TECHNICAL CORRESPONDENCE

TO: Ryan Greenough, SATOP CC: Dr. Joseph Smith DATE: November 27, 2007
ID NO.:

SUBJECT: Computational Verification of Unique Bandage Design: RTA #3048

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Overview

Analytic consideration of a revolutionary bandage design proposed by Doctors International Incorporated (herein DII) was requested to verify, analytically, the benefit of the proposed geometric bandaged design. A review of pertinent literature from medical, adhesive, and pharmaceutical journals was first performed. From the literature, a number of verified experimental techniques are available by which the effectiveness or superiority of a new bandage design can be tested. There are a number of challenges and complexities that are associated with the behavior characteristics of a bandage, most of which are best suited for experimental attention, such as polymer interaction with the adherend and dynamic factors including moisture exposure and surface conditions as these factors are not inherent properties to the adhesive itself. The first analytical approach would be to construct two models of identical coverage area, one of which being a standard, conventional bandage currently on the market, the other being the pedaled design proposed by DII. The two models would receive the same loading conditions and would possess the same adhesive. From this, a comparison as to their respective behavior can be drawn. It was found, after review of the literature that there appears to be no theoretical or modeling treatment of this type of problem. Further investigation by means of personal contact with professionals in the bioadhesive and polymer industry confirmed this finding. It is thereby suggested that experimental verification of the bandage be performed, and a means by which this can be achieved is presented in this report.

Literature Review

In past experimental studies of adhesive bonding, for bioadhesives as well as other applications, reported data from various experimental methods which employed the use of probes, have not been reproducible. It is well-known in the bioadhesive industry that comprehensive stress-strain behavior of a bioadhesive under loading is important to the assessment of a complete performance evaluation. The ability to record and analyze such behavior is therefore essential. Chuang et. al. [1] reported evaluation of performance of and utility of the Avery Denison Adhesive Testing Method which is a unique testing procedure which utilizes the prior established probe mechanism approach, but incorporates an array of controls which allows for variation in testing parameters.

Additionally, the method allows for the use of various probe configurations and geometries which provide for testing of various bioadhesive configurations, and have been shown to be reproducible. Stress and strain data are recorded digitally from which a number of parameters important to the complete design of a bandage are brought out for analysis and comparison; moreover, multiple adhesive performance data can be obtained from a single test. A thorough and comprehensive review of adhesive testing and related parameters was performed by Johnson [2], who also presents pertinent details on the testing procedure outlined by Chuang et. al., such as mechanics of adhesive testing as well as the significance of several associated testing parameters. Further testing using texture profile analysis (i.e. the force-time behavior) includes the work of Jones et. al. [3] who report the mechanical characterization of several bioadhesive materials for pharmaceutical applications. In this work, three materials are examined independently to assess their mechanical behavior (hardness, adhesiveness, elasticity, compressibility), along with blends of these materials. It is noted that choice of adhesive is of significant importance in the design of a bioadhesive for reasons discussed later in the report. Zosel [4] has investigated the adhesive failure energy parameter in the determination of the tack (stickiness), peel strength, and shear resistance of pressure sensitive adhesives (PSA) and include the effects of molecular structure of the adhesive on the adhesion properties, pointing out several quantities which dictate adhesion on the molecular level. The use of bioadhesives for drug delivery in a percutaneous manner has also been experimentally investigated. The physical and performance properties, such as diffusivity and adhesion, of drug delivery bioadhesives have been quantitatively assessed by Feldstein et. al. [5], examining such quantities as adhesive fracture energy which provides a measure of adhesion. In this work, an analytical expression is derived relating adhesive strength to the molecular structure and self-diffusion coefficient of an adhesive polymer using adhesive fracture energy, providing a measure of adhesion. For transdermal drug delivery, it is reported by Houze [6] that drug release rates can be manipulated by altering adhesive blend ratios of acrylic pressure sensitive adhesives which would otherwise be employed for varying mechanical properties. Further characterization of factors affecting transdermal bioadhesive drug delivery is reported by Woolfson et. al. [7].

In addition to the literature reported and contained in this report, an extensive digital library is available online from The Pressure Sensitive Tape Council (http://www.pstc.org/papers/categories-titles.php) in which papers covering a plethora of topics concerning adhesives, fundamentals of adhesion, testing, and trends of pressure sensitive adhesives are available for download. Further references which would be of value in assessment of the bandage design included that authored by Philip M. Parker, entitled, "The 2007-2012 Outlook for Medicated and Non-Medicated Surgical Dressings, Adhesive Plaster, and Self-Adhering Bandages in the United States" (ISBN 978-0497553005). Additional texts on topics relevant to bandages and their design include: "Pressure-Sensitive Adhesives and Applications", Second Edition, by Istvan Benedek (ISBN 0824750594), and "Development and Manufacture of Pressure-Sensitive Products", by Istvan Benedek (ISBN 0824702069).

Discussion and Recommendations

Development of a Model for Analytical Solution

There appears to be no mathematical or theoretical model addressing the behavior of a "bandage", "transdermal patch", "adhesive dressing", "pressure sensitive adhesive", or "bioadhesive dressing" in the literature, nor through professional contact of the Adhesive and Sealant Science Professor in Engineering Science and Mechanics at Virginia Tech, Dr. David Dillard, of Dr. Janice Paige Phillips, Physical Organic Chemistry, Polymer Science and Nanomaterials at the University of Southern Mississippi, or through contact of The Adhesive and Sealant Council (Larry Sloan, President). There are a number of difficulties associated with the development of such a model, which typically invoke several assumptions to arrive at behavioral prediction, principal of which is the complexity involved in assessing characteristics of a bioadhesive which are not intrinsic to the adhesive itself or characteristic of a particular geometry. A classical free-body diagram (FBD) is not sufficient since it only predicts static reaction forces and cannot take into account the dynamic adhesive forces involved in an adhesion process. A practical solution would be generation of a finite element model (FEM) which can predict the performance of such parameters, requiring accurate and precise material properties which are readily attainable in the literature and specified geometry. The difficulty in creating such a model lies in accounting for real variability in surface properties and quantities that, again, are not related to the properties of the adhesive or of one particular geometry.

Testing and Experimentation

The construction of a prototype bandage would provide for the most accurate real-world responsiveness, thereby giving verification to the performance of the bandage design proposed by DII relative to the standard bandages on the market. An experimental method by which a given selection of dimensions and adhesive type can be tested is to adhere the bandage to a force gage and apply a constant force upon the sticky surface of the bandage over a given period of time until the bandage displaces from the surface to which it was applied. A series of experiments examining various types of adhesive and geometric sizes will reveal the adhesive strength of a dimension/adhesive combination for determination of the most suitable one. Figure 1 shows, graphically, generalized results which can be obtained from such a method. From the experimental data, there are several considerations from which a judgment of the effectiveness and performance of a bandage can be assessed [2], and these factors are discussed in detail by Chuang [1]; note that the factors described below are depicted for bandage A in the figure:

1. Adhesive Strength – Measured peak force

2. Adhesive Work – Area existing under the force-time curve

3. Stringiness – The stringiness of a bioadhesive patch is measured by the (time) distance to complete separation (i.e. no measured force)

4. Relative Cohesiveness – Percentage of area under the curve or percentage distance after the peak

5. Initial Bond Strength – The initial bond strength (energy required to begin to break adhesive bond) is measured by the initial slope of the curve.

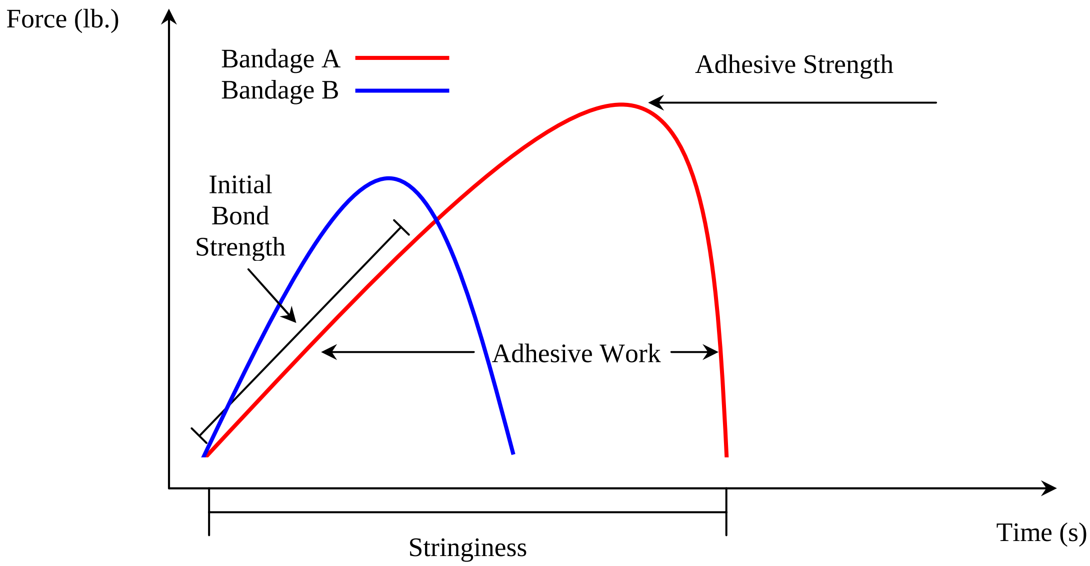

Figure 1 – Experimental Technique for Bandage Adhesion Strength

There are a number of design characteristics which contribute to the overall adhesion performance of a bandage. In particular, it is important for the bandage to be constructed out of a flexible material such that it is able to conform to the various motions for typical human movement. The geometric configuration selected by DII is one which, for the same perimeter as a circular or square bandage, affords enhanced flexibility in movement which would provide prolonged adhesive life of the bandage.

Texture Technologies (www.texturetechnologies.com, Atlanta, GA) is a company established in 1989 who provides for measurement of physical parameters of a wide variety of products by manufacturing measurement instruments which are used for adhesive and bandage testing by corporations including Johnson & Johnson and 3M [8]. The use of the apparatus is buttressed by the aforementioned Chuang study. Economical options to utilize this equipment include contracting a set of measurements to a company who owns one (International Food Network, Naples, FL; University of Florida, Gainesville; Florida A&M, Tallahassee) or renting the equipment directly from the company at a cost of about $1650/mo. The cost to purchase the measurement device is $26,000. With either the purchase of the unit or rental of the unit directly from the company, comes unlimited customer and testing support with recommendations and literature on previously conducted tests. The point of contact at Texture Technologies for purchases, rental information, or general inquiries is Randy Koch (770/419-9420).

Enclosed is an applications directory for the aforementioned test equipment, along with material which describes the software program employed for data acquisition and analysis.

References

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[8] Texture Technologies, Personal Communication, Randy Koch.