n(\hat{\boldsymbol{\beta}},\hat{\sigma})^{-1}\mathbf{A}\}^{1/2}\big] \times [\exp(\mathbf{Z}'\hat{\boldsymbol{\beta}} + \hat{\sigma}\cdot z_\kappa) - \hat{B}_n], \quad (7)$$

where $\mathbf{A}' = (\mathbf{Z}', z_\kappa)$,

$$\mathbf{i}_{j,\beta}(\hat{\boldsymbol{\beta}},\hat{\sigma}) = \frac{1}{\hat{\sigma}^2}\mathbf{Z}_j\mathbf{Z}_j'\left[\delta_j + (1-\delta_j)w\left(\frac{\log X_j - \mathbf{Z}_j'\hat{\boldsymbol{\beta}}}{\hat{\sigma}}\right)\right],$$

$$\mathbf{i}_{j,\beta\sigma}(\hat{\boldsymbol{\beta}},\hat{\sigma}) = \frac{\mathbf{Z}_j}{\hat{\sigma}^2}\left[\delta_j\frac{\log X_j - \mathbf{Z}_j'\hat{\boldsymbol{\beta}}}{\hat{\sigma}} + (1-\delta_j)w\left(\frac{\log X_j - \mathbf{Z}_j'\hat{\boldsymbol{\beta}}}{\hat{\sigma}}\right)\frac{\log X_j - \mathbf{Z}_j'\hat{\boldsymbol{\beta}}}{\hat{\sigma}}\right],$$

$$i_{j,\sigma}(\hat{\boldsymbol{\beta}},\hat{\sigma}) = \frac{\log X_j - \mathbf{Z}_j'\hat{\boldsymbol{\beta}}}{\hat{\sigma}^3}\left[2\delta_j\frac{\log X_j - \mathbf{Z}_j'\hat{\boldsymbol{\beta}}}{\hat{\sigma}} + (1-\delta_i)\left\{\lambda\left(\frac{\log X_j - \mathbf{Z}_j'\hat{\boldsymbol{\beta}}}{\hat{\sigma}}\right) + w\left(\frac{\log X_j - \mathbf{Z}_j'\hat{\boldsymbol{\beta}}}{\hat{\sigma}}\right)\frac{\log X_j - \mathbf{Z}_j'\hat{\boldsymbol{\beta}}}{\hat{\sigma}}\right\}\right],$$

and

$$\lambda(x) = \phi(x)/\{1-\Phi(x)\} \qquad \text{and} \qquad w(x) = -x\lambda(x) + \lambda^2(x).$$

3.3 Extension of the Proposed Tolerance Limit

It is possible to modify the proposed methods to upper tolerance limits or tolerance intervals. The upper $(1-\kappa)$-content, $(1-\alpha)100\%$-confidence tolerance limits under a condition $\mathbf{Z}$ have the form $\hat{K}_{\alpha,n}^{Z}\cdot\{\hat{G}^{-1}(1-\kappa|\mathbf{Z}) - \hat{B}_n^Z\}$, where the value $\hat{K}_{\alpha,n}^{Z}$ and $\hat{B}_n$ can be obtained in a way similar to the lower tolerance limits. If $\underline{L}_Z(\boldsymbol{\chi})$ is the lower $(1-\kappa_1)$-content, $(1-\alpha_1)100\%$-confidence tolerance limit and $\bar{L}_Z(\boldsymbol{\chi})$ is the upper $(1-\kappa_2)$-content, $(1-\alpha_2)100\%$-confidence tolerance limit, then $[\underline{L}_Z(\boldsymbol{\chi}), \bar{L}_Z(\boldsymbol{\chi})]$ can be used as a $(1-\kappa_1-\kappa_2)$-content, $(1-\alpha_1-\alpha_2)100\%$-confidence tolerance interval. Under similar conditions as Theorem 1, we have

$$\lim_{n\to\infty}\Pr\{G(\bar{L}_Z(\boldsymbol{\chi})|\mathbf{Z}) - G(\underline{L}_Z(\boldsymbol{\chi})|\mathbf{Z}) \geq 1-\kappa_1-\kappa_2\} \geq 1-\alpha_1-\alpha_2.$$

Thus, even when the sample size goes to infinity, $[\underline{L}_Z(\boldsymbol{\chi}), \bar{L}_Z(\boldsymbol{\chi})]$ is still conservative because its coverage probability may be greater than $(1-\alpha_1-\alpha_2)100\%$.

It may be of interest in some applications to find simultaneous tolerance limits at different covariate values. That is, we hope to find a collection of $\{L_{Z_l}(\boldsymbol{\chi}); l = 1,\ldots,L\}$ so that $\Pr(1-G(L_{Z_l}(\boldsymbol{\chi})|\mathbf{Z}_l) \geq 1-\kappa; l = 1,\ldots,L) = 1-\alpha$. We can find each $L_{Z_l}(\boldsymbol{\chi})$ by directly applying the proposed methods. However, the confidence associated with all of the tolerance limits is no longer $(1-\alpha)100\%$. A convenient way to adjust the confidence level is based on the Bonferroni method. It might be of interest to explore more sophisticated procedures for constructing simultaneous tolerance limits.

4. COMPARISON WITH EXISTING METHODS

4.1 Existing Tolerance Limits Under the Log-Location-Scale Regression Models

Jones et al. (1985) proposed a tolerance limit for log-location-scale regression models. They considered the regression model under the following assumptions:

$$\log(T_j) = \mathbf{Z}_j'\boldsymbol{\beta}^* + \sigma^* W_j^*, \quad (8a)$$

$$E(W_j^*) = 0, \qquad \mathrm{var}(W_j^*) = 1. \quad (8b)$$

The parameters $(\boldsymbol{\beta}^*, \sigma^*)$ in Equation (8a) and $(\boldsymbol{\beta}, \sigma)$ in Equation (1) can have different meanings since W_j in Equation (1) does not always have mean 0 and variance 1. In the absence of censoring and under Equations (8a) and (8b), Jones et al. (1985) proposed the following approximate tolerance limit. Let $(\hat{\boldsymbol{\beta}}^*, \hat{\sigma}^*)$ be the MLE under Equations (8a) and (8b). The key of their derivation is that, under Equation (8a) and in the absence of censoring, the distributions of $(\hat{\boldsymbol{\beta}}^* - \boldsymbol{\beta}^*)/\sigma^*$ and $(\hat{\sigma}^* - \sigma^*)/\sigma^*$ are pivotal quantities. They utilized the analytical form of the asymptotic covariance matrix for $\sqrt{n}(\hat{\boldsymbol{\beta}}^* - \boldsymbol{\beta}^*, \hat{\sigma}^* - \sigma^*)/\sigma^*$ for selected distributions of W_j^*. Based on these results, they were able to obtain the approximate tolerance limit as a lower confidence limit for the κth quantile of T given $\mathbf{Z}$. Note that Equation (8b) played the role of stabilizing their proposed tolerance limits (Jones et al. 1985, p. 110). The extension of their method to deal with Type II censoring is considered in the absence of covariates.

An important practical difference between the method proposed by Jones et al. (1985) and the one proposed in this study is the treatment of censoring. As already mentioned, the proposed methods can handle a class of independent right-censoring schemes in the presence of covariates. On the other hand, Jones et al. (1985) treated cases with Type II censoring only in the absence of covariates. It is not obvious that their method can be directly applied to the other censoring schemes. To accommodate censoring in our approach, we directly approximate the distribution of $\sqrt{n}(\hat{\boldsymbol{\beta}} - \boldsymbol{\beta}, \hat{\sigma} - \sigma)$ without going through pivotal quantities. The asymptotic covariance matrix of $\sqrt{n}(\hat{\boldsymbol{\beta}} - \boldsymbol{\beta}, \hat{\sigma} - \sigma)$ is approximated by the observed Fisher information matrix.

The assumption in Equation (8b) is imposed for their approach but not for ours. In fact, in recent standard textbooks, such as Kalbfleisch and Prentice (2002) and Lawless (2003), it is customary not to impose Equation (8b) for the error term. Usually, the Weibull regression model refers to Equation (1) with the density $f(w) = \exp\{w - e^w\}$ of W_j, which has mean $-\gamma$, where $\gamma = 0.5772\ldots$ is Euler's constant, and variance $\pi^2/6$. Many computer codes, such as "survreg" in R and "LIFEREG" in SAS, can be adapted to do calculation under Equation (1). The observed Fisher information matrix is easily calculated from these programs, irrespective of the types of censoring under consideration.

Equations (1) and (8a) with (8b) are equivalent for the log-normal regression model, where the densities of W_j and W_j^* have the same form, $f(w) = e^{-w^2/2}/\sqrt{2\pi}$. In this case, it is possible to compare the two methods. Following the formulas from Jones et al. (1985), in the absence of censoring, their proposal for a $(1-\kappa)$-content, $(1-\alpha)100\%$-confidence lower tolerance limit under $\mathbf{Z}=(1,\mathbf{z}')'$ is given by

$$L_Z^*(\boldsymbol{\chi}) = \exp\Bigg[-z_{1-\alpha}\frac{\hat{\sigma}}{(n-p-1)^{1/2}}\frac{\{\tau^2+z_\kappa^2/2-z_{1-\alpha}^2\tau^2/(2n)\}^{1/2}}{1-z_{1-\alpha}^2/(2n)} - \hat{\sigma}\left\{z_\kappa - \left(\frac{n}{n-p-1}\right)^{1/2}\frac{z_\kappa}{1-z_{1-\alpha}^2/(2n)}\right\}\Bigg] \times \hat{G}^{-1}(\kappa|\mathbf{Z}), \quad (9)$$

where $\tau^2 = 1+\mathbf{z}'\{\sum_j \mathbf{z}_j\mathbf{z}_j'/n\}^{-1}\mathbf{z}$ and $\hat{G}^{-1}(\kappa|\mathbf{Z}) = \exp\{\mathbf{Z}'\hat{\boldsymbol{\beta}} + \hat{\sigma}\cdot z_\kappa\}$. On the other hand, the proposed tolerance limit is Equation (7). Now it is clear that both methods utilize the quantile estimator. A major difference between Equations (7) and (9) is due to our inclusion of the bias adjustment term $\hat{B}_n$ in Equation (7). Also, the formulas in the square bracket of Equation (9) differ from their counterparts in Equation (7) due to the different ways in which the normal approximation is applied. Note that Equation (7) is applicable to data with independent right-censoring while Equation (9) is not. Numerical studies comparing Equations (7) and (9) will be presented in Section 5.2.

4.2 Comparison With the Exact Tolerance Limits

Although the proposed approach is formulated in the presence of covariates, by setting $\mathbf{Z}_j = 1$, the resulting formula is also applicable under one-sample problems. Exact tolerance limits exist in a special case under one-sample settings. In such cases, they can serve as a theoretical basis for evaluating the accuracy of approximate tolerance limits. Although there is no reason to apply the approximate tolerance limits to data under these specific cases, when the exact solution is available, the result of this section may provide a strong theoretical basis for the proposed approach.

Now we revisit the example in Section 3.1, where T_j follows an exponential distribution function $G_{\exp}(t) = 1-\exp(-t/e^{\beta_0})$. But now, the data may be Type II censored so that $C_j = T_{(r)}$, where $r \le n$ is a prespecified number and $T_{(r)}$ is the rth observed failure time. In this case, the MLE of the quantile is given by

$$\hat{G}_{\exp}^{-1}(\kappa) = \{-\log(1-\kappa)\}\exp(\hat{\beta}_0) = \{-\log(1-\kappa)\}\sum_j X_j/r,$$

which is unbiased for $G_{\exp}^{-1}(\kappa) = \{-\log(1-\kappa)\}\exp(\beta_0)$. Setting $\hat{B}_n = 0$ and following the formula in Example 1, the proposed tolerance limit becomes $L_{Z=1}(\boldsymbol{\chi}) = \exp(-z_{1-\alpha}r^{-1/2})\cdot\hat{G}_{\exp}^{-1}(\kappa)$. On the other hand, the optimal tolerance limit provided by Goodman and Madansky (1962) is given by $L_{Z=1}^{\mathrm{Opt}}(\boldsymbol{\chi}) = 2r/\chi_{1-\alpha}^2(2r)\cdot\hat{G}_{\exp}^{-1}(\kappa)$.

We compare the proposed tolerance limit with the optimal one. The ratio of the optimal tolerance limit to the proposed one is

$$R(r) = \frac{L_{Z=1}^{\mathrm{Opt}}(\boldsymbol{\chi})}{L_{Z=1}(\boldsymbol{\chi})} = \frac{2r\exp(z_{1-\alpha}r^{-1/2})}{\chi_{1-\alpha}^2(2r)}.$$

Figure 1 shows the plot of $R(r)$ for $r \in [4, 100]$.

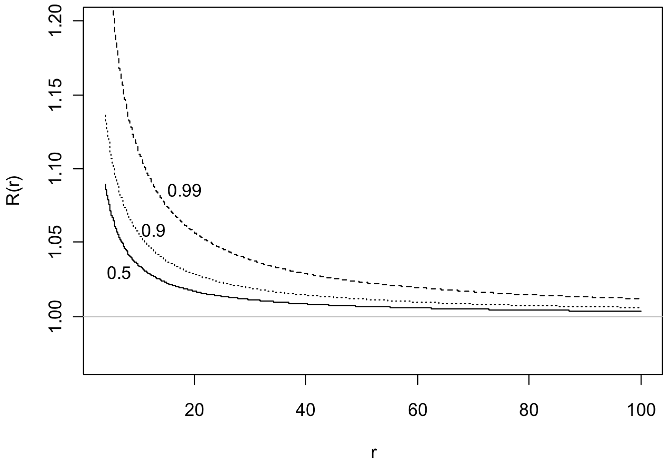

Figure 1. The plot of $R(r) = L_z^{\mathrm{Opt}}(\boldsymbol{\chi})/L_z(\boldsymbol{\chi})$ for the number of failure events $r \in [4, 100]$. The numbers 0.99, 0.9, and 0.5 represent the confidence level $1-\alpha$.

It is seen that $R(r) \ge 1$. This implies that the optimal tolerance limit is larger than the approximate limit for a finite value of r. It also indicates that the proposed tolerance limit is conservative in finite samples. The discrepancy between the two methods gets larger when the confidence level $1-\alpha$ increases. However, it becomes negligible when r is large and, for any α, $R(r) \to 1$ as $r \to \infty$ (see Appendix B).

5. SIMULATION STUDIES

5.1 Finite Sample Properties of the Proposed Method

To investigate the properties of the proposed tolerance limit with finite sample sizes, we conducted extensive simulation studies. Four models are considered:

Model 1: T_j follows the Weibull regression model with $\mathbf{Z}_j = (1, z_{1j})'$
Model 2: T_j follows the Weibull regression model with $\mathbf{Z}_j = (1, z_{1j}, z_{2j})'$
Model 3: T_j follows the log-normal regression model with $\mathbf{Z}_j = (1, z_{1j})'$
Model 4: T_j follows the log-normal regression model with $\mathbf{Z}_j = (1, z_{1j}, z_{2j})'$.

The parameters to be estimated are $(\beta_0, \beta_1, \sigma)$ for Models 1 and 3 and $(\beta_0, \beta_1, \beta_2, \sigma)$ for Models 2 and 4, respectively. The covariate z_{1j} takes 0 or 1 with equal probability while the covariate z_{2j} has a uniform distribution on [0, 1]. Failure times T_j are then generated according to Models 1 through 4, with censoring times C_j generated from the same model, so that $\Pr(C_j < T_j|\mathbf{Z}_j) = 0.5$. Subjects are treated as censored if $C_j < T_j$.

We generate 1000 sets of $\{(X_j, \delta_j, \mathbf{Z}_j); j = 1, \ldots, n\}$ with $n = 25, 50, \ldots, 275, 300$, and then calculate the proposed tolerance limit $[L_Z(\boldsymbol{\chi})]$ and the Wald-type limit $[L_Z^0(\boldsymbol{\chi})]$. Recall that $L_Z(\boldsymbol{\chi})$ utilizes the jackknife bias-adjustment while $L_Z^0(\boldsymbol{\chi})$ does not. When computing these tolerance limits, fixed values for $\mathbf{Z}' = (1, 1)$ and $\mathbf{Z}' = (1, 0.5, 0.5)$ are chosen for Models 1 and 3 and Models 2 and 4. The prediction at $\mathbf{Z}' = (1, 0.5, 0.5)$

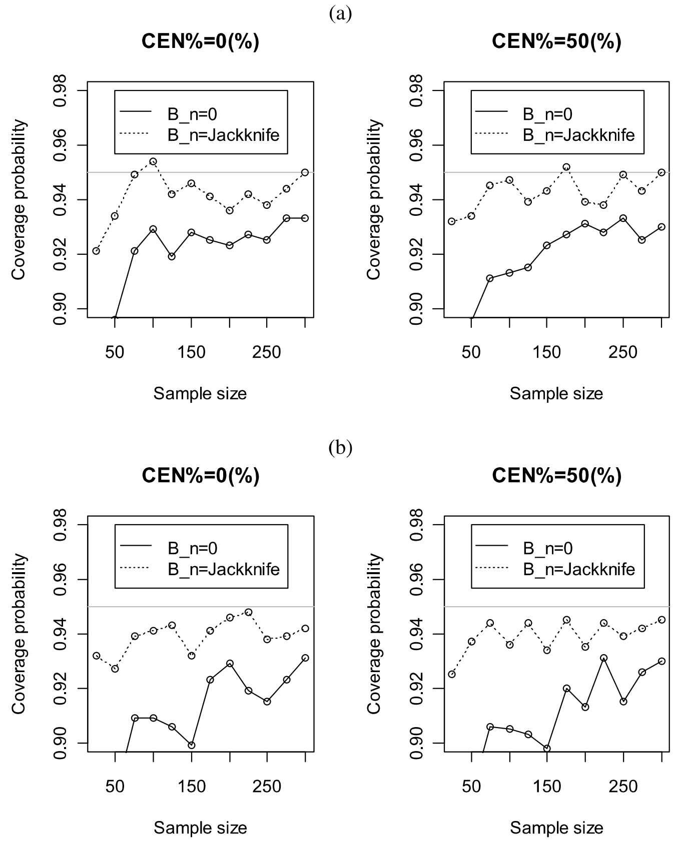

Figure 2. Coverage probabilities for the proposed tolerance limit $L_Z(\boldsymbol{\chi})$ (denoted by $B_n =$ jackknife) and the Wald-type limit $L_Z^0(\boldsymbol{\chi})$ (denoted by $B_n = 0$). The 0.90-content, 95%-confidence tolerance limits are calculated at $n = 25, 50, \ldots, 275, 300$. The percentage of censoring is denoted by CEN% $= 100\,\Pr(C_j < T_j|\mathbf{Z}_j)$. (a) Weibull regression with $\mathbf{Z}_i'\boldsymbol{\beta} = \beta_0 + z_{1i}\beta_1$, where $(\beta_0, \beta_1, \sigma) = (0, 1, 1)$. (b) Weibull regression with $\mathbf{Z}_i'\boldsymbol{\beta} = \beta_0 + z_{1i}\beta_1 + z_{2i}\beta_2$, where $(\beta_0, \beta_1, \beta_2, \sigma) = (0, 1, 1, 1)$.

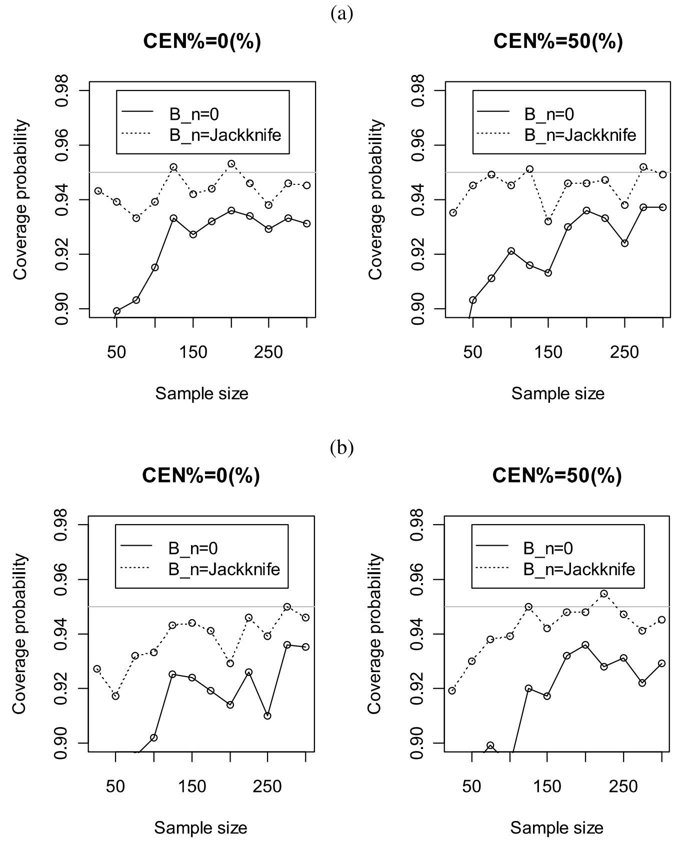

Figure 3. Coverage probabilities for the proposed tolerance limit $L_Z(\boldsymbol{\chi})$ (denoted by $B_n =$ jackknife) and the Wald-type limit $L_Z^0(\boldsymbol{\chi})$ (denoted by $B_n = 0$). The 0.90-content, 95%-confidence tolerance limits are calculated at $n = 25, 50, \ldots, 275, 300$. The percentage of censoring is denoted by CEN% $= 100\,\Pr(C_j < T_j|\mathbf{Z}_j)$. (a) Log-normal regression with $\mathbf{Z}_i'\boldsymbol{\beta} = \beta_0 + z_{1i}\beta_1$, where $(\beta_0, \beta_1, \sigma) = (0, 1, 1)$. (b) Log-normal regression with $\mathbf{Z}_i'\boldsymbol{\beta} = \beta_0 + z_{1i}\beta_1 + z_{2i}\beta_2$, where $(\beta_0, \beta_1, \beta_2, \sigma) = (0, 1, 1, 1)$.

considers a value of z_{1j} that is intermediate to the two values used in the experiment.

We compare the coverage probabilities of $L_Z(\boldsymbol{\chi})$ and $L_Z^0(\boldsymbol{\chi})$ with the nominal level $1-\alpha$. The coverage probability is the proportion of limits satisfying $1 - G(L_Z(\boldsymbol{\chi})|\mathbf{Z}) \geq 1-\kappa$ [or $1 - G(L_Z^0(\boldsymbol{\chi})|\mathbf{Z}) \geq 1-\kappa$] over 1000 datasets.

Figure 2 shows the results under the Weibull regression models. It is clear that the performance of coverage probabilities is significantly improved by adding the bias-correction term $\hat{B}_n$. For both methods, the coverage probabilities get closer to the nominal 95% level when the sample size increases. The coverage probabilities for the bias-corrected tolerance limits are between 93% and 95% for $n \geq 75$, and they sometimes deviate to 92% for $n = 25$. On the other hand, the tolerance limits calculated without bias-correction clearly suffer from undercoverage.

Figure 3 shows the results under the log-normal regression models. The results are very similar to the case of Weibull regression models. Again, including the bias term $\hat{B}_n$ significantly improves the coverage probabilities in all cases. As a result, the bias-corrected version of the tolerance limits has coverage probabilities between 93% and 95% for $n \geq 75$. The results for other values of $(\beta_0, \beta_1, \sigma)$ and $\mathbf{Z}'$, not shown here, also suggest that the bias-correction contributes positively to coverage performance.

In summary, despite the additional computational burden due to the jackknife, the bias-correction method leads to much better results. In our numerical experience, the undercoverage of the Wald-type limit is due to the upward bias of $\hat{G}^{-1}(\kappa|\mathbf{Z})$. As a result, the tolerance limit $L_Z^0(\boldsymbol{\chi}) = \hat{K}_{\alpha,n}^Z \cdot \hat{G}^{-1}(\kappa|\mathbf{Z})$ is stochastically larger than desired. The effect of bias-correction becomes less significant when sample sizes get very large since the bias of $\hat{G}^{-1}(\kappa|\mathbf{Z})$ converges to zero as $n \to \infty$.

5.2 Numerical Comparison With Other Tolerance Limits

The performances of the proposed tolerance limit $[L_Z(\boldsymbol{\chi})]$, the Wald-type limit $[L_Z^0(\boldsymbol{\chi})]$, and the limit proposed by Jones et al. (1985) are compared by a simulation study. In the absence of censoring, the coverage probabilities of the three approaches based on 1000 replications under the log-normal regression models (Model 3 and 4) are presented in Tables 1 and 2.

Table 1 shows the results under Model 3. As the sample sizes increase, the coverage probabilities for $L_Z(\boldsymbol{\chi})$ and $L_Z^0(\boldsymbol{\chi})$ get

Table 1. Coverage probabilities of the three methods under Model 3

	$\mathbf{Z}' = (1, 0)$			$\mathbf{Z}' = (1, 1)$		
	$L_Z(\chi)$	$L_Z^0(\chi)$	Jones	$L_Z(\chi)$	$L_Z^0(\chi)$	Jones
			(1) $1-\alpha = 0.90$			
			$\beta_0 = 0, \beta_1 = 0, \sigma = 1$			
$n = 25$	0.908	0.804	0.865	0.882	0.833	0.911
$n = 50$	0.902	0.848	0.858	0.891	0.842	0.923
$n = 100$	0.908	0.879	0.865	0.883	0.876	0.911
$n = 200$	0.900	0.885	0.850	0.906	0.878	0.932
			$\beta_0 = 0, \beta_1 = 1, \sigma = 1$			
$n = 25$	0.875	0.821	0.829	0.882	0.838	0.907
$n = 50$	0.897	0.876	0.836	0.902	0.863	0.934
$n = 100$	0.893	0.874	0.847	0.910	0.851	0.942
$n = 200$	0.906	0.879	0.855	0.904	0.897	0.931
			(2) $1-\alpha = 0.95$			
			$\beta_0 = 0, \beta_1 = 0, \sigma = 1$			
$n = 25$	0.932	0.880	0.908	0.927	0.888	0.958
$n = 50$	0.939	0.899	0.904	0.947	0.910	0.963
$n = 100$	0.945	0.912	0.911	0.957	0.938	0.974
$n = 200$	0.952	0.934	0.916	0.942	0.927	0.968
			$\beta_0 = 0, \beta_1 = 1, \sigma = 1$			
$n = 25$	0.914	0.874	0.885	0.933	0.872	0.957
$n = 50$	0.931	0.911	0.896	0.933	0.916	0.961
$n = 100$	0.934	0.925	0.895	0.942	0.935	0.964
$n = 200$	0.948	0.930	0.906	0.955	0.927	0.978

NOTE: Coverage probabilities for 0.90-content, $100(1-\alpha)\%$-confidence tolerance limits are calculated under the log-normal regression models:

$$\log(T_j) = \beta_0 + \beta_1 z_{1j} + \sigma W_j.$$

closer to the nominal levels. However, the coverage probabilities of $L_Z(\chi)$ are much closer to the nominal levels than those of $L_Z^0(\chi)$ in all cases. On the other hand, the correctness of the Jones et al. approach appears to vary with the values of $\mathbf{Z}$ selected. For instance, the first four entries in the third column of Table 1 show that the coverage probabilities are between 0.850 and 0.865, and do not get closer to 0.90 as the sample size increases. The results under Model 4 are provided in Table 2. The behaviors of the three tolerance limits are analogous to that of Table 1. In almost all entries, $L_Z(\chi)$ provides the best coverage performance compared to the other two methods.

From the previous results, it is shown that $L_Z(\chi)$ provides more reliable coverage probabilities than $L_Z^0(\chi)$ and the method of Jones et al. (1985). Jones et al. justified the correctness of their method by simulations in the absence of covariates (i.e., one-sample case). In the presence of covariates, however, the accuracy of their methods may be questionable, at least in our simulation settings.

Remark 2. For certain data, it is impossible to find the maximum of the likelihood function. One of the major reasons for this problem is the small number of observed failure times. The problem is also partly due to the ability of the maximization program for the software at hand. In our simulations, the "survreg" in R implements a sophisticated maximization program which successfully found the maximum in all 1000 datasets that we simulated with $n = 25$ and $\Pr(C_j < T_j|\mathbf{Z}_j) = 0.5$. However, small datasets contain little information about the

Table 2. Coverage probabilities of the three methods under Model 4

	$\mathbf{Z}' = (1, 0, 0)$			$\mathbf{Z}' = (1, 0.5, 0)$			$\mathbf{Z}' = (1, 0.5, 0.5)$		
	$L_Z(\chi)$	$L_Z^0(\chi)$	Jones	$L_Z(\chi)$	$L_Z^0(\chi)$	Jones	$L_Z(\chi)$	$L_Z^0(\chi)$	Jones
					(1) $1-\alpha = 0.90$				
					$\beta_0 = 0, \beta_1 = 0, \beta_2 = 0, \sigma = 1$				
$n = 25$	0.916	0.836	0.787	0.915	0.822	0.828	0.881	0.760	0.915
$n = 50$	0.907	0.863	0.776	0.901	0.834	0.816	0.891	0.824	0.934
$n = 100$	0.905	0.876	0.750	0.897	0.858	0.835	0.888	0.853	0.927
$n = 200$	0.901	0.879	0.783	0.904	0.862	0.828	0.898	0.860	0.936
					$\beta_0 = 0, \beta_1 = 1, \beta_2 = 1, \sigma = 1$				
$n = 25$	0.913	0.813	0.753	0.927	0.811	0.838	0.889	0.788	0.925
$n = 50$	0.924	0.842	0.751	0.894	0.853	0.821	0.893	0.822	0.916
$n = 100$	0.902	0.863	0.740	0.910	0.863	0.826	0.886	0.860	0.926
$n = 200$	0.901	0.863	0.755	0.903	0.891	0.829	0.910	0.858	0.940
					(2) $1-\alpha = 0.95$				
					$\beta_0 = 0, \beta_1 = 0, \beta_2 = 0, \sigma = 1$				
$n = 25$	0.935	0.871	0.818	0.949	0.875	0.892	0.919	0.857	0.960
$n = 50$	0.941	0.924	0.828	0.949	0.918	0.881	0.933	0.894	0.967
$n = 100$	0.959	0.923	0.820	0.960	0.939	0.888	0.944	0.910	0.969
$n = 200$	0.948	0.943	0.820	0.947	0.934	0.886	0.944	0.937	0.970
					$\beta_0 = 0, \beta_1 = 1, \beta_2 = 1, \sigma = 1$				
$n = 25$	0.946	0.891	0.836	0.938	0.894	0.879	0.910	0.871	0.963
$n = 50$	0.942	0.905	0.824	0.959	0.909	0.905	0.943	0.898	0.980
$n = 100$	0.946	0.922	0.820	0.939	0.923	0.870	0.956	0.901	0.973
$n = 200$	0.954	0.932	0.829	0.943	0.913	0.874	0.946	0.918	0.980

NOTE: Empirical coverage probabilities for 0.90-content, $100(1-\alpha)\%$-confidence tolerance limits are calculated under the log-normal regression models:

$$\log(T_j) = \beta_0 + \beta_1 z_{1j} + \beta_2 z_{2j} + \sigma W_j.$$

model, and therefore asymptotic approximation is questionable. Another potential problem resulting from small sample size is that $L_Z(\boldsymbol{\chi})$ can be negative if $\hat{G}^{-1}(\kappa|\mathbf{Z}) < B_n^Z$. This condition is noted only occasionally when $\hat{G}^{-1}(\kappa|\mathbf{Z})$ is fairly close to zero. Such a case can occur, for example, if $\kappa \le 0.99$, $1-\alpha \le 0.95$, and $n \le 25$. In our numerical experience, we found that $L_Z(\boldsymbol{\chi})$ is always positive as long as $n \ge 50$.

6. DATA ANALYSIS

The proposed tolerance limits are illustrated by two data examples in this section.

6.1 Fiber Strengths Data

The first analysis uses the fiber strengths data provided in Crowder (2000). The data consist of failure stresses (T_j) along with the lengths (z_j) of $n = 257$ fiber samples. The sample does not include any censoring. In many engineering applications, covariate effects may be modeled by the inverse power law of the form

$$\log(T_j) = \beta_0 + \beta_1 \log(z_j) + \sigma W_j. \tag{10}$$

To choose the right model for W_j, we follow section 3.8 of Kalbfleisch and Prentice (2002). The method utilizes the generalized log-gamma distribution for W_j, defined as

$$f(w) = \frac{m_1^{m_1}}{\Gamma(m_1)} \exp(m_1 w - m_1 e^w),$$

where $m_1 \ge 0$. If we set $q = m_1^{-1/2}$, then $q = 0$ and $q = 1$ correspond to the log-normal and Weibull regression models, respectively, as special cases. The likelihood ratio statistics are 6.33 (p-value $= 0.012$) for $H_0: q = 0$ and 17.69 (p-value $= 0.000$) for $H_0: q = 1$, respectively. Neither $q = 0$ nor $q = 1$ is satisfactory at the 5% level. Therefore, we choose the generalized log-gamma distribution with $m_1 = 16$ whose test for $H_0: q = 0.25$ generates better confidence (p-value $= 0.419$). Parameter estimates are $\hat{\beta}_0 = 1.456$ (p-value $= 0.000$), $\hat{\beta}_1 = -0.167$ (p-value $= 0.000$), and $\hat{\sigma} = 0.800$.

For the purpose of illustration we consider three different censoring schemes of the original data, which are shown in Table 3A. For all three censoring schemes, we generate artificial censorings so that approximately half of the entire sample is censored. Specifically, for Type I censoring, we chose a deterministic value $C_i = 2.67$, which is the median breaking strength of the sample. For Type II censoring, censoring occurs when the first 28, 32, 32, and 32 subjects fail at $z_j = 1, 10, 20$, and 30, respectively. For random censoring, we generated random censoring times $C_i = \exp(D_i)$, where D_i has a normal distribution with mean $\mathbf{Z}_i'\hat{\boldsymbol{\beta}} - \sqrt{2}\hat{\sigma}\Phi^{-1}(0.5)$ and variance $\hat{\sigma}^2$, where $(\hat{\boldsymbol{\beta}}, \hat{\sigma})$ are the MLE under the log-normal regression model.

Table 3A. Artificial censoring schemes for the breaking strengths data

	No censoring	Type I censoring	Type II censoring	Random censoring
$z = 1$	0%	96.5%	50.9%	47.4%
$z = 10$	0%	64.1%	50.0%	53.1%
$z = 20$	0%	31.4%	50.0%	47.1%
$z = 50$	0%	15.2%	50.0%	57.6%
Total	0%	49.8%	50.2%	51.4%

NOTE: Each entry represents the percentages of censored subjects at each z. That is,

$$100 \times \sum_j I(C_j < T_j, z_j = z) \Big/ \sum_j I(z_j = z).$$

Table 3B. 0.90-content, 95%-confidence lower tolerance limits for the breaking strengths

	Without censoring	Type I censoring	Type II censoring	Random censoring
$z = 1$	3.058	1.930	2.843	2.781
$z = 10$	2.115	1.815	1.973	1.917
$z = 20$	1.881	1.766	1.758	1.700
$z = 50$	1.605	1.673	1.502	1.442

NOTE: Tolerance limits under the three types of censorings are calculated by the proposed method.

The 0.9-content, 95%-confidence lower tolerance limits under the log-gamma regression model with $m_1 = 16$ are shown in the first column of Table 3B at $z = 1, 10, 20$, and 50. For example, we can claim with 95% confidence that at least 90% of the fibers of length $z = 10$ have higher tensile strength than the limit $L_Z(\boldsymbol{\chi}) = 2.115$. In fact, the interval $[2.115, \infty)$ brackets 98% of the samples with $z_j = 10$.

Results under censoring are presented in Table 3B. The lower tolerance limits calculated under censoring are close to those calculated in the absence of censoring except for the case of $z = 1$ under Type I censoring. It may be due to the large percentage of censoring (96.5%).

6.2 Motorettes Data

The second dataset is presented in Nelson and Hahn (1972). Table 4 shows the numbers of hours to failure for motorettes at four different temperatures.

The third column contains 17 observed failure times among $n = 40$ motorettes. All the remaining mottoerets are censored at fixed times of 8064, 5448, 1680, and 528 hours under 150°C, 170°C, 190°C, and 220°C, respectively. Such studies are typically interested in estimating the failure time distribution under specified operating conditions. Following the suggestion of Nelson and Hahn (1972), we use a transformed covariate $z_j = 1000/(273.2 + °\mathrm{C})$ in the regression model. Therefore,

$$\log(T_j) = \beta_0 + \beta_1 z_j + \sigma W_j. \tag{11}$$

We determine the model for W_j using the same method as in Section 6.1. The likelihood ratio statistics are 5.60 (p-value $= 0.018$) for testing $H_0: q = 0$ and 1.03 (p-value $= 0.310$) for testing $H_0: q = 1$, respectively. Therefore, we adopt the Weibull regression model with $\hat{\beta}_0 = -13.36$ (p-value $= 0.000$), $\hat{\beta}_1 = 9.730$ (p-value $= 0.000$), and $\hat{\sigma} = 0.325$.

We compute the 0.9-content, 95%-confidence lower tolerance limits for failure times under Equation (11). The fifth column of Table 4 shows the lower tolerance limits under the four operating conditions. For example, the number 1977.2 in the second row shows that we are 95% confident that at least 90% of failure times exceed 1977.2 h with the operating condition of

Table 4. Data and results for hours to failure for motorettes and tolerance limits

Temperature	Sample size	Observed failure times	Censoring time	Tolerance limit
150°C	10	None	8064	5193.9
170°C	10	1764, 2772, 3444, 3542, 3780, 4860, 5196	5448	1977.2
190°C	10	408, 408, 1344, 1440	1680	778.3
220°C	10	408, 408, 504, 504, 504	528	203.9

NOTE: The third column represents the numbers of hours to failure for motorettes operating under four conditions of 150°C, 170°C, 190°C, and 220°C. The censoring is Type I at each temperature; failure times are observed only if failure occurred prior to the predetermined censoring times at each temperature. 0.90-content, 95%-confidence lower tolerance limits are calculated for each temperature.

170°C. Nine out of ten failure times exceed the tolerance limit of 1977.2 h at 170°C.

7. CONCLUSION

This study provides a unified approach for obtaining approximate tolerance limits under the log-location-scale regression models in the presence of censoring. The proposed tolerance limit has an explicit formula and is easy to calculate without using special tables and resampling methods. We also adopt a bias-correction technique via the jackknife method to improve small sample accuracy. In particular, the simulations show that the bias-corrected tolerance limit provides more accurate coverage probability. Asymptotic theory is also provided to justify the proposed approach.

R codes for implementing the proposed method are available online, on the *Technometrics* web site, as supplemental material. For instance, the "survreg" function in the R "survival" library is useful to obtain the MLE and its observed information matrix. Routine implementations of the procedure in other high-level language such as SAS should be straightforward.

APPENDIX A: LARGE SAMPLE PROPERTIES

A.1 Regularity Conditions for Normal Approximation

Define a counting process $N_j(t) = I(X_j \le t, \delta_j = 1)$ and at-risk indicator $Y_j(t) = I(X_j \ge t)$. Also, define $\alpha_j^{\boldsymbol{\theta}}(t) = h(t|\mathbf{Z}_j)$ as a function of $\boldsymbol{\theta}' = (\boldsymbol{\beta}', \sigma)$. Under Equation (1) and Assumption A, the likelihood function can be re-written as

$$L(\boldsymbol{\beta}, \sigma) = \prod_{0 \le t < \infty} \left[\prod_j \{Y_j(t)\alpha_j^{\boldsymbol{\theta}}(t)\}^{dN_j(t)} \left\{ 1 - \sum_j Y_j(t)\alpha_j^{\boldsymbol{\theta}}(t) \right\} \right],$$

and the score function becomes

$$\mathbf{U}(\boldsymbol{\theta}) = \sum_j \int_0^\infty \frac{\partial}{\partial \boldsymbol{\theta}} \log\{\alpha_j^{\boldsymbol{\theta}}(t)\}\, dM_j(t),$$

where $dM_j(t; \boldsymbol{\theta}) = dN_j(t) - Y_j(t)\alpha_j^{\boldsymbol{\theta}}(t)\, dt$. The MLE is now defined as the solution $(\hat{\boldsymbol{\beta}}, \hat{\sigma})$ to the martingale type estimating equation $\mathbf{U}(\boldsymbol{\theta}) = \mathbf{0}$, and the asymptotic behavior follows from the counting process and martingale theory. The regularity conditions for the consistency and asymptotic normality of $(\hat{\boldsymbol{\beta}}, \hat{\sigma})$ are covered by condition VI.1.1 of Andersen et al. (1993). Since this condition is provided for very general settings, including recurrent event models, it is convenient to rewrite them for our setting. We use $\boldsymbol{\theta}_0$ to denote the true value of the parameter and reserve $\boldsymbol{\theta}$ for the free parameter in the parameter space $\Theta = \{\boldsymbol{\theta}' = (\boldsymbol{\beta}', \sigma) : \boldsymbol{\beta} \in R^{p+1}, \sigma > 0\}$.

(A) For all j, the first, second, and third partial derivatives of $\alpha_j^{\boldsymbol{\theta}}(t)$ and $\log\{\alpha_j^{\boldsymbol{\theta}}(t)\}$ with respect to $\boldsymbol{\theta}$ exist and they are continuous in the neighborhood of $\boldsymbol{\theta}_0$.

(B) For all l and m, there exist a number $\sigma(\boldsymbol{\theta}_0)_{l,m}$ such that

$$\frac{1}{n} \int_0^\infty \sum_j \frac{\partial}{\partial \theta_l} \log\{\alpha_j^{\boldsymbol{\theta}_0}(t)\} \frac{\partial}{\partial \theta_m} \log\{\alpha_j^{\boldsymbol{\theta}_0}(t)\} Y_j(t)\alpha_j^{\boldsymbol{\theta}_0}(t)\, dt \xrightarrow{P} \sigma(\boldsymbol{\theta}_0)_{l,m}.$$

(C) (Lindeberg condition) For all l and $\varepsilon > 0$,

$$\frac{1}{n} \int_0^\infty \sum_j \left[\frac{\partial}{\partial \theta_l} \log\{\alpha_j^{\boldsymbol{\theta}_0}(t)\} \right]^2 \times I\left[\left| \frac{1}{\sqrt{n}} \frac{\partial}{\partial \theta_l} \log\{\alpha_j^{\boldsymbol{\theta}_0}(t)\} \right| > \varepsilon \right] Y_j(t)\alpha_j^{\boldsymbol{\theta}_0}(t)\, dt \xrightarrow{P} 0.$$

(D) The matrix $\Sigma(\boldsymbol{\theta}_0) = \{\sigma(\boldsymbol{\theta}_0)_{l,m}\}$ is positive-definite.

(E) There exist deterministic functions $G_j(t)$ and $H_j(t)$ such that

$$\sup_{\boldsymbol{\theta} \in \Theta} \left| \frac{\partial^3}{\partial \theta_l\, \partial \theta_m\, \partial \theta_r} \alpha_j^{\boldsymbol{\theta}}(t) \right| \le G_j(t),$$

$$\sup_{\boldsymbol{\theta} \in \Theta} \left| \frac{\partial^3}{\partial \theta_l\, \partial \theta_m\, \partial \theta_r} \log\{\alpha_j^{\boldsymbol{\theta}_0}(t)\} \right| \le H_j(t)$$

for all l, m, and r. Also,

$$\frac{1}{n} \int_0^\infty \sum_j G_j(t)\, dt,$$

$$\frac{1}{n} \int_0^\infty \sum_j h_j(t) Y_j(t)\alpha_j^{\boldsymbol{\theta}_0}(t)\, dt,$$

$$\frac{1}{n} \int_0^\infty \sum_j Y_j(t) \left[\frac{\partial^2}{\partial \theta_l\, \partial \theta_m} \log\{\alpha_j^{\boldsymbol{\theta}_0}(t)\} \right]^2 \alpha_j^{\boldsymbol{\theta}_0}(t)\, dt,$$

all converge in probability to finite quantities. Moreover, for all $\varepsilon > 0$,

$$\frac{1}{n} \int_0^\infty \sum_j H_j(t) I\left[\sqrt{\frac{H_j(t)}{n}} > \varepsilon \right] Y_j(t)\alpha_j^{\boldsymbol{\theta}_0}(t)\, dt \xrightarrow{P} 0.$$

A.2 Proof of Theorem 1

By some algebraic calculation, we can write

$$\begin{aligned}
&n^{1/2}\big[\log\{\hat{G}^{-1}(\kappa|\mathbf{Z}) - \hat{B}_n^Z\} - \log\{G^{-1}(\kappa|\mathbf{Z})\}\big] \\
&= n^{1/2}\log\left(1 - \frac{\hat{B}_n^Z}{\hat{G}^{-1}(\kappa|\mathbf{Z})}\right) \\
&\quad + n^{1/2}\big[\log\{\hat{G}^{-1}(\kappa|\mathbf{Z})\} - \log\{G^{-1}(\kappa|\mathbf{Z})\}\big] \\
&= -\frac{n^{1/2}\hat{B}_n^Z}{\hat{G}^{-1}(\kappa|\mathbf{Z})} + o_P\big(n^{1/2}\hat{B}_n^Z\big) \\
&\quad + n^{1/2}\big[\log\{\hat{G}^{-1}(\kappa|\mathbf{Z})\} - \log\{G^{-1}(k|\mathbf{Z})\}\big],
\end{aligned}$$

where the second equation is derived from a Taylor expansion $\log(1-x) = -x + o(x)$. From the assumption that $B_n^Z = O(n^{-1})$ as $n \to 0$ and the second-order correctness of the jackknife estimator, we have $n^{1/2}\hat{B}_n^Z = o_P(1)$ (Lehmann and Casella 1998, p. 84). Thus, the preceding display can be further written as

$$\begin{aligned}
&n^{1/2}\big[\log\{\hat{G}^{-1}(\kappa|\mathbf{Z}) - \hat{B}_n^Z\} - \log\{G^{-1}(\kappa|\mathbf{Z})\}\big] \\
&= o_P(1) + n^{1/2}\big[\log\{\hat{G}^{-1}(\kappa|\mathbf{Z})\} - \log\{G^{-1}(\kappa|\mathbf{Z})\}\big] \\
&= o_P(1) + n^{1/2}\mathbf{A}'(\hat{\boldsymbol\beta}' - \boldsymbol\beta', \hat\sigma - \sigma)'.
\end{aligned}$$

Now, by the delta method and Slutsky's lemma, it follows that the preceding equation converges weakly to a mean zero random variable with variance

$$\Omega(\boldsymbol\beta, \sigma) = \mathbf{A}'\mathbf{J}^{-1}(\boldsymbol\beta, \sigma)\mathbf{A},$$

where $\mathbf{J}(\boldsymbol\beta, \sigma)$ is the Fisher information matrix. $\Omega(\boldsymbol\beta, \sigma)$ is consistently estimated by $n\mathbf{A}'\mathbf{i}_n(\hat{\boldsymbol\beta}, \hat\sigma)^{-1}\mathbf{A}$. Again, by Slutsky's lemma,

$$\frac{\log\{\hat{G}^{-1}(\kappa|\mathbf{Z}) - \hat{B}_n^Z\} - \log\{G^{-1}(\kappa|\mathbf{Z})\}}{\{\mathbf{A}'\mathbf{i}_n(\hat{\boldsymbol\beta}, \hat\sigma)^{-1}\mathbf{A}\}^{1/2}},$$

converges weakly to the standard normal distribution. Rewriting the convergence result,

$$\begin{aligned}
&1-\alpha \\
&= \lim_{n\to\infty} \Pr\left(\frac{\log\{\hat{G}^{-1}(\kappa|\mathbf{Z}) - \hat{B}_n^Z\} - \log\{G^{-1}(\kappa|\mathbf{Z})\}}{\{\mathbf{A}'\mathbf{i}_n(\hat{\boldsymbol\beta}, \hat\sigma)^{-1}\mathbf{A}\}^{1/2}} \le z_{1-\alpha}\right) \\
&= \lim_{n\to\infty} \Pr(1 - G(L_Z|\mathbf{Z}) \ge 1-\kappa).
\end{aligned}$$

APPENDIX B: PROOF OF $R(r) \to 1$ AS $r \to \infty$

By a Taylor series expansion, it can be shown that

$$\begin{aligned}
R(r) &= \frac{2re^{z_{1-\alpha}r^{-1/2}}}{\chi^2_{1-\alpha}(2r)} = \frac{2r\{1 + z_{1-\alpha}r^{-1/2} + O(r^{-1})\}}{\chi^2_{1-\alpha}(2r)} \\
&= \frac{2r + 2z_{1-\alpha}r^{1/2}}{\chi^2_{1-\alpha}(2r)} + O(r^{-1}). \qquad \text{(B.1)}
\end{aligned}$$

Let W_r be a chi-square random variable with $2r$ degrees of freedom. Then, by the central limit theorem, we have

$$\lim_{r\to\infty} \Pr\left(\frac{W_r - 2r}{(4r)^{1/2}} \le z_{1-\alpha}\right) = 1-\alpha. \qquad \text{(B.2)}$$

On the other hand,

$$\Pr\left(\frac{W_r - 2r}{(4r)^{1/2}} \le \frac{\chi^2_{1-\alpha}(2r) - 2r}{(4r)^{1/2}}\right) = 1-\alpha. \qquad \text{(B.3)}$$

Equations (B.2) and (B.3) together imply

$$\lim_{r\to\infty} \frac{\chi^2_{1-\alpha}(2r) - 2r}{(4r)^{1/2}} = z_{1-\alpha}. \qquad \text{(B.4)}$$

Combining Equations (B.1) and (B.4) yields the desired result

$$\begin{aligned}
R(r) &= \frac{(2r + 2z_{1-\alpha}r^{1/2})/(4r)^{1/2}}{\{\chi^2_{1-\alpha}(2r) - 2r + 2r\}/(4r)^{1/2}} + O(r^{-1}) \\
&= \frac{r^{1/2} + z_{1-\alpha}}{O(1) + r^{1/2}} + O(r^{-1}) \to 1 \qquad (r \to \infty).
\end{aligned}$$

SUPPLEMENTAL MATERIALS

Computer code: R codes that implement the proposed tolerance limit under the Weibull regression model. They contain an R function that calculates the proposed tolerance limit and an example for analyzing motorettes data. Analysis results of the motorettes data can be easily reproduced using these codes. (Supplemental Materials_0402.pdf)

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