Trends in Fidelis Lead Survival
Transition From an Exponential to Linear Pattern of Lead Failure Over Time

Jim W. Cheung, MD; Aviva Tobin-Hess, BA; Apoor Patel, MD; David J. Slotwiner, MD; Bruce G. Goldner, MD

Background—The Sprint Fidelis implantable cardioverter-defibrillator lead was recalled in 2007 because of an elevated risk of lead fracture. Several studies have demonstrated an accelerating risk of lead failure over time. We sought to identify predictors and characterize trends of Fidelis lead failure.

Methods and Results—We evaluated 604 Fidelis leads with ≥90 days of follow-up implanted at our institution. Fidelis lead survival was analyzed by the Kaplan-Meier method. Analysis of log-log plots of cumulative hazard plots was performed to assess changes in lead failure rate over time. During follow-up of 3.3±1.7 years, 51 (8.4%) Fidelis lead failures were identified. The 3-year and 5-year Fidelis lead survival rates were 93.5% and 85.3%, respectively. Female sex was the only significant predictor of lead failure (heart rate, 2.1; 95% CI, 1.1–3.9; P<0.0001). The rate of lead failure initially increased exponentially with a power of 2.3 (95% CI, 2.22–2.43; P<0.0001). However, log-log analysis of cumulative hazard for leads functioning at 2 and 4 years revealed a stable rate of failure of 4.5%/year. Mathematical modeling of the Fidelis lead failure demonstrated a transition from an exponential to linear pattern of lead failure at 2.9 years.

Conclusions—After 3 years, failure rates of Fidelis leads stabilize but at a significantly elevated rate. Female sex is associated with a doubling of the risk of Fidelis lead failure. These findings have implications for Fidelis lead management decisions that are based on the prediction of lead failure risk. (Circ Arrhythm Electrophysiol. 2012;5:906-912.)

Key Words: implantable cardioverter-defibrillator ■ lead failure ■ lead advisory ■ failure rate

In 2007, Medtronic recalled the Sprint Fidelis implantable cardioverter-defibrillator (ICD) lead after an increased rate of lead fracture was observed.1 By that time, a total of 268 000 Fidelis ICD leads had been implanted. Although reports by Medtronic have indicated Fidelis lead survivals of 94.6% after 3 years of implantation,2 lower rates of lead survival of 88% to 93% at 3 years have been observed by several centers.3–8 Several clinical factors have been associated with an increased risk of Fidelis lead failure, which include younger age, female sex, and higher ejection fraction.8–11 Studies have also reported an accelerating increase in the risk of Fidelis lead failure over time.4,11 However, it is unclear with long-term follow-up whether the risk of Fidelis lead failure is continuing to increase in an exponential trend or whether it is stabilizing in a linear manner with respect to time. We sought to identify the clinical predictors of lead failure and to determine the change in hazard rates of Fidelis lead fracture over time.

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atrial or left ventricular lead implantation. Patients were followed up at 2 to 4 weeks after ICD implantation and at 3-month intervals thereafter in the device clinic and via remote monitoring.

**Definition of Lead Failure**

Lead failure was defined as one of the following: (1) sudden increase in chronic pacing threshold or defibrillation lead impedance of ≥20% during a 24-hour period, (2) oversensing of nonphysiological electric noise artifacts because of make-break potentials, or (3) failure to deliver defibrillation therapy because of lead fracture or insulation break. Lead dislodgments, exit block, physiological oversensing, T-wave oversensing, and header problems were not considered lead failures for this study. The presence of any inappropriate shocks associated with lead failure was recorded. For survival analysis, the date of lead failure was identified using device interrogation as the first occurrence of any lead abnormality fulfilling the definition of lead failure, as stated above. All patient deaths were recorded. If a patient died and no lead failure had been identified, then the date of last known device interrogation was recorded as the last follow-up date for Kaplan-Meier analysis.

**Statistical Analysis**

Continuous variables were expressed as median (interquartile range, 25%–75%). Comparisons between continuous variables were calculated by the use of the Mann-Whitney U test. Comparisons between categorical variables were performed using the χ² test. For each variable that was significantly associated with the occurrence of lead failure, a hazard ratio with 95% CIs was calculated using Cox regression analysis. The proportional hazard assumption was tested using graphical analysis of log-log survival curves.

Survival and cumulative hazard were calculated by the Kaplan-Meier method. Survival curves were compared by the use of the log rank test. Conditional survival probabilities of leads surviving at 2 and 4 years were calculated by performing a Kaplan-Meier analysis on leads surviving past time 2 and 4 years, with time 0 defined as follow-up time minus 2 or 4 years, as applicable. To assess the change in lead failure risk over time, a log-log plot of the cumulative hazard function (log H versus log t) was performed. If the cumulative hazard of lead failure at time t is defined by the function $H(t) = a + nt$ where a and n are constants, then log $H(t) = \log a + n \log t$. Linear regression analysis using the least squares method was performed on the log-log H-t plot to estimate the slope n and the constant log a. This analysis was also repeated for the subgroup of leads surviving past 2 years and the subgroup surviving past 4 years. If the slope of the conditional survival log H-log t plot was found to be close to 1 (ie, constant lead failure rate over time), then linear regression was performed directly on the cumulative hazard plot (H versus t) to define the lead failure rate per year.

All statistical analysis was performed using SPSS version 19.0 (Chicago, IL). *P* <0.05 was considered statistically significant.

**Results**

We evaluated 602 patients who had 604 Fidelis leads (594 [98%] model 6949, 9 [1.4%] model 6931, and 1 [0.1%] model 6948) implanted between September 2004 and October 2007 at our center and had follow-up ≥90 days. During a median follow-up of 3.5 (interquartile range, 1.9–4.7) years (range 90 days–6.6 years), a total of 51 (8.4%) Fidelis lead failures were seen. The baseline clinical and device implantation characteristics of the study patients are summarized in Table 1. A higher proportion of patients with Fidelis lead failure were women (38%) compared with patients without Fidelis lead failure (24%) (*P* =0.02). There were no significant differences between patients with lead failure and patients without lead failure with respect to age, ejection fraction, implantation of atrial lead or left ventricular lead, or use of cephalic venous access. Among the 51 patients who experienced lead failures, 22 (43%) received inappropriate ICD shocks as a result. Of the remaining 29 patients who did not receive inappropriate ICD shocks, 14 (48%) had nonphysiological oversensing detected by the device, and 18 (62%) had significant changes in lead impedances. There were 34 (5.6%) deaths in the study population, with no significant difference in mortality seen between patients who had lead failure and patients who did not (2.0% versus 6.0%; *P* =0.24). There were no deaths that were directly attributed to lead failure.

The Kaplan-Meier survival curve for the Fidelis lead in our study is displayed in Figure 1. The 1-, 3-, and 5-year survival rates for the Fidelis lead were 99.6%, 93.5%, and 85.3%, respectively. The only clinical predictor of lead failure was female sex (hazard ratio, 2.1; 95% CI, 1.1–3.9; *P* =0.02). The survival of Fidelis leads implanted in female patients at 5 years was 79.1% compared with 87.4% in male patients (*P* =0.026) (Figure 2). Analysis of the log-log plot of cumulative hazard versus time yielded a curve of excellent fit with a linear slope of 2.3 (R², 0.98; 95% CI, 2.2–2.43; *P* <0.0001), consistent with an exponential model of Fidelis lead failure with a power of 2.3 (Figure 3). In this model, the hazard function $H(t) = e^{2.3t}$ can be described as $(e^{-5.335})^{t/2} = 0.00482^{t/2}$.

Conditional survival curves for leads that were functioning normally at 1, 2, and 4 years of follow-up are displayed in Figure 4. The probability of a functioning Fidelis lead at 1 year of surviving an additional 1 and 2 years was 97.5% and 93.9%, respectively. The probability of a functioning Fidelis lead at 2 years of surviving an additional 1 and 2 years was 96.1% and 90.9%, respectively. The probability of a functioning Fidelis lead at 4 years of surviving an additional 1 and 2 years was 95.8% and 90.7%, respectively. A log-log plot of hazard versus time generated with the population of leads that were functional at 2 years after implantation (Figure 5A). Linear regression analysis yielded a straight line with a slope of 0.85 (R², 0.96; 95% CI, 0.80–0.91; *P* <0.0001). The same analysis was performed for leads surviving past 4 years after implantation (Figure 5B), which revealed a straight line with a slope of 1.00 (R², 0.97; 95% CI, 0.83–1.18; *P* <0.0001). Given that the log cumulative hazard-log time plots slopes were close to 1 for leads surviving past 2 and 4 years, linear regression was performed directly on the hazard plots for these 2 groups of leads (Figure 6A and 6B). The failure rate per year for leads surviving past 2 years as defined by the slope of the hazard plot was 4.5% per year (R², 0.99; 95% CI, 0.044–0.047; *P* <0.0001) and for leads surviving past 4 years was also 4.5% per year (R², 0.99; 95% CI, 0.040–0.051; *P* <0.0001).

Based on these findings, we refined our mathematical model of the Fidelis cumulative hazard function $H(t)$ by defining it as an exponential function between time 0 and time $t_1$ and a linear function from time $t_1$ onward, where $t_1$ is defined as the time point of transition of the hazard function (Figure 7). Using the 4.5% per year fractile rate to define the linear portion of the cumulative hazard function, we determined time $t_1$ =2.9 years as the point at which lead failure rate became constant (online-only Data Supplement). Therefore, the cumulative hazard plot of Fidelis lead failure in our study can be represented as an initial exponential function, followed by a straight line for all time points after 2.9 years.
Discussion

In this study, we identified female sex as the only significant predictor of Fidelis lead failure. We demonstrate that the rate of Fidelis lead failure rises exponentially initially but levels off after 3 years. Fidelis lead surviving past 2 years demonstrated a significantly elevated rate of failure of 4.5% per year, with no signs of slowing. These findings have significant implications for the management of patients who currently still have functioning Fidelis leads.

Prior Studies on Fidelis Lead Survival

Beginning in 2007 when Hauser et al. first described early failure of the Sprint Fidelis lead compared with the Sprint Quattro Secure lead, several studies have demonstrated an increased failure rate of the Fidelis lead (summarized in Table 2), with reported rates between 2.9% and 3.8% per year. The most recent Medtronic System Longevity Study (SLS) data have shown a 3-year survival of the Sprint Fidelis 6949 lead of 94.6%, and CareLink PLUS data have shown a 3-year survival of 96.3%. However, several centers initially demonstrated lower 3-year survival rates of 88% to 93%. Our study revealed Fidelis survival at 3 years of 93.5% and at 5 years of 85.3%. Our 3-year Fidelis survival rate of 93.5% is higher than what was seen in initial studies with shorter follow-up but is comparable to the 93% to 95.3% rates reported in 3 recent large studies with comparable follow-up time to ours.

In any case, our Fidelis survival rates are still lower than those that have been published by the manufacturer from the SLS and CareLink PLUS cohorts.

We found that female sex was the only significant clinical predictor of Fidelis lead failure and was associated with a doubling of the risk of lead failure. This is consistent with the findings from 2 recent multicenter studies, with extended follow-up of the Fidelis lead which also found female sex to be an independent predictor of Fidelis lead failure. This observation may not be restricted only to Fidelis leads because a large registry study of all ICD leads by Kleeman et al. also showed that female sex was associated with a higher rate of lead defects. Interestingly, several studies have identified female sex as a significant risk factor for early complications from ICD implantation. Smaller body habitus and anatomic issues, such as thinner blood vessels and right ventricular walls, have

Table 1. Baseline Demographic and Implant Characteristics of Study Patients

<table>
<thead>
<tr>
<th></th>
<th>All Patients (n=602)</th>
<th>Lead Failure Patients (n=50)</th>
<th>No Lead Failure Patients (n=552)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, median (y)</td>
<td>67 (IQR, 56–76)</td>
<td>65 (IQR, 53–76)</td>
<td>67 (IQR, 56–76)</td>
<td>0.24</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>146 (24)</td>
<td>19 (38)</td>
<td>127 (23)</td>
<td>0.02</td>
</tr>
<tr>
<td>Primary prevention, n (%)</td>
<td>547 (91)</td>
<td>46 (92)</td>
<td>501 (91)</td>
<td>0.77</td>
</tr>
<tr>
<td>EF at implant, median (%)</td>
<td>28 (IQR, 20–33)</td>
<td>30 (IQR, 20–36)</td>
<td>28 (IQR, 20–33)</td>
<td>0.32</td>
</tr>
<tr>
<td>Atrial lead implanted, n (%)</td>
<td>556 (92)</td>
<td>47 (94)</td>
<td>509 (92)</td>
<td>0.65</td>
</tr>
<tr>
<td>LV lead implanted, n (%)</td>
<td>206 (34)</td>
<td>21 (42)</td>
<td>185 (36)</td>
<td>0.23</td>
</tr>
<tr>
<td>Cephalic access, n (%)</td>
<td>47 (8)</td>
<td>2 (4)</td>
<td>45 (8)</td>
<td>0.30</td>
</tr>
</tbody>
</table>

IQR indicates interquartile range; EF, ejection fraction; LV, left ventricular.

Figure 1. Kaplan-Meier survival curve of 604 Sprint Fidelis leads.

Figure 2. Survival curves of Sprint Fidelis leads based on sex.
been proposed as possible reasons for increased immediate ICD implantation complications because of the difficulty with vascular access. The same anatomic factors that contribute to difficult lead implantation may also result in increased future lead failure because of excess mechanical stress on the lead from vessel tortuosity and impingement by extravascular structures. Further research is clearly needed to further elucidate the mechanism of early ICD lead failure in women.

Several studies have identified younger age, higher ejection fractions, and noncephalic access as significant predictors of Fidelis lead failure. We observed similar trends with each of these risk factors (mean age of Fidelis lead failure patients of 63 years versus nonlead failure patients of 66 years; mean ejection fraction of Fidelis lead failure patients of 30% versus nonlead failure patients of 28%; 4% of Fidelis lead failure patients had cephalic access versus 8% of nonlead failure patients with cephalic access), but none of these differences were statistically significant. Differences in study size, patient population, and implantation technique between our study and previous studies may account for our results. In particular, the low rate of lead implantation via cephalic access (8%) in our study group likely yielded an insufficient sample size to show a statistically significant protective effect of cephalic lead implantation.

Changes in the Rate of Fidelis Lead Failure Over Long-Term Follow-Up

Several groups have reported an accelerating risk of Fidelis lead failure over time. The use of log-log analysis of cumulative hazard for Fidelis lead failure in 2 studies yielded powers of 2.13 and 2.74 in exponential models of lead failure. Similarly, in our analysis of our entire cohort of Fidelis leads, an exponential model of lead failure with a power of 2.3 was seen. However, when we restricted our analysis to leads surviving past 2 and 4 years, our log-log analysis of cumulative hazard for lead failure yielded powers of only 0.85 to 1.0, which was consistent with a linear pattern of Fidelis lead failure. Interestingly, in a recent study of 3169 Fidelis leads with extended follow-up of over 3 years, log-log analysis of lead failure hazards revealed only a power of 1.28. The significantly lower exponential power of lead failure seen in that study may be explained, in part, by leveling of Fidelis lead failure rates over time.

To our knowledge, this is the first study to show a linear phase of Fidelis lead failure after an initial exponential rise. We determined the failure rate of Fidelis leads surviving past 2 and 4 years to be constant and significantly elevated at 4.5% per year. It should be emphasized that there were no signs of deceleration of lead failure rates. Indeed, the lead failure rate we report for leads surviving past 2 years is far higher than the 0.43% to 1.07% per year failure rates of the Sprint Quattro, Endotak Reliance, and Riata leads, which have been reported from multicenter registries. The 4.5% per year Fidelis failure rate seen in our study is also higher than the 2.9% to 3.8% Fidelis failure rate per year that has been found by prior studies. This is likely because of the fact that our reported lead failure rate of 4.5% per year is derived from data on leads surviving past 2 years, whereas previous studies approximated lead failure rates based on early time points with mean follow-up of <3 years. Given that the early phase of Fidelis lead failure is exponential, lead failure rates approximated at earlier time points will be lower than rate approximated at later time points, as defined by the nature of exponential trends with powers >1.

The explanation for the shift in the trend of Fidelis lead failure rates over time from an exponential model to a linear model is unclear. The probability of failure of an ICD lead is defined by lead properties, patient characteristics, implantation technique, and time as the algebraic sum of the aforementioned factors. There may be specific patient and lead factors that distinguish cases of early Fidelis lead failure from cases of late Fidelis lead failure, resulting in a biphasic time course of lead failure. For example, younger patients may be more predisposed to early insulation break because of increased
activity that results in increased mechanical stress on the lead.\textsuperscript{13} Furthermore, the mechanism of early Fidelis lead failure may differ from late lead failure. Different lead failure mechanisms may exhibit distinct time courses of failure. Longer follow-up will be needed to determine whether Fidelis leads will fail at the same rate over time or if there will be a third phase of either deceleration or reacceleration of lead failure risk.

**Clinical Implications**

The stable rate of lead failure seen in our study in Fidelis leads surviving past 2 and 4 years may allow accurate prediction of long-term lead failure probabilities for Fidelis leads that are currently still functioning. In our model, all current surviving Fidelis leads will track in the linear portion of the hazard curve. According to our lead failure rate estimations, the probability of a Fidelis lead that is functioning today of failing at 5 years and 10 years from now would be 23\% and 45\%, respectively. This has significant clinical implications. Currently, there is no established indication for the routine prophylactic replacement of normally functioning Fidelis leads. However, in high-risk patients who are young and active, pacer dependent, or survivors of recurrent malignant ventricular arrhythmias, prophylactic Fidelis lead replacement may be necessary.

**Figure 5.** Log time-log cumulative hazard plots for Sprint Fidelis leads functioning at 2 years (A) and 4 years (B). Linear regression analysis of both plots yield straight lines of good fit, with slopes of 0.85 and 1.00 for leads functioning at 2 years and 4 years, respectively. H indicates hazard; t, time.

**Figure 6.** Cumulative hazard of Sprint Fidelis lead failure for leads functioning at 2 years (A) and 4 years (B). Linear regression analysis of both plots yield straight lines of good fit, with identical slopes of 0.045 corresponding to a lead failure rate of 4.5\% per year. H indicates hazard; t, time.
In certain cases, the risks of Fidelis lead failure and its associated consequences of inappropriate ICD shocks, asystole, and ineffective delivery of ICD therapy may significantly outweigh the risks of lead extraction and replacement. Ultimately, accurate prediction models of lead survival are critical for informed lead management decisions, given the time-dependent nature of risks of lead failure and lead extraction. Our study showed that although the risk of Fidelis lead failure may have ceased accelerating, it has also shown no signs of abatement. This finding, together with the identification of female sex as a significant predictor of lead failure, may impact the decision to prophylactically replace Fidelis leads in certain high-risk patients, possibly at the time of generator replacement.

Study Limitations

This study was retrospectively performed at a single center. As such, our Fidelis lead failure rates and patterns may not be generalizable to experiences at other centers. We did not include returned product analyses into our analysis. Therefore, we did not ascertain the precise mechanism and location of lead failure in each instance. We did not have a cohort of non-Fidelis leads to allow a comparison of lead failure rates. The elevated rate of Fidelis lead failure compared with that of other ICD leads has been well established by numerous studies.

Conclusions

In this study, we describe an initial exponential increase in Fidelis lead failure rates, which was followed by stabilization of the lead failure rate at 4.5% per year. Female sex was the only significant clinical predictor of lead failure. Our findings have significant implications for lead management decisions that hinge on balancing risks of lead failure versus lead replacement. Further follow-up of the Fidelis lead is needed to assess for further changes in the rates of lead failure.

Disclosures

Dr Cheung has received speaker honoraria and fellowship grant support from Boston Scientific, Medtronic, and St. Jude Medical. The other authors have no conflicts to report.

References


Table 2. Summary of Studies With Estimated Fidelis Lead Survival Data at 3 Years Postimplantation

<table>
<thead>
<tr>
<th>Study</th>
<th>No. of Leads in Study</th>
<th>Mean Follow-Up (mo)</th>
<th>Reported Fracture Rate (%/y)</th>
<th>Three-Year Survival Rate</th>
<th>Exponential Power of Fracture Hazard With Time</th>
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</thead>
<tbody>
<tr>
<td>Farwell et al6</td>
<td>480</td>
<td>19.8</td>
<td>NA</td>
<td>NA</td>
<td>2.74</td>
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<tr>
<td>Hauser et al5</td>
<td>848</td>
<td>22.5</td>
<td>3.75</td>
<td>87.9%</td>
<td>NA</td>
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<tr>
<td>Faulkner et al6</td>
<td>426</td>
<td>27.6</td>
<td>3.6</td>
<td>90.8%</td>
<td>2.13</td>
</tr>
<tr>
<td>Morrison et al6</td>
<td>451</td>
<td>21.3</td>
<td>NA</td>
<td>89.3*</td>
<td>NA</td>
</tr>
<tr>
<td>Hauser et al5</td>
<td>1023</td>
<td>NA</td>
<td>2.86</td>
<td>93%*</td>
<td>NA</td>
</tr>
<tr>
<td>Ricci et al6</td>
<td>414</td>
<td>35</td>
<td>3.2</td>
<td>90.8%</td>
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<tr>
<td>Birnie et al6</td>
<td>3169</td>
<td>40.8</td>
<td>NA</td>
<td>95.3%</td>
<td>1.28</td>
</tr>
<tr>
<td>Tzogias et al6</td>
<td>971</td>
<td>46.3</td>
<td>NA</td>
<td>95%*</td>
<td>NA</td>
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<tr>
<td>Current study</td>
<td>604</td>
<td>39.6</td>
<td>4.5*</td>
<td>94%</td>
<td>2.3</td>
</tr>
</tbody>
</table>

NA indicates not applicable.
*Survival reported for 30 mo.
†Survival at 3 y estimated from published Kaplan-Meier curve.
‡Fracture rate pertaining to leads surviving past 2 y only.


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**CLINICAL PERSPECTIVE**

The Sprint Fidelis implantable cardioverter-defibrillator lead was recalled in 2007 because of an elevated risk of lead fracture. Several studies have demonstrated an accelerating risk of Fidelis lead failure over time, but it has not been clear whether or not such trends persist with long-term follow-up. In this study of 604 Fidelis leads implanted at a single institution with mean follow-up of over 3 years, we identified 51 (8.4%) Fidelis lead failures. Female sex was associated with over a 2-fold increased risk of lead failure. Although the rate of lead failure initially increased exponentially with a power of 2.3, log-log analysis of cumulative hazard rates of leads surviving past 2 and 4 years after implantation revealed a stabilization of the lead failure rate at 4.5% per year. Although Fidelis lead failure rates seem to cease accelerating after 3 years, they appear to remain constant at an elevated rate. This finding, together with the identification of female sex as a significant predictor of Fidelis lead failure, may have significant implications for the management of patients who currently still have Fidelis leads in place.
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SUPPLEMENTAL MATERIAL

Online Supplemental Data: Expanded Methods

Calculation of transition time $t_z$ and derivation of the equation for linear portion of cumulative hazard curve

In our model of Fidelis lead failure, we assumed the cumulative hazard function $H(t) = at^n$ (exponential function) for $0 \leq t \leq t_z$ and $H(t) = bt + c$ (linear function) for $t \geq t_z$ where $b$ and $c$ are constants. Time $t_z$ is defined as the transition point between the exponential and linear portions of the hazard function.

If we assume a continuous $H(t)$ curve, then at time $t = t_z$, $H(t) = at^n = bt+c$. If we further assume a smooth $H(t)$ curve, then we can take the derivative of the hazard function and equate $H'(t)$ for time $t = t_z$ equals $nat_z^{n-1} = b$. Based on our log-log hazard plot analysis (see Results), we calculated the power of the exponential portion of the cumulative hazard function $n$ to be 2.3, the constant $a$ to be 0.00482 and the linear failure rate $b$ to be 0.045. Hence, $(2.3)(0.00482)t_z^{1.3} = 0.045$. Solving for $t_z$, we determine $t_z = 2.9$ years. Finally, to calculate the linear equation for $H(t) = bt+c$ for time $t \geq t_z$, we know that at time $t = t_z = 2.9$, $H(t) = at^n = bt+c$. Hence, $(0.00482)(2.9)^{2.3} = 0.045(2.3) + c$. Solving for $c$, we find $c = -0.075$. 