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PROBABILISTIC RISK ASSESSMENT AND SERVICE LIFE PERFORMANCE OF LOAD BEARING BIOMEDICAL IMPLANTS

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ABSTRACT
It is important to consider the performance of load bearing biomedical implants as a stochastic problem. This provides scope to optimise their whole life performance in terms of design and lifetime performance management measures with the aim of minimisation of the need for replacement, or the number of replacement, during the expected life of the patient. An important parallel is developed with the field of structural reliability analysis (i.e. probabilistic assessment) which has developed in recent years with great success in optimisation of whole life performance of load bearing infrastructure systems. The methodology considers the stochastic nature of loading on and resistance of an individual structure/structural network, within a probabilistic framework, to optimise performance over the whole life and at the same time to minimise the number of interventions required during the structures life. This paper demonstrates how this same methodology can be employed in the field of biomedical engineering to optimise the design and whole life performance of implants considering factors such as (i) deterioration with age, (ii) stochastic variation in load – e.g. as a function of the age of the patient, level of physical activity, weight etc. The paper also demonstrates the importance of Bayesian updating and correlation modelling in considering the design and whole life performance optimisation of biomedical implants.

1. INTRODUCTION

The twentieth century has brought enormous advances in the field of orthopaedic surgery. Total hip and knee joint replacements are effective interventions for people to repair gross physical joint damage or relieve pain due to severe arthritis and demand for these operations is increasing as our population ages. By their very nature prosthetic joint components wear as they shift against each other during use. Biomedical devices are not as robust and hard wearing as the organic joint. The extent and rate of deterioration depends on a number of random variables, e.g. the precision of placement of the surgical implant, the patient's physical condition and age, level of activity, and body mass etc., with the result that the life span of prosthetics and biomedical devices is stochastic, varying from patient to patient. It is frequently found necessary to replace or repair the biomedical device which increases the burden on the health service and the risk and pain of the patient.

The performance of load bearing systems such as bridges, building, dams and other large structural and mechanical systems is variable due to uncertainties and variabilities in material properties, dimensions, loads, environment, etc. For this reason, probabilistic methods are highly suited to assessing the safety and service life prediction of these engineering systems (e.g., Stewart and Melchers 1997, Nowak and Collins 2000). Many orthopaedic implants, such as hip and knee replacement implants and knee tribial trays are load-bearing with similar sources of variabilities, as well as those unique to implants - typical uncertainties relate to material properties, dimensions, loads, and alignment. Probabilistic analyses for orthopaedic applications has become an important area of research in the past decade or so (e.g., Browne et al. 1999, Dar et al. 2002, Nicolella et al. 2002, Grasa et al. 2005, Easley et al. 2007, Dopico-Gonzalez et al 2010a,b, Laz 2007, Laz and Browne, 2010, etc.). Most of the research to date has focused on either (i) point-in-time reliability analysis – i.e. the probability of failure given a single worst-case post-operative loading (Nicolella et al. 2002) or (ii) a time-dependent reliability analysis based on number of cycles to cause fatigue failure (Grasa et al. 2010). Most existing reliability analyses of load-bearing biomedical implants use probabilistic methods to refine the design of implants based on sensitivity analyses assuming 'failure' to be localised material failure that may or may not progress to clinical failure.

These issues and limitations of probabilistic and reliability analysis are not restricted to biomedical implants, as similar challenges have been faced with the safety and service life prediction of structural and mechanical components. The authors and other structural reliability specialists have extensive experience in addressing these challenges with respect to bridge design and safety assessment (e.g., Stewart 1998, 2001, O'Connor and Enevoldsen 2007, 2008, O'Connor et al. 2009). Systems reliability techniques are used to model the progression of localised failure (such as exceeding yield strength, excessive deflection, etc.) to overall structural collapse. Bayesian updating is used to update reliabilities based on inspection or condition data. For example, the observation that a structure has survived several years of service loading means that the structure has essentially passed a proof load test, so there is more confidence in the structure's resistance leading to less uncertainty and increased reliability (e.g., Stewart 1997).

Another key motivation for probabilistic and reliability analysis is its utility for risk-based decision-making (e.g., Stewart 1998, Stewart and Val 1999, Stewart 2001, Val and Stewart 2005, O'Connor et al. 2009). The decision of interest is whether the reliability exceeds an acceptable level of reliability, and if so, the length of time that the reliability is acceptable. Thus, risk-based predictions of service life are possible (O'Connor et al. 2004). In the context of biomedical implants, their design and placement can be optimised to ensure an acceptable level of reliability for the design life of the implant, or the remaining safe service life can be predicted for existing implants. Another criteria for decision-making is risk-based life cost analysis that minimises the sum of design, fabrication, installation, and maintenance costs, and the expected costs of failure (e.g., Val and Stewart 2003).

The aim of the present paper is to aid researchers and clinicians in better understanding probabilistic and reliability analyses and the benefits which can be expected to accrue from their application as a risk-based decision support tool for design and whole life management of load-bearing biomedical implants. As such, the present paper will explore the capabilities of time-dependent and systems reliability analysis to the relatively new application of service life performance of load-bearing biomedical implants. The reliability analysis of cemented hip implants developed by Nicolella et al. (2002, 2007) will provide the probabilistic characterisation of key parameters reflecting uncertainty and variability of material properties (e.g., bone cement and bone cement-implant interface), joint and muscle loads, and finite element model response. In their study, Nicolella et al. (2002, 2007) used six limit states and a body mass of 75 kg considered separately, all random variables were considered statistically independent (i.e. no correlations between variables), and defined 'failure' as exceedance of a single limit state which denotes localised failure. These are all conservative assumptions likely to reduce computed reliabilities. In the approach outlined in this paper these probabilistic characterisations are employed to calculate time-dependent reliabilities and to illustrate the following: (i) the effect of knowledge of prior service loads on updated time-dependent reliability, (ii) the effect of series and parallel system definitions of failure on time-dependent reliability, (iii) the effect of progressive failure leading to clinical failure, (iv) the effect of body mass on time-dependent reliability, (v) the effect of correlated material properties (e.g., if shear strength is low then higher likelihood that compressive strength is also low), and (vi) the effect of time-dependent deterioration of material properties due to corrosion, wear-particles and other degradation mechanisms.

2. TIME-DEPENDENT STRUCTURAL RELIABILITY THEORY

If the limit state of interest is related to load bearing capacity, then failure is deemed to occur when a load effect (S) exceeds the structural resistance (R). The probability of failure (p_f) is defined as:

$$p_f = \Pr(R \le S) = \Pr(R - S \le 0) = \Pr(G(R,S) \le 0) \tag{1}$$

where G() is termed the "limit state function", in the present case this is equal to R-S. Thus the probability of failure is the probability of exceeding the limit state function. For the simplest case with one random variable for load (S) and another for resistance (R), the probability of failure is given by the well known ‘convolution’ integral:

$$p_f = \int_{-\infty}^{\infty} F_R(x) f_S(x) dx \tag{2}$$

where $f_S(x)$ is the probability density function of the load S and $F_R(x)$ is the cumulative probability density function of the resistance [$F_R(x)$ is the probability that $R \le x$].

For many realistic problems the simplified formulation given by Eqn. (2) is not sufficient as the limit state function often contains more than two variables. If the limit state function is expressed as G(**X**), the generalized form of Eqn. (2) becomes:

$$p_f = \Pr\left[G(\mathbf{X}) \le 0\right] = \int \ldots \int_{G(\mathbf{X}) \le 0} f_{\mathbf{X}}(\mathbf{x}) d\mathbf{x} \tag{3}$$

where the vector **X** represents the basic variables involved in the problem and $f_{\mathbf{x}}(\mathbf{x})$ is the joint probability density function for the n-dimensional vector $\mathbf{X}=\{X_1,....,X_n\}$ of random variables each representing a resistance random variable or a loading random variable acting on the system. For a more details of reliability analyses see Stewart and Melchers (1997).

2.1 Updating Based on Service Proven Performance

Most probabilistic and reliability analyses of load-bearing biomedical implants treat load and resistance as statistically independent and do not consider the effect of prior service load and other updating on reliability predictions. For example, the 'worst-case' loads for hip implants often occurs at the early post-operative period (e.g., Nicolella et al 2002), and these loads are generally not exceeded by common activities such as rising from a chair or level walking (Keaveny and Bartel 1993). A 'worst-case' loading may be interpreted as a 'proof load', and if the implant survives the 'worst-case' load then its reliability will be enhanced conditional on survival of the proof load. This means that if an implant is subjected to a known proof load then the distribution of structural resistance is truncated at this known load effect, thus reducing the probability of failure. Moreover, walking or other daily activities constitute 'service loads' which may be treated as a proof load with uncertainty. In this case, the revised distribution of structural resistance at time t is

$$f''_R(r) = \frac{F_S^T(r) f'_R(r)}{\int_{-\infty}^{\infty} F_S^T(r) f'_R(r)\ dr} \tag{4}$$

where $F_S^T(r)$ is the cumulative distribution function of the maximum actual load effect experienced up to time T and $f'_R(r)$ is the distribution of resistance prior to loading. For more details see Stewart (1997) and O'Connor and Eichinger (2007).

It follows that the probability of failure in t subsequent years given survival of T years of service is

$$p_f(t \mid T) = \int_{-\infty}^{\infty} F_R^{''}(r) f_S^T(r)\ dr \tag{5}$$

where $F_R^{''}(r)$ is the revised cumulative distribution function of structural resistance obtained from Eqn. (4) and $f_S^T(r)$ is the distribution function of the T-year maximum actual load effect. This conditional probability may also be referred to as a 'hazard function' (Stewart and Melchers 1997). Equations (4) and (5) assume that there is no time-dependent reduction in resistance due to ageing or deterioration.

Clearly, the probability of failure is time-dependent and also dependent on performance and condition data collected during its service life. Bayesian methods are a powerful tool to use this new information to update knowledge about the performance and reliability of load-bearing systems (e.g., Jordaan 2005). In many case, new information reduces the uncertainty of variables leading to increased estimates of reliability.

2.2 Ageing and Deterioration Modelling

Corrosion of biomedical implants, unless made from inert materials, will probably occur (Batchelor and Chandrasekaran 2004). Moreover, many orthopaedic implants will release wear-particles from moving surfaces. The body provides a relatively hostile environment to many materials as body fluids are largely composed of salt water. There are other corrosion and degradation mechanisms specific to the location and materials used in the implant (e.g., Batchelor and Chandrasekaran 2004). For the purposes of this study it is assumed that (i) material properties are not affected by ageing up to an initiation time T_i, and (ii) after this initiation period, material strengths reduces linearly with time, i.e. a classical two phase deterioration process.

$$\begin{aligned} R_i(t) &= R_i & t &\le T_i \\ R_i(t) &= R_i\left(1 - \alpha\left(t - T_i\right)\right) & t &> T_i \end{aligned} \tag{6}$$

A linear reduction in material strengths with time is idealistic as for many materials the deterioration function is non-linear. However, for the purposes of illustration, and in the absence of specific data on time-dependent deterioration, a linear deterioration function is sufficient to illustrate the utility of the approach.

For deteriorating systems, Eqns. (4) and (5) can be recast to give the cumulative probability of failure up to time t, expressed as:

$$p_{fi}(0,t_n) = 1 - \Pr\left[R_i^{'}(t_0) > S_i(t_0) \cap R_i^{''}(t_1) > S_i(t_1) \cap \ldots \cap R_i^{''}(t_n) > S_i(t_n)\right] \quad t_0 < t_1 < t_2 < \ldots < t_n \qquad (7)$$

where $R_i^{'}(t_o)$ represents the initial distribution of resistance and $R_i^{''}(t_1)$, $R_i^{''}(t_2)$,..., $R_i^{''}(t_n)$ represent the structural resistances at time t_j updated on survival of the previous load events. It is evident that the updated structural resistances are influenced by the load history $S_1, S_2, \ldots, S_n$ as well as time-dependent changes in material strengths. Thus, the cumulative probability of failure is dependent upon the prior and updated load and resistance histories. The probability of failure in t subsequent years given survival of T years of service is

$$p_{fi}(t \mid T) = \left[p_{fi}(0,T+t) - p_{fi}(0,T)\right] / \left[1 - p_{fi}(0,T)\right] \qquad (8)$$

where $p_{fi}(0,T+t)$ and $p_{fi}(0,T)$ are defined by Eqn. (7).

3. ILLUSTRATIVE EXAMPLE: CEMENTED HIP IMPLANT

3.1 Review of Nicolella et al (2002, 2006) Study

An important type of implant, certainly the one with the highest load capacity, is the hip implant (Batchelor and Chandrasekaran 2004) - this is a suitable implant for detailed analysis herein. Nicolella et al. (2002, 2006) describe a point-in-time reliability analysis of a cemented hip implant. Model parameters such as the applied loads, material properties, and material strengths were modelled as statistically independent random variables to account for their uncertainty and variability. The individual limit states considered related to failure of the bone cement and interface failure of the proximal femur. The limit states considered were:

1. Bone Cement Compressive Failure
2. Bone Cement Shear Failure

3. Bone Cement Fatigue Failure
4. Bone Cement Strain Energy Density (SED) Fracture
5. Interface Tensile Failure
6. Interface Shear Failure

The limit state function was represented as:

$$G_i(\mathbf{X}) = R_i(\mathbf{X}) - S_i(\mathbf{X}) \tag{9}$$

with R_i the resistance or material strength for limit state i, and S_i the load effect or model response for limit state i. Peak load effects were obtained from a three dimensional finite element model (FEM) of a femur-implant system (Nicolella et al. 2002). All materials in the analysis were modelled as linear elastic isotropic materials. A stochastic analysis was conducted where bone and bone cement elastic moduli, and joint and muscle loads were taken as input random variables. For a more detail explanation of the stochastic FEM analysis see Nicolella et al. (2002). The statistical parameters for these variables are reproduced here in Tables 1 and 2. Note that the probability distributions for resistance are inferred from plots provided by Nicolella et al. (2002). While the probabilistic analysis by Nicolella et al. (2002) included many random variables, it did not consider model error or accuracy. For structural and mechanical systems model error, defined as observed (test) response divided by predicted (or theoretical) response, is often an important source of uncertainty and must be included in a reliability analysis.

Load effects given in Table 2 assume a body weight of 750 N (75 kg) and are equivalent to a resultant joint reaction force of 4.54 times body weight - and are representative of strenuous loading of the hip in the early post-operative period, and represents a 'worst case' loading scenario (Keaveny and Bartel 1993). These loads are similar to what has been measured during stair ascent (Davy et al. 1988). For level walking, a review of direct measurements reveal forces of 1.6 to 3.3 of body weight (Brand et al. 1994). Other common activities such as rising from a chair or using a cane resulted in lower loads than level walking. In this study it is assumed that over many cycles level walking results in 50% mean lower loads than the worst-case loading given in Table 2. It is considered reasonable to assume less uncertainty about loads from walking, to say a third of the uncertainty of the worst-case loading. As a result the COV (Coefficient of Variation is standard deviation divided by mean) for walking loads is 33% of the COV of worst-case loading.

Failure Mode	R_i - Resistance (Failure Level)	Mean	σ	COV	Distribution
Bulk Cement Failure:	1. Bone cement compressive stress (MPa)	81.40	2.14	0.026	Normal
	2. Bone cement shear stress (MPa)	30.00	2.70	0.090	Normal
	3. Bone cement fatigue limit (MPa)[1]	7.98	4.32	0.541	Lognormal
	4. Critical level of Sed_{er} (kJ/m^3)	75.70	7.57	0.100	Normal
Interface Failure:	5. Interface tensile strength (MPa)[2]	7.90	1.60	0.203	Lognormal
	6. Interface shear failure (MPa)	33.30	17.60	0.529	Lognormal

Note: 1 - Conservative fatigue limit based on lowest of Simplex, Zimmer LVC and Zimmer Regular fatigue limits. 2 - conservative strength based on three minute formation time.

Table 1. Probabilistic Models of Resistance (Nicolella et al. 2002)

Failure Mode	S_i - Load Effect (Model Response)	Mean	σ	COV	Distribution
Bulk Cement Failure:	1. Minimum principal stress (MPa)	8.70	2.63	0.302	Lognormal
	2. Tresca stress (MPa)	7.48	2.23	0.298	Lognormal
	3. Von Mises stress (MPa)	6.88	2.07	0.301	Lognormal
	4. Strain energy density (kJ/m^3)	16.63	10.60	0.637	Lognormal
Interface Failure:	5. Maximum principal stress (MPa)	5.07	2.03	0.400	Lognormal
	6. Von Mises stress (MPa)	27.04	8.20	0.303	Lognormal

Table 2. Probabilistic Models of Model Response (Nicolella et al. 2002)

Schmalzried et al. (1998) found that patients aged over 60 years who had hip joint replacement averaged 4,400 steps per day which is approximately 800,000 cycles per year. However, the number of steps causing peak resultant stress in a single hip implant will be half this number - resulting in N = 400,000 cycles per year for a single implant. In this case, the time-variant cumulative distribution function of the maximum actual load effect experienced up to time t is

$$F_S^t = \left[F_S\right]^{Nt} \tag{10}$$

where t is time in years, N is the number of annual load cycles, and F_S is the cumulative distribution function of a single step. Annual maximum loads are assumed statistically independent.

Many hip implants last 15 years (Hargreaves 2000), but a more desirable service life would be approximately 30 years (Batchelor and Chandrasekaran 2004). The reliability analyses will thus be conduced for up to 30 years design life.

3.2 Time-Dependent and System Reliability Analyses

3.2.1 Cumulative Probabilities of Failure

The point-in-time reliabilities at time t $p_{fi}(t)$ for each limit state i are calculated using Eqn. (2) and the limit states in Eqn. (9). At time t = 0 the statistics of this load effect (S_i) are given in Table 2. Subsequent service loading when T≥1 year assumes level walking with mean and COV of load effects of 50% and 33% of the statistics given in Table 2, respectively, with 400,000 cycles per year. The cumulative probability of failure $p_{fi}(0,t)$ is then calculated from Eqn. (7). Figure 1 illustrates the computed cumulative probabilities of failure. Clearly, the probabilities are very high, and if the definition of 'clinical failure' is taken conservatively as local failure (exceedance of a single limit state) then the probabilities of failure of this particular hip implant are too high to be acceptable to most clinicians and patients. Probabilities of failure for limit states 3 and 6 are close to 0.5 after first loading. These are exceptionally high failure rates, and would suggest that limit state characterisation may be too conservative. Further attention paid to these limit states may result in improved or more accurate probabilistic modelling; hopefully leading to reductions in failure probabilities.

Such an analysis is very useful at the design stage to assess how reliabilities may reduce with time, and whether the reliability after a certain period of time is higher than that accepted by clinicians as 'acceptable'. What constitutes an 'acceptable' definition of risk is the topic of much debate in the structural, nuclear, offshore, chemical, and other large-scale industries where worker and public safety is paramount. However, a broad consensus has been reached (e.g. Stewart and Melchers, 1997); for example, an annual fatality risk of less than one in a million per year is acceptable (or tolerable) to society. Risks higher than this may be accepted, but only if the benefits outweigh the costs. What constitutes an acceptable level of risk (or failure probability) for biomedical implants is challenging, and beyond the scope of the present paper, however, the issue needs to be addressed as this definition is crucial to service life prediction and design optimisation.

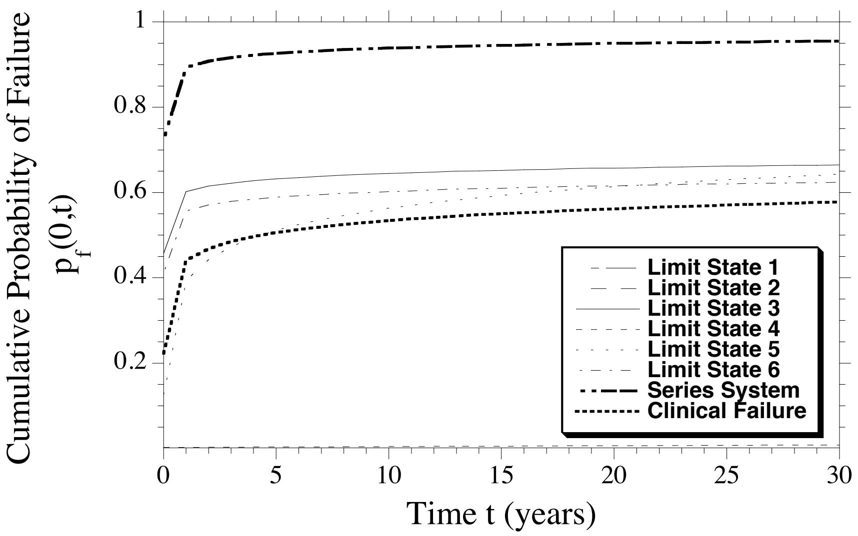

Figure 1. Cumulative Probabilities of Failure for Six Limit States and Two System Models.

3.2.2 Service Proven Reliability

While the previous section is highly useful at the design stage, to assess the reliability after the implant has been in-place for some time requires a different approach as now the analyst has new information to update time-dependent reliabilities. This 'new information' is that the implant has been functioning perfectly well with no signs of distress for T years. Loads immediately following early post-operative are the 'worst case' loading. Subsequent service loadings such as walking constitute a series of proof loads. The updated annual probability of failure conditional on the implant surviving T years of service is denoted as $p_{fi}(1|T)$. The updated annual probability of failure is calculated for each limit state i assuming: (i) proof load at T=0 is taken as strenuous loading of the hip in the early post-operative period ('worst case' loading scenario) with statistics of this load effect (S_i) given in Table 2, (ii) annual service loading when T≥1 year assumes level walking with mean and COV of load effects of 50% and 33% of the statistics given in Table 2, respectively, with 400,000 cycles per year. Figure 2 shows the influence of prior load history on revised probability distribution of structural resistance $f_R''(r)$ for bone cement fatigue limit (limit state 3) calculated from Eqns (4) and (10) for (a) no updating $f_R'(r)$, (b) survival of post-operative (proof) loading (T=0), and (c) survival after T=10 years. It is evident as the load history increases the lower tail of the probability distribution of structural resistance reduces and is truncated at increasingly higher resistances. It is the truncation effect that reduces the updated annual service-proven probabilities of failure as will become evident in the reliability analysis to follow.

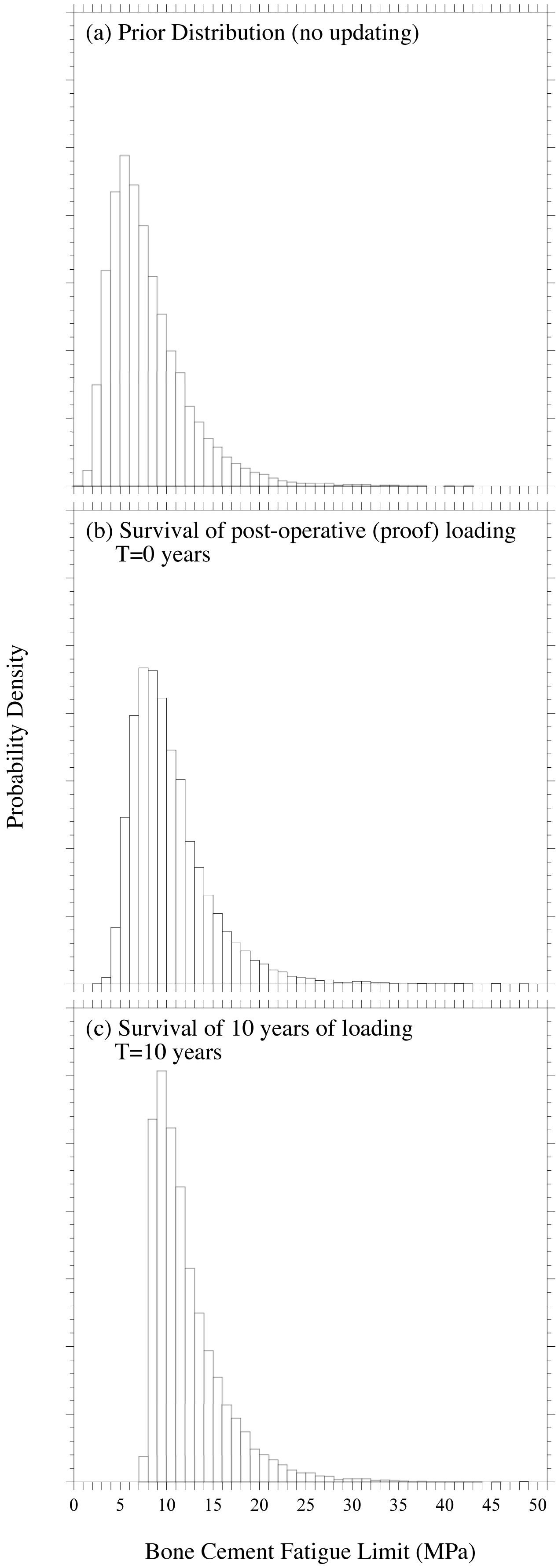

Figure 2. Effect of Prior Loading on Updated Distributions of Bone Cement Fatigue Strength.

The time-dependent reliability for service proven loads is calculated from Eqns. (4), (5) and (8) using revised probability distributions of structural resistance $f_R^{''}(r)$ similar to those shown in Figure 2. Figure 3 shows the service proven reliabilities pf(1|T) as a function of survival age for the six limit states. It is observed that if the implant survives initial loading then the probability of failure decreases as survival age increases. This is expected, as the longer the implant is in service the greater the likelihood that it has experienced a higher loading, which gives more confidence (and less uncertainty) about its resistance. If fatigue is the criteria for failure, or of there is material degradation or increases in load effects, then service proven reliabilities may increase with time. The key concept here is that reliability is time-dependent and influenced by prior load history and as such must be considered as such in any reasonable probabilistic analysis.

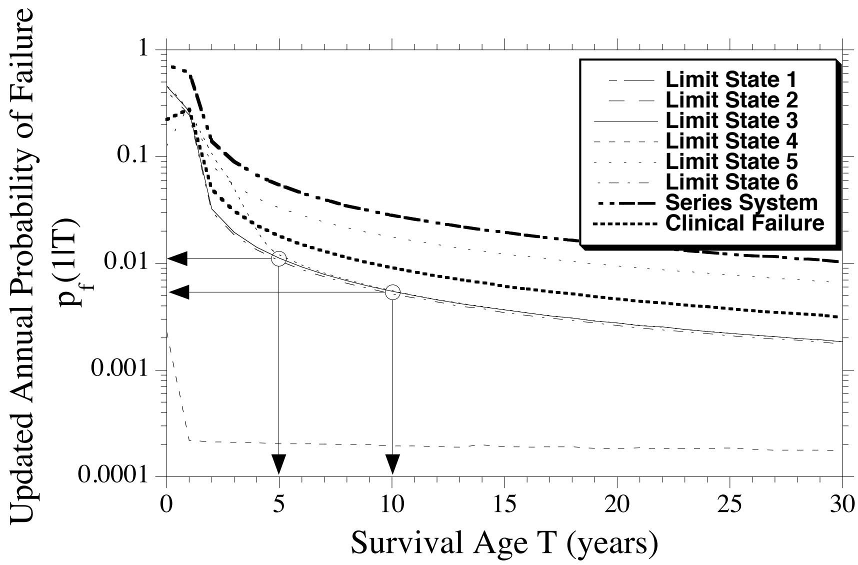

Figure 3. Annual Probabilities of Failure Conditional on Surviving T Years of Service.

For example, take the case of a patient who presents for a check-up at 5 years and the hip implant is giving no signs of distress, then the probability that the implant will fail anytime in the next year due to bone cement fatigue (Limit State 3) is 0.011 or approximately one in a hundred. If the implant survives to 10 years, then the probability of failure anytime in the next year reduces to 0.005 or less than 1 in 200.

3.2.3 Clinical Failure and System Reliability

As there are six limit states (or modes of failure), a more accurate definition of 'failure' may be when one or more limit states are exceeded. In this way the system is represented in terms of a *series system* where:

$$p_f(1 \mid T) = 1 - \prod_{i=1}^{6}\left(1 - p_{fi}(1 \mid T)\right) \tag{11}$$

Figure 3 illustrates the updated annual probability of failure assuming a series system definition of failure. Since only one limit state is needed to be exceeded to constitute failure then this will produce high probabilities of failure which are clearly evident in Figure 3.

The limit states considered here define local failure and not 'clinical failure' (e.g., Nicolella et al. 2002, 2006). As a result the series system given by Eqn. (11), with results shown in Figures 1 and 3, is conservative and will most likely over-estimate the probability of failure where exceedence of multiple limit states is required to constitute 'clinical failure'. In these cases a system reliability analysis is needed to consider the effect of multiple failure modes. System and reliability modelling may be used to model the progression of failure, where for example, shear failure may increase compressive stress, and compressive failure may increase interface stresses, and so on until clinical failure is evident. Event-based Monte-Carlo simulation methods are well suited to modelling progressive failure where localised failure results in load or stress redistribution which ultimately can lead to cascading limit state exceedence (e.g., Stewart 2009).

For sake of illustration, assume that 'clinical failure' is defined as exceedance of (i) any bulk cement failure limit state (1 - 4) <u>and</u> (ii) failure of any interface failure limit state (5 – 6). In this case, the system can be presented as shown in Figure 4. Clinical failure in this case refers to 'failure' requiring replacement of the hip implant. Figure 4 shows that the system is a combination of series and parallel systems. In this case, the probability of failure is conveniently computed using event-based Monte-Carlo simulation methods where at each time step the limit state functions are checked for limit state exceedence. If one or more bulk cement limit states are exceeded at any time up to time t, and one or more interface limit states are exceeded at any time up to time t, then this is counted as failure and a new simulation run is started. After many simulation runs the number of failures is summed at each time interval, and the probability of failure at time t is the number of failures divided by the total number of simulation runs. The results of the analysis are also shown in Figures 1 and 3. The updated annual probabilities of failure for this system definition of failure are considerably less than assuming a series system since more than one limit state needs to be exceeded to constitute failure. It is argued that this is likely to be more realistic than a series system definition of failure.

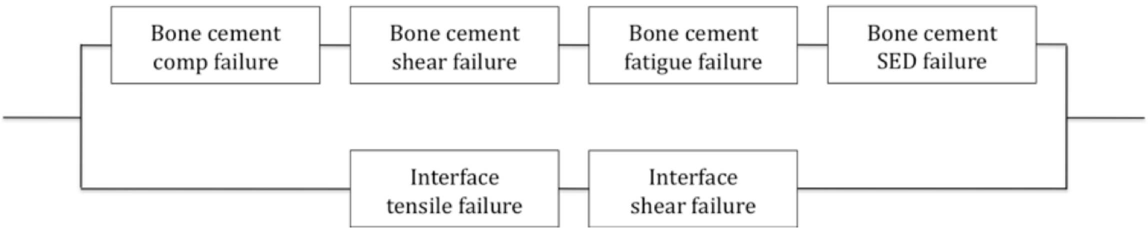

Figure 4. Illustrative Reliability Block Diagram of ‘Clinical Failure’.

3.2.4 Effect of Body Weight

While there is no clear link between body weight, length of femoral stem and resultant stresses, there is some evidence to suggest that peak stresses and strains increase linearly with body weight (Harrington et al. 2002). Hence, and for sake of illustration, it is assumed here that load effect stresses given in Table 2 are directly proportional to body weight since model response was obtained from a linear elastic FEM. Since Table 2 is based on a body weight of approximately 75 kg which is approximately a population average (Schmalzried et al. 1998), then stresses for body weights of 60 kg and 90 kg are 0.8 and 1.2 times the mean values given in Table 2. It is assumed that the COV of stresses remains constant for all body weights. Figure 5 shows the annual updated probabilities of clinical failure (Figure 4) for body weights of 60 kg, 75 kg and 90 kg. The effect of body weight can be considerable, with up to three-fold differences in probabilities. Body weight therefore appears to be an important variable in a reliability analysis of load-bearing biomedical implants.

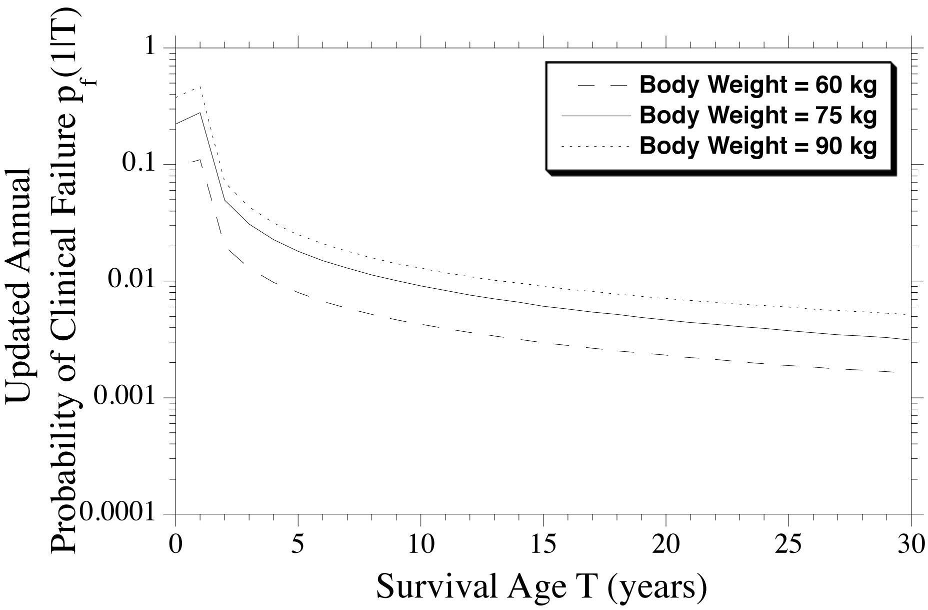

Figure 5. Updated Annual Probabilities of Failure Conditional as Function of Body Weight.

3.2.5 Correlated Load Effects and Material Strengths

Many reliability analyses assume that random variables are statistically independent. However, while this makes solutions more tractable, this assumption lacks realism. For instance, for concrete there is a clear correlation between compressive strength, tensile strength and Young's Modulus (Mirza et al. 1979). This means that if a batch of concrete has weaker compressive strength, then tensile strength and Young's Modulus will also be weaker. Similarly, a higher applied load will increase compressive, shear, interface and other stresses. These types of correlation can be represented by a correlation coefficient (ρ) where ρ=0.0 and ρ=1.0 denote no correlation (statistical independence) and full correlation, respectively (e.g., Ang and Tang, 2007). The preceding reliability analyses have assumed statistical independence between load effects and material strengths.

To demonstrate the importance of consideration of correlation, the time-dependent reliabilities described in Sections 3.2.2 and 3.2.3 are now calculated assuming that material strengths are strongly correlated based on (i) bone cement shear, fatigue and SED strengths are strongly correlated (ρ=0.8) with bone cement compressive strength, and (ii) interface shear strength is strongly correlated (ρ=0.8) with interface tensile strength. These correlations can be conducted relatively easily through analytical or Monte-Carlo methods.

Figure 6 demonstrates the significance of inclusion of correlated material strengths in computing probabilities of failure for the considered system. For the cases considered the results are 15% to 35% lower when compared to statistically independent random variables. Note that the probabilities of failure for each limit state remain unchanged as correlated performance will only affect system reliabilities. For example, the reliability of a series system is higher for correlated performance because in this case the most likely outcome is many limit states are exceeded, or none are exceeded. So what is evident here is that assuming statistical independence between material strengths or loads is conservative, and in the examples presented herein, conservative by up to 35%. This suggests that a better understanding of the correlations between material properties or loads for different limit states is essential if realistic reliabilities are to be calculated.

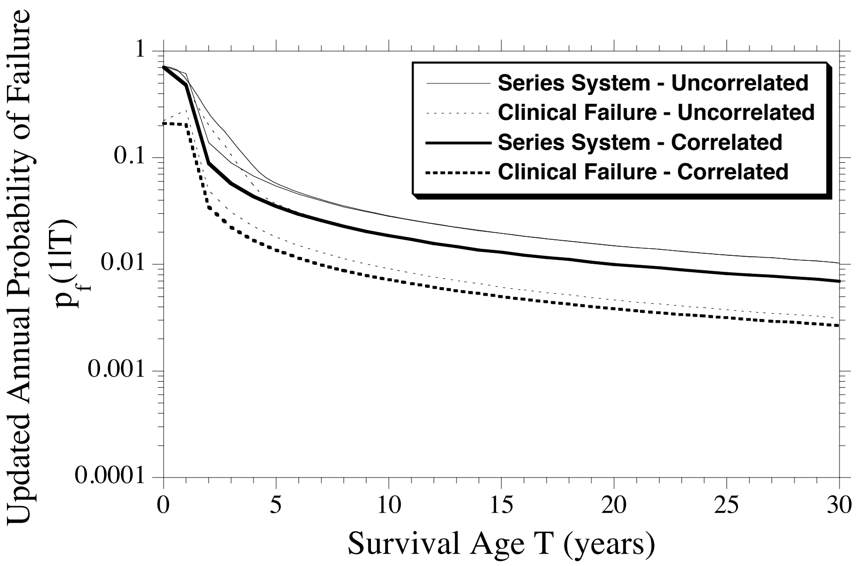

Figure 6. Updated Annual Probabilities of Failure Considering Correlation of Material Strengths.

3.2.6 Material Ageing and Deterioration

While bone cement has high strength, there are some service problems that may degrade their strength over time. This includes, inter alia, (i) progressive decline in mechanical strength with possible fracture, (ii) release of debris into tissues, or (iii) loss of bonding between bone and cement due to necrosis (death) of bone cells after prolonged contact with PMMA (Poly-Methyl-Meth-Acrylate Resin) (Batchelor and Chandrasekaran 2004). Acrylic bone cements are also prone to ageing which would also affect mechanical strength. After an extensive literature review, Lewis et al. (2007) remarked that there is "lack of consensus on the influence of either real-time in vitro or in vivo aging on the properties of acrylic bone cement."

A linear rate of material strength deterioration with time is assumed in Eqn. (6). For the purpose of illustration, it is assumed here that degradation of bone cement material strengths occurs after T_i=5 years and then decreases linearly by either (i) α=1% each year (minor deterioration), or (ii) α=2% each year (severe deterioration). Hence, after 30 years there will be a 25% or 50% reduction in material strengths, respectively. The updated probabilities of clinical failure defined in Figure 4 are shown in Figure 7. Figure 7 shows how the updated annual probabilities of clinical failure gradually increase as soon as deterioration is initiated in the hip implant.

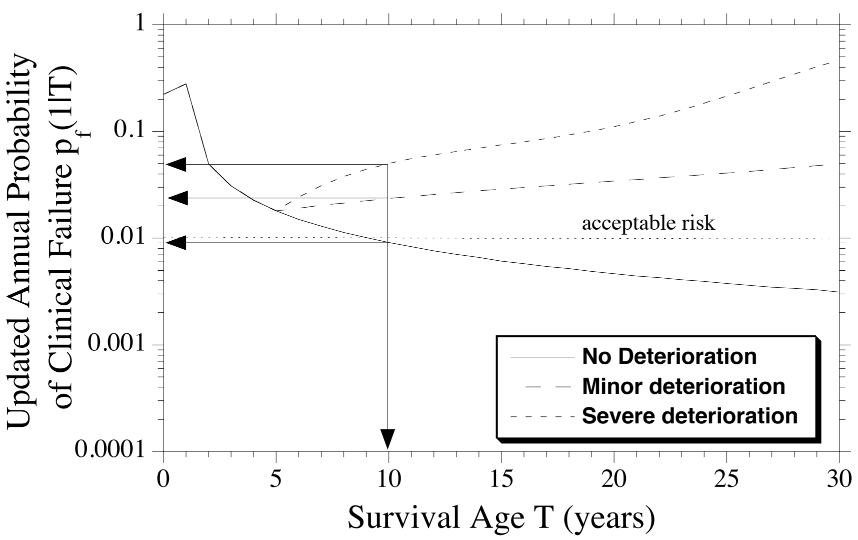

Figure 7. Updated Annual Probabilities of Failure Considering Effects of Deterioration.

If it is assumed that an acceptable level of implant risk is a probability of clinical failure no higher than 0.01 in any one year, then if the implant has survived for 10 years, Figure 7 demonstrates that the probability that it will clinically fail in the next year is 0.009 assuming no deterioration. However, if the rate of deterioration is expected to exceed 1% then the probability of clinical failure after 10 years is 0.0235 and 0.0501 for α=1% and α=2%, respectively. These risks exceed the acceptable level, and so a clinician may recommend replacing the hip plant.

An alternate metric for decision support is to calculate the cumulative probability of failure conditional on survival at time T, and to compare this with an appropriate lifetime acceptable risk criteria. In this case, the cumulative probabilities of clinical failure conditional on the implant surviving satisfactorily after 5 years are shown in Figure 8. For the purpose of illustration, it is assumed that the lifetime risk acceptance criteria is a cumulative (total) risk not exceeding 0.1 (10%) during the lifetime of the implant. If there is no implant deterioration, then Figure 8 shows that the probability of clinical failure exceeds 0.1 after 17 years; this suggests that the remaining service life is 12 years. However, if the rate of deterioration is 1% or 2% then the remaining service life reduces to 5 and 3 years, respectively.

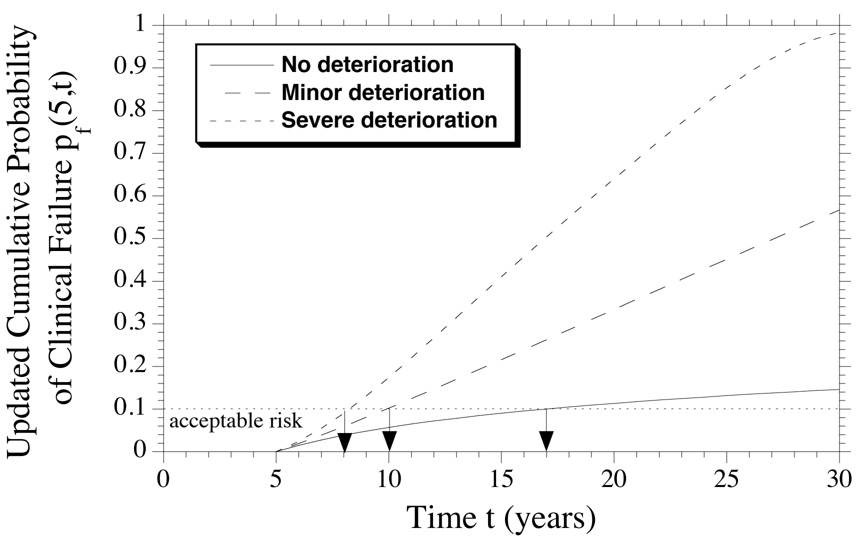

Figure 8. Cumulative Probabilities of Failure Conditional on Implant Surviving T=5 Years of Service.

This and other types of time-dependent reliability analyses will provide utility to risk-based decision making for load-bearing biomedical implants. Service life prediction is a challenging task where risks, costs and benefits need to be carefully assessed and weighed. For example, the timing and type of hip replacement will be conditional on the age, weight, level of physical activity, cost of implant, clinical observations, and so on. This requires a multi-faceted decision criteria, where knowledge of reliability and risks will help designers and clinicians to determine optimal design and placement parameters, and effective treatments /strategies which provide for acceptable service lives for new and existing load-bearing biomedical implants.

4. CONCLUSIONS

This paper demonstrates the scope for application of the principles of structural reliability theory in the design and whole life performance optimisation of biomedical implants. Time dependent reliability computation is demonstrated to be a statistically appropriate and robust computation methodology for relative performance rating of implants. The paper demonstrates the ability of the methodology to incorporate (i) information on condition assessment (i.e. clinical information) and loading history (i.e. proof loading) through Bayesian updating and (ii) to facilitate stochastic modelling of time dependent deterioration of the implant. The example of a cemented hip implanted is presented to demonstrate how consideration of these factors as well as important statistical effects such as system modelling and correlation can influence the computed probability of failure of the implant and as a result its expected life and the required cycles of replacement during the recipients expected remaining life. Combining these effects with factors such as the patients age, weight, level of physical activity etc. in an overall stochastic computation framework are seen as significant. Future work should focus on refining the simplifying assumptions which were made regarding deterioration laws and rates, degree of correlation between load effects and material strengths, acceptable probabilities of failure and consequently thresholds for repair/replacement etc. However the work presented represents an important first step towards optimisation of the design and whole life performance of biomedical implants.

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