Medical Engineering and Physics 38 (2016) 427–432

Contents lists available at ScienceDirect

Medical Engineering and Physics

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

Product limit estimation for capturing of pressure distribution dynamics

Michael Wininger[a,b,c], Barbara A. Crane[a,1,*]

[a] University of Hartford, Department of Rehabilitation Sciences, West Hartford, CT 06117, United States
[b] Veterans Affairs Cooperative Studies Program, VA Connecticut Healthcare System, West Haven, CT 06150, United States
[c] Yale School of Public Health, Department of Biostatistics, New Haven, CT 06520, United States

ARTICLE INFO

Article history:
Received 23 March 2015
Revised 10 December 2015
Accepted 3 February 2016

Keywords:
Pressure
Wheelchair
Kaplan–Meier
Product Limit Estimator
Time series
Correlation
Ulcer

ABSTRACT

Measurement of contact pressures at the wheelchair-seating interface is a critically important approach for laboratory research and clinical application in monitoring risk for pressure ulceration. As yet, measures obtained from pressure mapping are static in nature: there is no accounting for changes in pressure distribution over time, despite the well-known interaction between time and pressure in risk estimation. Here, we introduce the first dynamic analysis for distribution of pressure data, based on the Kaplan–Meier (KM) Product Limit Estimator (PLE) a ubiquitous tool encountered in clinical trials and survival analysis. In this approach, the pressure array-over-time data set is sub-sampled two frames at a time (random pairing), and their similarity of pressure distribution is quantified via a correlation coefficient. A large number (here: 100) of these frame pairs is then sorted into descending order of correlation value, and visualized as a KM curve; we build confidence limits via a bootstrap computed over 1000 replications. PLEs and the KM have robust statistical support and extensive development: the opportunities for extended application are substantial. We propose that the KM-PLE in particular, and dynamic analysis in general, may provide key leverage on future development of seating technology, and valuable new insight into extant datasets.

1. Introduction

Measuring – and manipulating – contact pressures at the seating interface is a critically important paradigm in minimizing risk for pressure ulceration in a highly at-risk population [1,2]. Mapping the pressures under the buttocks is a widely-used approach in both clinical decision making and laboratory research, and is an integral practice in developing technologies and treatment strategies for mitigating ulcer risk factors [3–8]. Naturally, there is incumbent need for robust and interpretable descriptors to support both scientific inquiry and clinical practice.

Most commercially available pressure mapping systems yield a 2-dimensional dataset (a 2-D array of data points corresponding to the sensor grid). While there are presently no "gold standard" measures by which pressure risk is quantified [9,10], a handful of measures are in frequent use, with well-established merits and demerits. While it is beyond the scope of the present work to review all such measures, we note that peak pressure, peak pressure index, average pressure, and pressure variance are among those most commonly reported.

Notably, these metrics are all static in nature: they operate on the 2-D dataset, and they do not easily avail to reporting changes in the nature of the pressure distribution over time. And yet, time is universally recognized as a factor in pressure ulcer risk: even low pressure loads can be injurious to tissues if maintained for an extended time [11].

The extant approaches are – at best – a "repeated measures" style approach utilizing the traditional static measures previously mentioned. While others have measured changes in interface pressure parameters over time or with dynamic activities [12], these studies merely take a static parameter, e.g. peak pressure, and note its change across several time points. Integrated measures, e.g. the pressure time integral – the area under the curve of peak pressures over the designated time [12,13] – reflect cumulative effects of pressure at the seating interface, and do not yield information about pressure dynamics. Furthermore, without normalization, integral-based measures are labile to average pressure and time of record, and are insensitive to the character of the pressure distribution [14].

While all of these studies note the potential importance of pressure redistribution over time or with activity as a potentially key

* Corresponding author. Tel.: +1 860 768 5371; fax: +1 860 768 4558.
E-mail address: bcrane@hartford.edu (B.A. Crane).
[1] Present address: 180 Middletown Avenue, Wethersfield, CT 06109, United States.

http://dx.doi.org/10.1016/j.medengphy.2016.02.006
1350-4533/

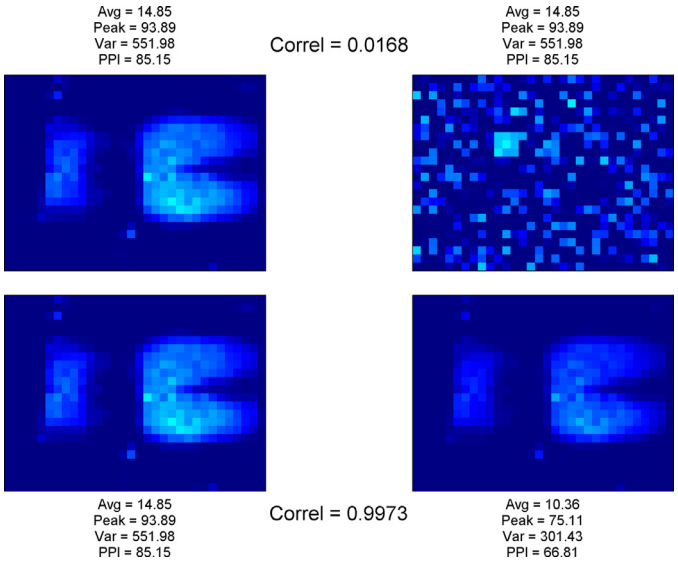

Fig. 1. Many "static" features extracted from pressure maps obscure differences in pressure distribution, as might change over time, for example veridical data obtained empirically from a research subject (Left) and hypothetical data obtained by random reassignment of the empirical data (Right); both pressure maps have identical average pressure, peak pressure, pressure variance, and peak pressure index.

factor in risk reduction for pressure ulceration, none are actually measuring re-distribution [12,15–18].

We illustrate this in a simple example where raw data collected from a patient can be seen to yield identical parameters when scrambled across the pressure array into a random 2-D scatter (Fig. 1, Top). Hypothetically, if the pressure distribution were to change over time as depicted, there would be substantial reduction of risk for ulceration, given the substantial redistribution of pressure across the interface. Naturally, this is an extreme and unrealistic example, but it illustrates the principle that even the most widely used parameters of interfacial pressure measurement are inadequate to assess the effectiveness of pressure re-distribution over time. Likewise, the converse is also true: it is tempting to conclude that an absolute reduction in these parameters indicates substantial reduction in ulcer risk. While it is generally accepted that reduction of these parameters might correspond to a reduction in risk, if the broader character of the interfacial contact has not changed, the risk for ulceration remains high: even more-than-moderate pressure parameters can be considered "low risk" if the pressures are frequently re-distributed – the greatest risk factor for ulceration is sustained pressure in a location [19]. In this way, it is more desirable to have a measure of distribution similarity (or dissimilarity) over time, than it is to have static descriptors that measure parameters of the distribution at a single time point. We propose that the simple correlation function would be a suitable index of distribution similarity over time, and would provide greater value than analysis of changes in the "traditional measures" over time (Fig. 1, Bottom).

Pressure redistribution, although not commonly characterized in research involving interface pressure, remains a frequent recommendation for clinical best practices [20]. Here, we propose a measure to succinctly quantify the pressure re-distribution over a window of observation, i.e. for when the dataset expands to a third dimension (time): product limit estimation (PLE).

PLE was originally designed as a tool for computing probabilities of occurrence of an event at a certain point in time; multiplying successive probabilities by any earlier known probability to get the final estimate [21]. The most common application of PLE is in pursuit of a survival analysis, as might be performed in the study of outcomes of a clinical trial with a mortality end-point; the National Center for Biotechnology Information (NCBI) PubMed database contains more than 50,000 references to the Kaplan–Meier (KM) PLE in all manners of medicine and applied science research. The KM is probably the simplest and most widely-used method for computing survival over time [22,23].

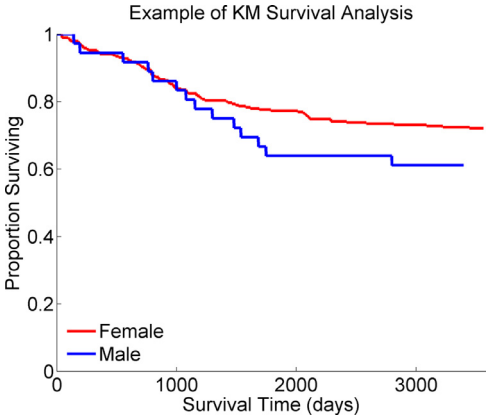

Fig. 2. Exemplar of Kaplan–Meier survival analysis based on survival data from the Mayo clinic trial in primary biliary cirrhosis of the liver.

Here, we propose that PLE may provide leverage on a problem hitherto unrealized: quantifying the dynamics of the contact pressure image recorded at the seating interface over time. In this study, we describe the method, and illustrate its use through its application to two sample datasets. We discuss foreseeable constraints to interpretation, and opportunities for expansion.

2. Methods

2.1. Product-limit formulation

The Kaplan–Meier PLE is posed as follows: let t_n be the time to the nth event (typically: death, given as d_n), and let $S(t_n) = P(T > t_n)$ be the probability of survival at time T beyond t_n. The probability at t_{n+1} depends conditionally on $S(t_n)$, so the KM-PLE is built recursively:

$$S(t) = \prod_{i=1}^{j} \left(1 - \frac{d_i}{n_i}\right)$$

where j is the total sample size, and $S(t)$ is the piecewise-constant estimator of survival function over time t. For a living participant in a clinical trial, the probability of survival is always $0 \leq S(T > t) \leq 1$. In Fig. 2, we show an example application of KM analysis to a classic survival dataset from the Fleming and Harrington textbook, conveying data from the Mayo Clinic trial in primary biliary cirrhosis of the liver conducted between 1974 and 1984 [24].

Here, we see two survival curves (male versus female), yielding an intuitive and interpretable view into the differences in survival benefit by sex. Such a plot could also be constructed for survival benefit by any categorical variable, e.g. treatment arm or risk category.

2.2. Correlation as event analog

Here, we seek to characterize the distribution (or, more specifically: the re-distribution) of pressures across the seating interface over time. Where the pressure mat data yields a time-series of 2-D datasets, a re-distribution would be reported as a non-trivial change in values across many cells in the matrix M between time points t_a and t_b. This is quantified in a straight-forward way by