Biotribology 17 (2019) 40–48

Contents lists available at ScienceDirect

Biotribology

journal homepage: www.elsevier.com/locate/biotri

Investigation of Wear Mechanisms in Silicone Sleeved Implantable Cardiac Device Leads using an *In Vitro* Approach

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A B S T R A C T

Cardiac implantable electronic devices (CIED), such as pacemakers and defibrillators, have a titanium casing which holds the electronics, connected to insulated leads which deliver therapeutic pulses to regulate heart activity. CIED lifetimes are often limited by wear of their polymer components, as on the surface of the elastomeric insulation of the leads, which is frequently silicone. Insulation wear during regular activity can yield patient discomfort or surgical complications upon replacement. Little is known about the wear mechanisms of these silicone materials *in situ*, but it is known that wear occurs between the leads and either the titanium casing, other leads, or bodily tissue. This study investigated titanium-on-silicone wear of lead insulation used in CIEDs. Surgically retrieved silicone insulated leads showed unusual wear scars that were polished and smooth. The goal of this study was twofold: replicate the unique wear scar with a testing apparatus, and determine wear mechanisms of the silicone insulation. Silicone cardiac leads were obtained from the manufacturer and an apparatus was constructed to simulate in-body conditions while accelerating the wear process. Three key parameters were chosen to investigate the wear mechanisms of this system: load, environmental fluid, and third-body abrasive. A factorial matrix with two replications was used to test these variables. Wear scars were examined using white light profilometry, optical microscopy, and scanning electron microscopy (SEM). An analysis-of-variance (ANOVA) showed that all test factors did not significantly affect the size and depth of the wear scars, but revealed key mechanisms that could affect other known wear configurations such as lead-on-lead wear.

1. Introduction

Pacemakers and cardioverter-defibrillators are cardiac biomedical devices that treat patients with disorders related to frequency and/or stability of the heart beating. In general, these cardiac implantable electronic devices (CIEDs) generate an electrical signal that stimulates cardiac muscles to facilitate normal heart rhythms. The devices are typically composed of a titanium enclosure, which houses the battery and electronic monitoring system, and multiple electrical lead wires depending on the required treatment. Though there are some variations in surgical placement, most such configurations employ an approach of implanting the titanium housing under the skin in the general vicinity of the heart, while the lead wires are run from the device through hard and soft tissue, and are ultimately transvenously inserted into the appropriate chamber in the heart [1,2]. While their exact structure can differ, CIED lead wires are generally composed of layers of insulating material which maintain electrical isolation of the multiple helical metal conductors from the *in vivo* environment and from other lead wires. Typically, the outer insulation layer – or sleeve – is either a polyurethane or silicone elastomer; these materials are both sufficiently biocompatible and durable to handle the internal chemical environment and mechanical stresses of the body [3]. As with any engineered system, failure of the lead wires can occur, however little is known about the specific tribological issues of the lead wires *in situ*. Lead wire failure here is defined as the loss of function of the lead wire that results in the CIED not able to fully perform the necessary therapy or any alteration of the lead wire that would result in danger to the patient.

Potential lead wire failure, *via* tribological mechanisms or otherwise, poses a critical problem for patient safety and reliability, but there is not a long reported history of research specifically focused on tribological performance. To give a sense of the scope of this issue, Kleeman, et al. studied devices implanted between 1992 and 2005, and reported that the failure rate of leads was as high as 15% after 5 years [4]. This does not indicate that the devices are not reliable, rather it suggests that the leads are subject to an aggressive *in vivo* environment and often require replacement during the lifetime of the device. Of the various causes of lead failure in CIED, one particular mechanism that can cause loss of device function, or in other cases complete device failure, is lead wire sleeve wear. It is likely that some amount of wear along the length of the sleeves is ubiquitous and typically does not affect safety, however, extreme enough wear can lead to deleterious consequences such as an electrical short [5], loss of sensing [6], or improper charge delivery leading to discomfort and pain [7]. In rare cases, some catastrophic outcomes are hypothesized to be caused by wear products, such as cardiac infection [8], or severe complications during lead extraction [9].

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https://doi.org/10.1016/j.biotri.2019.03.004
Received 26 October 2018; Received in revised form 22 January 2019; Accepted 6 March 2019
Available online 07 March 2019
2352-5738/

There are four primary zones of tribological concern in implanted CIEDs that can be readily identified, due to the design of the devices as well as their surgical placement. Firstly, the sleeves of two or more leads can be in intermittent sliding contact with each other, producing a lead-on-lead (elastomer on elastomer) wear mode. Secondly, leads may come into sliding contact with hard or soft tissues at multiple locations along their length [10]. Thirdly, the internal layers of the lead can experience sliding contact due to mechanical flexing of the lead during bodily motion [10]. Finally – and the topic of this investigation – is the contact that occurs between the lead sleeve and the edges of the metallic enclosure of the control module.

The wear performance of the sleeve material is likely a factor in all these modes [11]. Of the two primary elastomers used for the sleeves, polyurethane and its *co*-polymers are generally more wear resistant but subject to *in vivo* degradation. Silicone, which generally exhibits greater chemical stability, is less resistant to abrasion and generally has higher friction [1]. Several wear modes of elastomers exhibited in non-medical applications have been reported. In some materials, viscoelastic rolling produces characteristic ridges in the wear zone [12,13]. As the wear cycles accumulate, the ridges can detach and form wear debris *via* a fatigue-driven process [14]. This is in addition to fatigue cracking which can be initiated in the elastomer at high localized loading conditions [15]. Due to the placement of the lead, there is also the potential for more complex wear mechanisms involving viscoelastic creep, persistence of wear products at the interface, as well as possible lubricating action of biological proteins in the cardiac environment [16–19]. Finally, the silicone elastomer itself is reinforced with a hard phase, usually silica particles, to enhance mechanical properties. While the addition of this hard particulate raises concerns regarding abrasive damage, they are necessary in order for silicone to be a mechanically viable in most applications. Wear scars of retrieved silicone leads often have a shiny appearance which is indicative of third-body abrasion analogous to an aqueous polishing process [20].

This study focused on developing a baseline understanding the wear mechanisms and key parameters involved in the wear of silicone lead sleeves against the edges of the titanium device enclosure, and employed an experimental setup which was designed to simulate *in vivo* conditions. A better understanding of specific mechanisms can then be used to confirm or refute various tribological hypotheses regarding specific wear modes. Silicone sleeved leads were provided by the manufacturer for this testing. Three testing parameters were studied with regards to their impact on sleeve wear: applied normal load, testing fluid, and presence of a third-body abrasive. The study followed a factorial experimental design, and results were analyzed using both frequentist and Bayesian methods. Wear scars were examined using white light profilometry, optical microscopy, and scanning electron microscopy (SEM). The details and conclusions of this study are reported in this paper.

2. Materials and Methods

2.1. Experimental Materials

A 2^3 full factorial experimental design was developed to investigate the impact of three testing parameters on the wear behavior of silicone-sleeved CIED leads, as a means to simulate *in vivo* conditions of lead-on-device wear. A testing fixture was developed to load the leads against a counterface which mimicked the edge of a device enclosure. Surgically retrieved leads showing evidence of wear damage from device contact were provided as a benchmark to validate the simulations. The three factors investigated were: 1) applied normal load between lead and counterface, 2) presence or absence of albumin protein in the testing fluid, and 3) presence or absence of silica particulate in the wear fluid. Table 1 indicates the factors studied and their levels. Replication was employed to yield a total of two test runs for each experimental combination shown. The order of the 16 test runs was fully randomized to minimize the impact of any extraneous factors.

Table 1
Factors and levels used in the factorial study.

Factor	Level 1	Level 2
Normal load	0.1 N	0.3 N
Fluid type	Distilled (DI) Water	DI Water + Albumin
Fluid particulate	None	Silica

These three factors, and their respective levels, were chosen to be reasonably reflective of the *in vivo* application conditions, but also to accelerate the wear process while still maintaining fidelity to the tribological mechanism occurring in the body. It could be argued that the load levels chosen are somewhat higher than anecdotal evidence of the actual contact load between lead and enclosure. However, this particular range was chosen to be as low as possible yet still maintain load stability within the constraints of the research instrumentation used in this study. With regards to the second experimental factor, it is vital to know if protein content affects wear considering that there is a considerable amount of albumin protein found in the pericardial environment [21]. The third factor, presence of silica particulate in the wear fluid, was included in this study to investigate the possibility that third-body abrasion occurred during wear, and to determine whether such behavior had a measurable impact on the wear magnitude.

Unused silicone-sleeved CIED lead wires were provided by the manufacturer (Medtronic, Inc., Mounds View, Minnesota, USA), as were a number of surgically retrieved wires and associated micrographs showing wear damage from *in vivo* contact with the device enclosure. Lead wires were cut to 90-mm segments to be affixed in the testing apparatus (described below). Before each test, the leads were cleaned with ethanol and gently wiped with a lint-free cloth before being rinsed with distilled water and allowed to air dry for ten minutes. To accurately replicate the geometry and contact zone shape between the lead and enclosure, counterfaces were made from the same titanium alloy used in implanted devices, as provided by the manufacturer. The counterfaces were formed from sheet titanium bent into a U-shape to form a 40-mm diameter semi-circular edge, which represents the actual titanium casing diameter and forms cylinder-on-cylinder contact with the lead. The titanium counterfaces were cleaned with ethanol and distilled water prior to testing.

As stated above, two of the experimental factors involved the composition of the fluid which the wear interface was immersed in. The base fluid used was distilled (DI) water, held at 37 °C. Bovine Serum Albumin (BSA) supplemented fluid was prepared by mixing bovine albumin powder (Sigma-Aldrich Catalog No. A7906-1KG) in distilled water at a concentration of 3.0 g/dL, in line with reported representative pericardial albumin concentrations [21]. To attain this concentration, 1.5 g of powder was added to 50 mL of DI water, and the mixture was slowly stirred and heated at 37 °C for 30 min before testing. In the experimental treatments that involved fluid supplementation with silica particles, the goal was to mimic the size of particulate that could potentially be liberated from the silicone sleeves during wear. Silica particles of 1-μm sized (BeanTown Chemical, Catalog No. BT132665-25G) were selected. Based on information provided by the material formulator, as well as micrographs of unworn leads, this size and shape of particle was reasonably consistent with the filler particles used in the elastomer. To form the testing fluid, 50 mg of the silica particles was added to 50 mL of DI water for a target silica concentration of 1 mg/mL. The solution was then placed in a heated ultrasonic bath for 1 h at 35 °C so the silica particles could disperse. The resulting suspension was added to the testing fluid (DI water with or without BSA supplementation) as per the factorial matrix.

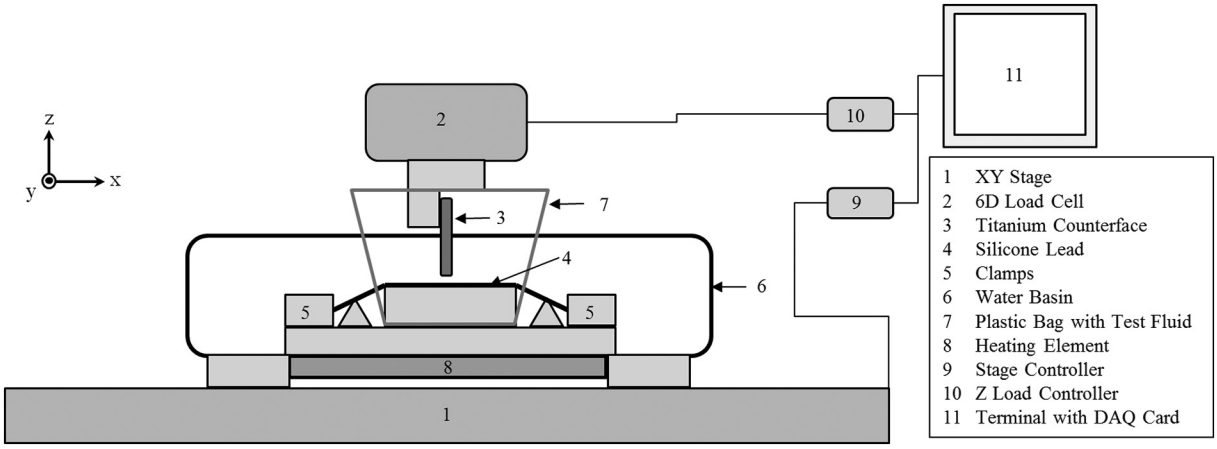

Fig. 1. Schematic of experimental setup of silicone lead wear tests. The lead was clamped at the ends while being immersed in a heated basin.

2.2. Wear Testing

Wear tests were conducted using a two-axis tribometer (Rtec Instruments, San Jose, California) with a customized testing fixture, as illustrated in Fig. 1. The CIED lead segment was held within the test fixture, which was mechanically connected to the tribometer stage. The substrate below the lead in Fig. 1 had a notch machined into the center so there was no slipping during sliding. An acrylic basin filled with the chosen testing fluid housed a mounting unit that clamped the lead wire at the ends of the lead while holding slight tension. This mount was then attached to the interior bottom of the basin. An adhesive heating element controlled by a solid state relay temperature controller was attached to the exterior bottom of the basin to maintain a fluid temperature of 37 °C during testing. Due to the nature of CIED implantation, there is a fibrous capsule that forms around the device post implantation. It is hypothesized that this capsule limits not only the amount of ambient fluid near the lead-device interface, but also limit the ability of wear debris to be flushed away from the interface. To simulate this condition, a plastic bag filled with the appropriate testing fluid was mounted around the sample lead during testing. The volume in the fluid was approximately 30 mL, but small gaps between the lead and the bag penetrations allowed for a limited – but desirable – amount of fluid egress/ingress during the test. Effectively, the large acrylic basin (250 mL volume) acted as a temperature buffer for the smaller volume of fluid held within the bag during testing.

The motion of the lead sample (as part of the larger basin fixture) was accomplished with two independent stepper motors controlling the tribometer stage. The titanium counterface remained stationary while the desired contact load was applied in the z-axis by a controlled linear motor. Relative velocity and path between the lead and counterface were regulated using motion control software. The wear path for all tests was linear reciprocation (perpendicular to wire) in the y-direction shown in Fig. 2. The length of the wear path was 5 mm for a total of 10 mm per cycle. The speed of the counterface movement was held constant for all tests at an average velocity of 9.09 mm/s. The total sliding distance of each test in the design was 180 m, corresponding to 18,000 reciprocation cycles. It was shown in preliminary testing that this total distance, coupled with the distance per wear cycle, produced wear scars of a size similar to surgically retrieved leads.

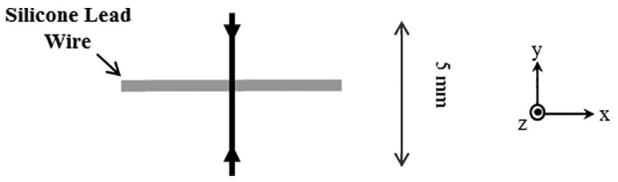

Fig. 2. Illustration of lead motion. The lead sample was reciprocated perpendicular to the titanium counterface resulting in a narrow contact zone on the lead and a 10-mm long zone on the counterface (5 mm on either side of the lead).

After the completion of the factorial matrix, additional experiments were conducted to study behavior of the leads during a longer duration test. These long duration tests were performed to determine whether albumin presence had an impact on results, and also to determine when the electrical conductors in the lead would be exposed due to wear through of the silicone sleeve. Each of the extended tests was conducted at a 0.3 N contact load for 400 m (40,000 cycles) in fluid with and without albumin supplementation, but without added silica particulate. Two tests of each fluid type were conducted.

2.3. Wear Analysis

A white-light profilometer (Zygo NewView700) was used to measure the three-dimensional shape of the wear scar produced by the above wear tests. An example of these measurements and the data gathered is shown in Fig. 3. To quantify the extent of wear, a line scan along the longitudinal center of the wear scar for each test specimen was collected as seen in Fig. 3a. The height data along this line scan was gathered and analyzed. Two parameters were collected from this profile data: maximum scar depth and the projected area of the wear scar profile. These metrics were recorded for each test in the factorial study and compared against each other to determine their correlation. A more traditional volumetric or gravimetric wear parameter was not used in this work because of the difficulties and uncertainties introduced by doing so. Firstly, the lead wires are a layered structure with metallic and elastomeric components, whose bulk mass could vary widely based on the precision of the cuts when preparing the samples. This mass variation would likely overwhelm the mass loss produced by wear. Secondly, silicone is a hygroscopic material and thus subject to substantial changes in mass through the course of immersion and wear testing, again likely obscuring wear mass loss. Finally, the cross sectional shape of the lead wires was not perfectly cylindrical from sample to sample, and thus obtaining a reliable and high-precision baseline geometry before wear was not possible. The uncertainty produced by these three factors led to the decision to use wear scar depth as the primary wear metric. The wear scar data was then used to perform a three-factor analysis of variance (ANOVA) to determine if any of the main effects or interactions had a statistically significant impact on wear amounts. A Bayesian analysis of the results using a robust Generalized Linear Model (GLM) approach was also conducted to provide insights which were beyond the applicability of ANOVA.

In order to investigate the potential wear modes acting during the tests, scanning electron microscopy (SEM-Quanta 250 FE-SEM, at

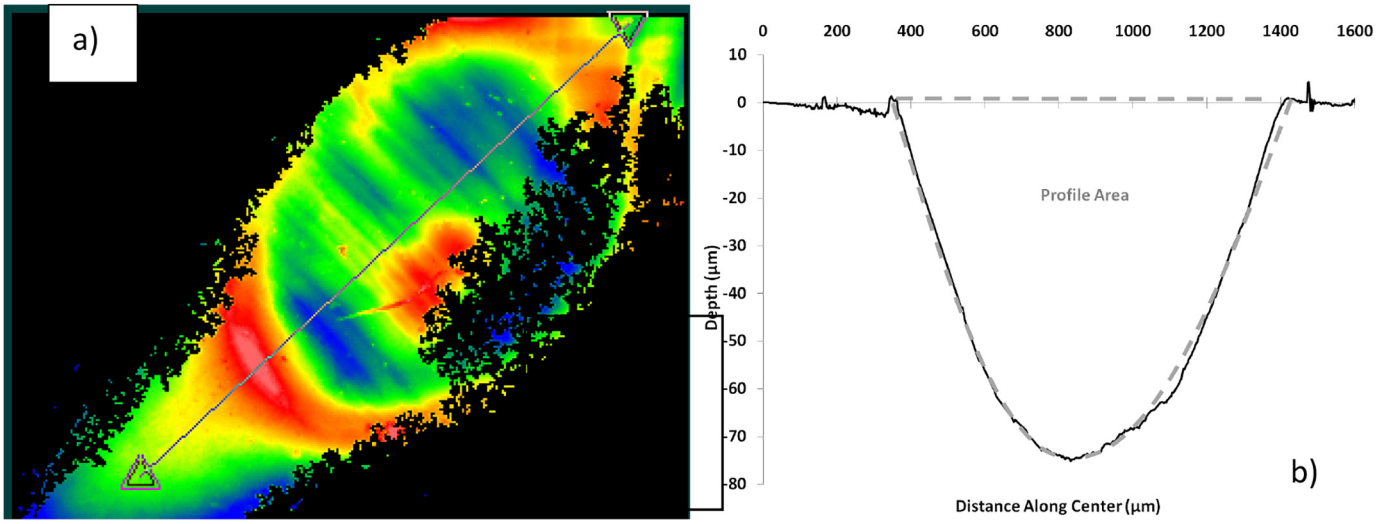

Fig. 3. An example of the topography data used to characterize the wear scar. a) The height map of the wear scar is displayed along with b) the profile height data taken from the center line of the scar. The projected wear scar area was used as the quantitative indicator of wear amount. These results were post processed by subtraction of a best-fit baseline cylinder.

3.5 keV) was conducted on tested lead samples. The selected leads were first washed with distilled water, wiped with a lint-free cloth, and rinsed again. After air drying for twenty minutes, the samples were coated with a uniform 2 nm thick layer of iridium for SEM examination. Various images were obtained and reviewed to identify possible wear modes. The possibility of wear scar formation by viscoelastic creep was also investigated. To determine if the silicone lead experienced substantial viscoelastic creep effects which would impact the wear scar profile, a constant radial load was applied to an untested CIED lead using a dynamic mechanical analysis (DMA) instrument (RSA-G2, TA Instruments, New Castle, Delaware, USA). The lead was positioned on top of an aluminum support and loading was applied at 50 °C for eight hours. Tests were conducted at 0.5 N and 1.5 N loads, and the lead wires were subsequently examined with the SEM for permanent deformation at the loading point.

3. Results and Discussion

3.1. Factor Effects on Wear

The mean wear amounts for each test setting are show in in Fig. 4, both in terms of wear scar depth and wear scar area, respectively. The depth and area data were highly correlated with each other, and thus only the wear scar area data was further used for the statistical analyses of the results. It can be observed immediately that all settings produced a statistically significant amount of wear, but also that there is not a strong trend apparent in the impact of any of the three factors on wear amount. As shown in the figure, one potentially discerning detail among the various results was that the variance in wear amounts at 0.3 N loading was somewhat smaller than at 0.1 N for the factors studied. However, this difference was not pronounced enough to provide strong credibility of an effect. An examination of the non-worn leads tested under continuous load confirmed that there was not permanent set at the loading point due to viscoelastic creep over the time period studied. Therefore, the geometry change measured after the wear tests was entirely due to material removal. This was further supported by the absence of a raised rim around any of the wear scars as would likely occur in the presence of significant creep.

Statistical analysis of the wear results indicated that there were no statistically significant differences in wear amount which could be attributed to any of the three main factors – load, protein inclusion and silica enrichment – nor was there strong evidence of any two or three-way interactions among the factors. This conclusion was confirmed using two different analysis approaches. A standard multi-factor analysis of variance (ANOVA) test was conducted for each response variable, maximum wear scar depth and area profile, respectively. Table 2 reports the '*p*-values' for the hypothesis that any of the individual main factors had an effect. However, some care must be taken with regards to interpreting the meaning of the p-value in this context. The p-value indicates the probability that the null hypothesis is true (i.e, changing the levels of the factor has no effect on wear), given the data collected and the probability space created by stopping criteria of the experiment. The stopping criterion in this study was to run a fixed number of experiments at each factor combination. Other potential stopping criteria, which were not used here, could include running as many experiments as possible within a given time or as many as possible until consumables are depleted. The resulting probability spaces for these latter criteria are different from that chosen in this study, and therefore the *p*-values reported here must be considered in light of the sampling intent used in this investigation. As shown in the table, the p-values are all much higher than the conventionally accepted decision criterion of 0.05 for statistical significance. While the ANOVA results are a strong indicator that there were no significant effects of the main factors, there was some concern with the fact that the wear data likely violated one of the fundamental assumptions of the ANOVA approach, namely the assumption that the overall variance of the data is equal to the variances of each individual factor and interaction comparison. Examination of the wear data in Fig. 4 suggests that the variance in wear among 0.3 N tests was likely smaller than 0.1 N tests and thus different from the overall variance. For these reasons, a Bayesian analysis approach was employed in order to gain some additional insight into these results.

To gain additional perspective on the wear testing results, and to add credibility to the results of the ANOVA, Bayesian analysis methods were employed using wear scar area. As in the frequentist approach, the wear results were assumed to be well modelled by the Generalized Linear Model (GLM) which incorporates a linear combination of factors, two- and three-way interactions, with their respective effects sizes. In standard GLM approaches, the final component of the model is a Gaussian-distributed noise function superimposed on the individual predicted means for each combination of factor levels. However, because of the limited number of data points collected at each setting, a robust analysis should be applied. The robust approach employs a Student-T distribution as a noise function to better handle potential outliers in the data. The strength of the Bayesian approach is that it

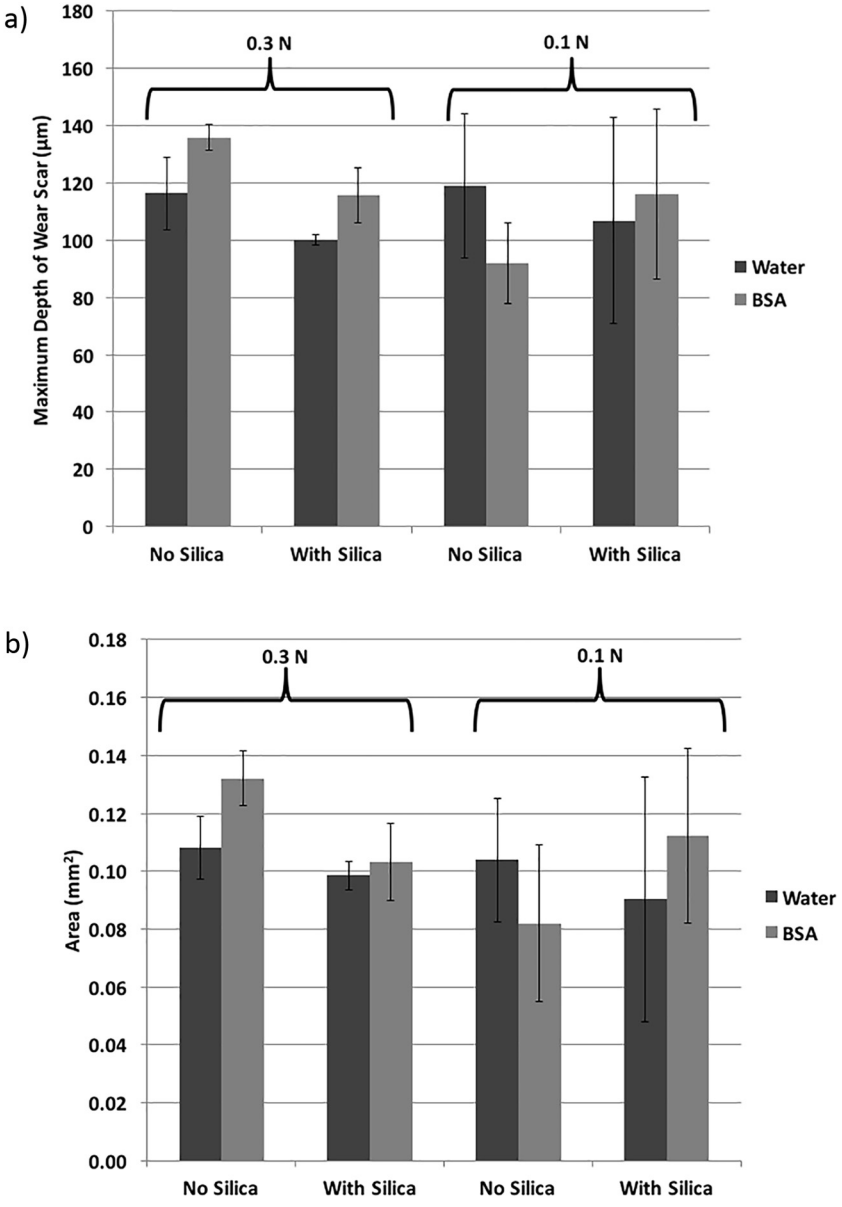

Fig. 4. Area(a) and maximum depth(b) of wear scars from wear tests with settings in Table 1. The mean is graphed, and errors bars indicate mean standard error for the two tests of each type conducted.

Table 2
Resulting *p*-values from ANOVA comparing the effect of load, fluid, and particulate on wear scar depth and area.

Factor	Wear scar depth	Wear scar area
Normal load	p = .532	0.391
Fluid type	0.735	0.638
Fluid particulate	0.654	0.726

employs prior knowledge and/or belief about the probability of a particular result, and rigorously combines this prior probability with the proposed model structure and the actual observed data to generate the posterior probabilities of the effects. Furthermore, these posterior probabilities are generated such that they represent the credibility of any given effect size based on the data. This is fundamentally different than a binary decision on significance that is obtained from the use of *p*-values. For this analysis, broad and noncommittal prior probabilities of effects sizes and variances were used because there was no prior knowledge of wear behavior. Artificial biasing of the prior probabilities can manipulate the predicted effects sizes if the amount of data is small, and so this was avoided. The analysis employed Markov Chain Monte Carlo (MCMC) computational exploration of the joint probabilities using Gibbs sampling (JAGS) and open-source code modified by the authors for this analysis [22]. Post analysis of the computational results indicated that the MCMC chains all converged very well (autocorrelation of chains effectively equal to zero) and all chains had effective lengths of > 10,000 samples. Fig. 5 shows the posterior probability (*i.e.*, the prediction based on the observed data and the prior beliefs) of each of magnitudes of the main effects. The Bayesian analysis produces a probability distribution of the most credible values for the effect size, given the data observed. The effects were defined as the mean wear scar area when the factor was at level 1 (*e.g.*, low normal load, no protein, or no silica enrichment) minus the area when the factor was a level 2 (*e.g.*, high normal load, with fluid protein, or with silica enrichment). A large probability density centered around zero suggests that the effect size is effectively equal to zero, that is, no effect. The 95% Highest Density Interval (HDI) produced by the Bayesian analysis indicates the range of effect sizes that are most probable given the data. In this study, a

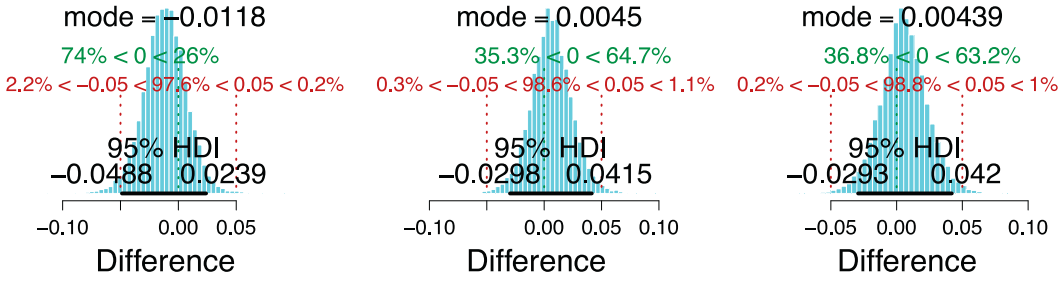

Fig. 5. Posterior probability distributions (blue) of effect sizes of: Load effect (left), protein effect (center) and particulate effect (right) on the magnitude of sleeve wear. The vertical red dashed lines indicate the boundaries of the range of practical equivalence (ROPE) and the black horizontal lines indicate the 95% Highest Density Interval (HDI) of the most likely sizes of the effect studied. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

difference in wear of 0.05 mm^2 in area was considered to be a meaningful effect, meaning that smaller differences were considered to be practically equivalent to no effect. Another way to consider this is whether there would be practical economic or engineering incentive to implement the findings if any change in wear was found less than this amount. A value of approximately 50% of the overall mean wear was adopted as a conservative threshold to avoid biasing the findings toward overly optimistic conclusions of efficacy. Thus a 'range of practical equivalence' (ROPE) of each effect was imposed consisting of the interval $[-0.05, 0.05]$ mm^2. When the results of the Bayesian analysis show a separation between the HDI and ROPE, this strongly indicates the likelihood of a non-zero effect. When the HDI and the ROPE overlap, this is evidence that the factor of interest did not have a meaningful effect. Examination of the figure shows that the modes of the probability distributions for each of the three main effects were nearly equal to zero and that the 95% HDI for each fell well within the ROPE. To summarize, this gives very strong credibility to the hypothesis – initially developed based on the ANOVA results – that no meaningful change in wear was produced by varying the levels of any of the three factors studied.

The lack of sensitivity of silicone sleeve wear to variation in the experimental factors was an unexpected result; however, this may be attributed to two specific reasons. Firstly, the loads used here might have been larger than what the leads experience *in vivo*. Anecdotal evidence and unpublished studies suggest that the actual loads may vary widely but with most of the activity occurring at loads of an order of magnitude less than those used here. The results observed in this study indicate wear extent is largely insensitive to load at high values. Only further testing at lower loads can provide support for this hypothesis, however. Secondly, as detailed below, the appearance of the wear scar was greatly affected by one of the factors – presence of silica particulate – even though this factor did not have a measureable impact on wear amount.

3.2. Wear Mechanisms

Although variation of the levels of each of the factors had no strong effect on wear amount, the various combinations of the three factors – load, fluid protein and particulate – did produce significant wear in each of the sleeves tested and thus provided a picture of the underlying wear mechanisms during lead-on-enclosure sliding. Fig. 6 shows a representative wear scar at two magnifications which indicate the overall shape of the wear scar, and also the fine topography of the wear surface. Examination of the high-magnification image shows a classic ripple structure suggestive of fatigue-driven wear of the elastomer. This wear mode is associated with adhesion and extension of surface asperities with relative motion against the counterface in one direction, followed by unloading and extension in the opposite direction as motion is reversed during reciprocation. The accumulation of strain cycles thus lead to eventual separation from the bulk and generation of wear debris. This is a widely reported wear mode found in elastomers and the wear surface produced has a matte appearance due to the topological features.

On the other hand, the addition of silica particulate to the wear fluid led to a drastic change in the appearance of the wear scar and the fine topography, as shown in Fig. 7, where the underlying fatigue-generated ripples are still present but appear to have been polished smooth, most likely by the additional silica particles. Close examination of Figs. 6 and 7 at the lower magnifications show a speckled appearance on the unworn surfaces of the sleeves. These are exposed silica filler particles which are embedded in the silicone matrix to reinforce the properties of the elastomer. The exposure of the particles suggests that they might play an aggressive role in lead-on-lead wear of the sleeves though this remains to be investigated. Fig. 8 shows a characteristic wear scar caused by contact with the device edge, clearly showing the shiny appearance of the worn zone.

The presence of albumin in the testing fluid also produced significant differences in the general behavior and appearance of the wear surface, even in the absence of an impact on wear amount. Fig. 9 (0.3 N, BSA, and no silica, 180 m) provides evidence that the presence of the protein led to adhered wear debris. There was a clear difference in surface topography compared to the previous figures in that the samples tested in albumin appear to have an underlying rippled structure like those seen in Fig. 7 that is covered by irregular patches. This may be due to the fact that the protein has some affinity for the elastomer surface and thus could not be completely removed during preparation for microscopy. This would suggest the possibility that it is persistent at the wear interface during sliding. Though no direct observations of such were made, this could possibly create a balance between enhanced lubrication counteracted by the protein-rich fragments acting to retain silica particles at the wear interface.

Extended duration testing of the leads indicated that in all cases, the silicone sleeve was worn through before 400 m of sliding. Fig. 10 shows a lead that has been worn through to the helical conductors of the lead. The higher magnification image shows that the wear interface maintained the characteristic fatigue-driven rippled topography even at this higher sliding distance. This suggests two things: Firstly, that the silicone is in a steady-state condition of wear even at 180 m, and that material removal continues largely unchanged in this mode until penetration of the sleeve. Secondly, the extended duration experiments show that the simulated testing protocol described here can produce a relevant simulation of tribological lead failure *in vivo*. The addition of albumin to the wear fluid produced a slightly different appearance of the wear scar, in line with that described above, however there did not appear to be a significantly different gross geometry or depth of the wear scar produced as seen in Fig. 4 and Table 2.

Though silica particles were not used to enrich the wear fluid in the extended duration tests, there was some evidence of third-body abrasion, likely the result of a significant amount of silica liberated during sliding. Well defined fatigue-induced ridges were observed in these

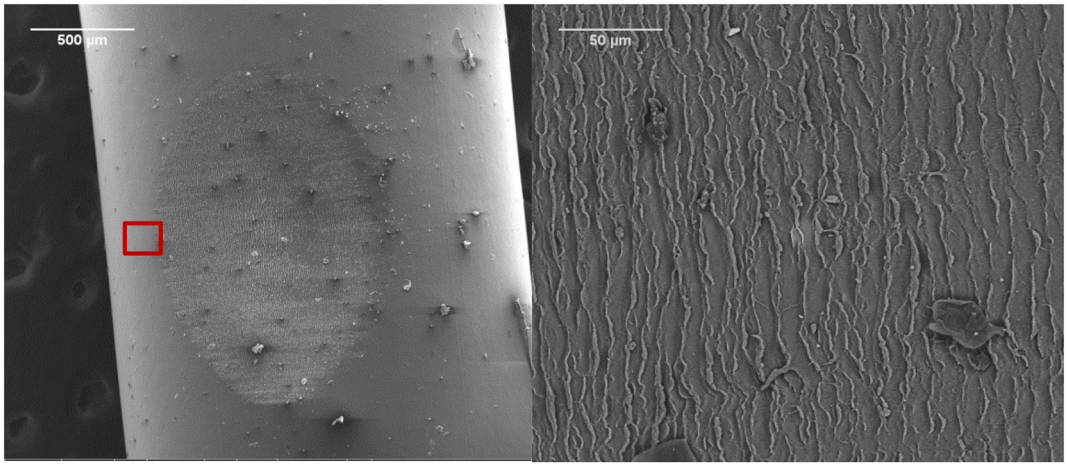

Fig. 6. SEM micrographs of silicone lead wear scar with test settings 0.3 N, distilled water, and no silica (180 m).

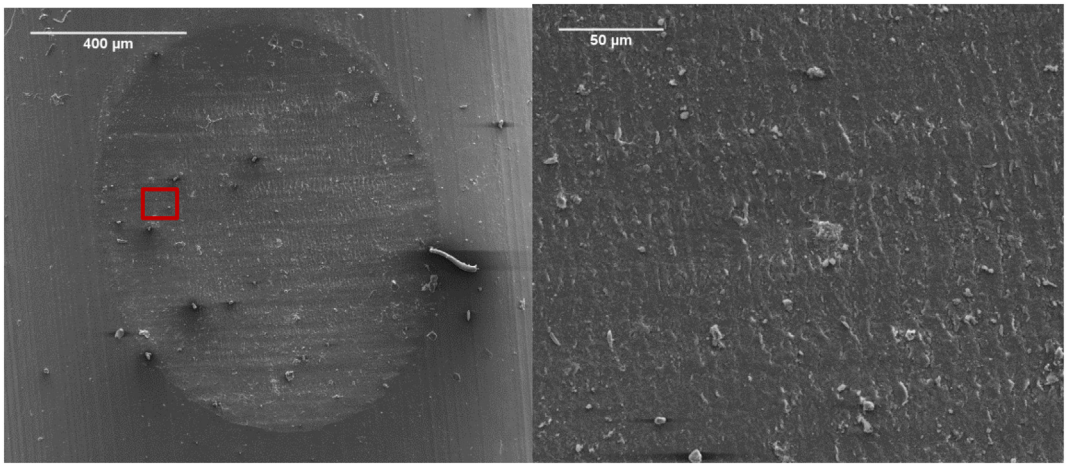

Fig. 7. SEM micrographs of silicone lead wear scar with test settings 0.1 N, distilled water, and with silica (180 m).

Fig. 8. Photograph of surgically explanted silicone lead exhibiting a characteristic shiny wear scar due to contact with the device edge. Scale indicated by length of text box.

samples, but energy dispersive spectroscopy (EDS) of wear debris adhered to the wear surface indicated high levels of silicon, possibly as part of fine silica particles. Further SEM imaging was conducted for titanium counterfaces with and without silica in solution. There was no evidence that silica was adhering to the counterface at the wear interface, a transfer film forming, nor was there evidence of damage to the titanium. Given the results of the analysis of wear amounts, coupled with the images of the wear surfaces, it appears that silica particles likely play a role in the wear of leads loaded against the edge of the metallic device enclosure. These results of this study further suggest that a simulated testing environment – such as the one developed in this study – provides a promising avenue to future investigation into the wear performance of sleeve materials for CIED applications.

4. Conclusions

The following conclusions have been drawn from the results of this study:

- Meaningful and accelerated simulation of *in vivo* lead-on-device wear was attained with the use of the test methods and instrumentation employed in this investigation. Mechanical damage to the leads was wear driven, and the appearance of the wear scars (in the cases of silica particle enrichment) closely matched those of explanted leads that had experienced long durations of service *in vivo*.
- The primary wear mechanism of the silicone sleeves observed in this study was one of fatigue-driven material removal due to the accumulation of strain cycles. In the absence of abundant silica particulate, reciprocated sliding produced a matte wear scar with periodic rippled features.
- Based on the results of this testing, *in vivo* wear of silicone-sleeved CIED leads is proposed to involve third-body wear by hard particles which are likely silica particles liberated from the silicone matrix. Free silica particles were not directly observed, but the presence of

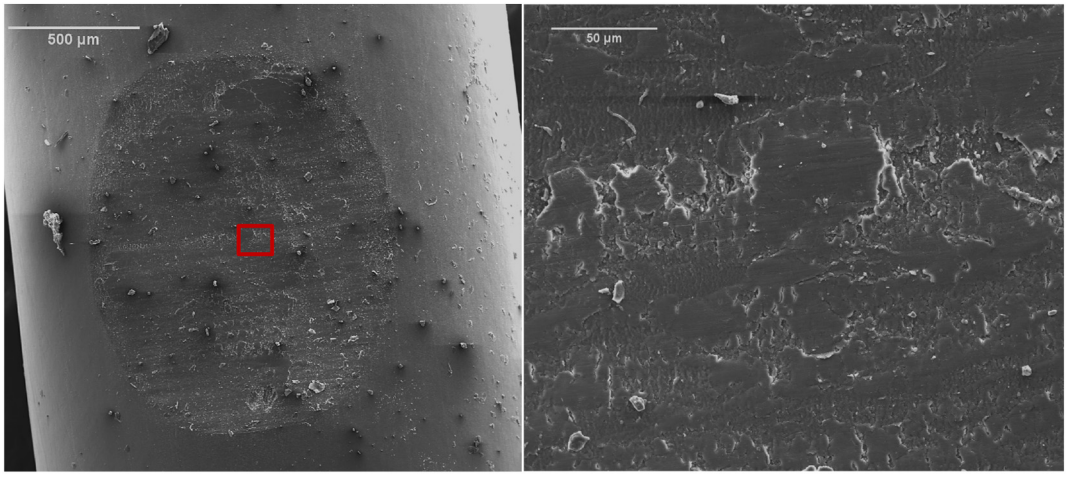

Fig. 9. SEM micrographs of silicone lead wear scar with test settings 0.3 N, BSA, and no silica (180 m).

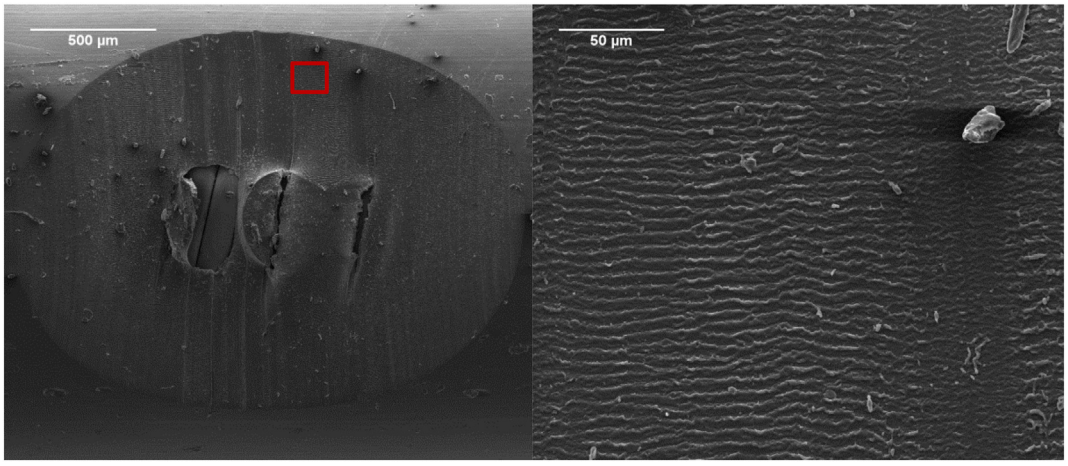

Fig. 10. SEM micrographs of silicone lead wear scar with test settings 0.3 N, distilled water, and no silica (400 m).

added silica particles in the wear testing had a drastic impact on the sheen of the wear scar, but not on the amount of wear experienced.

- The amount of wear of the silicone sleeves had very little sensitivity to variations in the factor levels within the ranges studied. Neither of the three main factors, nor their interactions, produced a statistically significant impact on wear amount. A limitation of this study was that the applied load may have been somewhat larger than loads experienced *in vivo* in lead-on-device contact, which may have had some impact on wear mechanisms observed.

Conflict of Interest

None.

Acknowledgements

Financial support of portions of this work was provided by Medtronic, Inc.

References

[1] H.M. Haqqani, H.G. Mond, The implantable cardioverter-defibrillator lead: principles, progress, and promises, Pacing Clin. Electrophysiol. 32 (10) (2009) 1336–1353.
[2] D.R. Ramsdale, A. Rao, Cardiac Pacing and Device Therapy, Springer Science & Business Media, 2012.
[3] C.D. Swerdlow, G. Kalahasty, K.A. Ellenbogen, Implantable cardiac defibrillator lead failure and management, J. Am. Coll. Cardiol. 67 (11) (2016) 1358–1368.
[4] T. Kleemann, et al., Annual rate of transvenous defibrillation lead defects in implantable cardioverter-defibrillators over a period of > 10 years, Circulation 115 (19) (2007) 2474–2480.
[5] M.O. Sweeney, Exploding implantable cardioverter defibrillator, J. Cardiovasc. Electrophysiol. 12 (12) (2001) 1422–1424.
[6] R. Gradaus, G. BREITHARDT, D. BÖCKER, ICD leads: design and chronic dysfunctions, Pacing Clin. Electrophysiol. 26 (2p1) (2003) 649–657.
[7] N. Mehta Oza, M. Taylor, S. Kalbfleisch, The impact of inappropriate shocks from implantable cardiac defibrillator lead failure on cardiovascular morbidity and mortality, Circulation 128 (2013) A12713.
[8] A. Kołodzińska, A. Kutarski, M. Grabowski, I. Jarzyna, Barbara Małecka, G. Opolski, Abrasions of the outer silicone insulation of endocardial leads in their intracardiac part: a new mechanism of lead-dependent endocarditis, Europace 14 (6) (2012) 903–910.
[9] S.M. Kurtz, et al., Implantation trends and patient profiles for pacemakers and implantable cardioverter defibrillators in the United States: 1993–2006, Pacing Clin. Electrophysiol. 33 (6) (2010) 705–711.
[10] A. Himes, C. Wilson, Wear of cardiac lead outer insulation due to internal cable motion, Tribol. Int. 62 (2013) 177–185.
[11] U.W.E. Dorwarth, et al., Transvenous defibrillation leads: high incidence of failure during long-term follow-up, J. Cardiovasc. Electrophysiol. 14 (1) (2003) 38–43.
[12] K. Friedrich, Friction and Wear of Polymer Composites, vol. 1, Elsevier, 2012.
[13] A.K. Bhowmick, Ridge formation during the abrasion of elastomers, Rubber Chem. Technol. 55 (4) (1982) 1055–1062.
[14] A.N. Gent, C.T.R. Pulford, Mechanisms of rubber abrasion, J. Appl. Polym. Sci. 28 (3) (1983) 943–960.
[15] A.N. Gent, C.T.R. Pulford, Wear of metal by rubber, J. Mater. Sci. 14 (6) (1979) 1301–1307.
[16] P.R. Sreekanth, S. Kanagaraj, Wear of biomedical implants, Tribology for Scientists and Engineers, Springer, 2013, pp. 657–674.
[17] A.P. Serro, M.P. Gispert, M.C.L. Martins, P. Brogueira, R. Colaco, B. Saramago, Adsorption of albumin on prosthetic materials: implication for tribological behavior, J. Biomed. Mater. Res. A 78 (3) (2006) 581–589.
[18] M.P. Gispert, A.P. Serro, R. Colaco, B. Saramago, Friction and wear mechanisms in hip prosthesis: comparison of joint materials behaviour in several lubricants, Wear

260 (1–2) (2006) 149–158.
[19] F.A. Alnaimat, D.E.T. Shepherd, K.D. Dearn, Crack growth in medical-grade silicone and polyurethane ether elastomers, Polym. Test. 62 (2017) 225–234.
[20] D.J. Nelson, Method for Polishing Silicone Products, (Jul, 1992).
[21] H. González-Pacheco, et al., Prognostic implications of serum albumin levels in patients with acute coronary syndromes, Am. J. Cardiol. 119 (7) (Apr, 2017) 951–958.
[22] J.K. Kruschke, Doing Bayesian Data Analysis: A Tutorial with R, JAGS, and Stan, 2nd ed., Academic Press/Elsevier, 2015.