

**A TECHNOLOGY & METHODOLOGY FOR MECHANICAL CHARACTERIZATION OF INTACT ELASTIC MATERIALS,
AND IN-VIVO BIOMECHANICAL ANALYSIS OF SOFT TISSUES AND LINEAR INCISION WOUNDS**

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INTRODUCTION

A new technology and methodology are presented which allow for *mechanical characterization of Intact elastic materials, and In-Vivo biomechanical analysis of soft tissues and linear incision wounds*. Specific applications with regard to types of analyses performed will be demonstrated.

In contrast to previous mechanical testing systems (uniaxial tensiometers), this technology (BTC-1000™:Surgical Research Laboratory, Inc., Nashville TN.) does not require the destructive excision of tissues or material samples prior to testing. Thus, this advanced methodology eliminates the artifact error and experimental variables introduced by excisional methods. These include non-viable tissue samples, inconsistent variation of sample dimensions, flawed edges from cutting, and loss of insitu or inherent mechanical properties. This methodology further permits non-destructive testing of biomaterials and tissues allowing for consecutive analysis over time. In addition, this methodology provides for sensitive measurements of fragile materials (i.e.. day2 post-op wounds), and yields a lower percent (%) coefficient of variation (CV.) from the mean, with fewer samples required to obtain reproducible data (Tables 1,2, & 3). The technology applies a multi-axial stress to a material which is more analogous to the stresses experienced in field use. Moreover, the technology integrates application software for complete objective measurements.

This technology and methodology are introduced as an alternative to uniaxial excisional methods.

METHODS: DATA ACQUISITION & ANALYSIS (Fig. 1)

A material or soft tissue model is attached to the end of a glass vacuum chamber with the aid of a plastic ring that is affixed to the test area, or by a simple contact self sealing fixture. Two infrared light reflecting targets are placed 10 mm apart in the center of the test area. With the aid of a

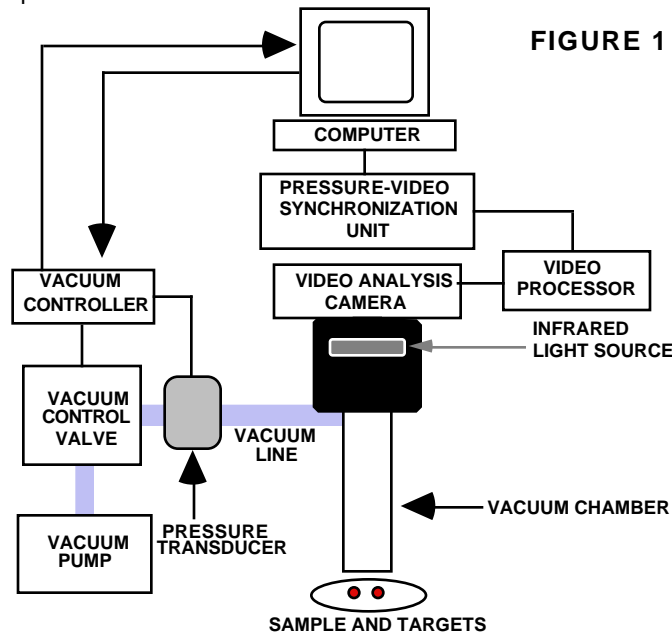


FIGURE 1

computer software program, a single processor communicates with a vacuum controller and pressure-video synchronization unit to collect real-time pressure (mmHg) and video deformation (mm) data. An interface reference voltage from the computer processor governs the vacuum controller to decrease the chamber pressure at a preselected rate (5,10, or 20mmHg per

second), applying a multiaxial stress to the area. This causes deformation of the material, and displacement of the targets. The reference voltage also triggers the collection of both negative pressure and video data. The vacuum controller communicates with a vacuum control valve to achieve proportional negative pressure. A pressure transducer monitors the in-line negative pressure, providing data to the vacuum controller and computer. A pressure-video synchronization unit linked to the computer processor provides corresponding video data. The unit communicates with a video processor to receive digital data (target x-y coordinates) from a video camera positioned atop the vacuum chamber. Light reflecting targets on the sample are automatically digitized using a miniature infrared light source. Within seconds of data acquisition, time synchronized pressure and video data are objectively interpreted, instantaneously displayed, and stored to hard disk. The data includes pressure vs. time, deformation vs. time, and unique pressure-strain characterization curves. Typical material properties measured are ultimate strength, structural modulus, and total energy absorption.

RESULTS

This technology and methodology have been used to characterized a variety of elastic materials and soft tissues, including different treatments of linear incision wounds. The following Tables 1,2, & 3 display results for some applications and types of analyses performed. Note: N=5 for all groups.

| Membrane to Failure Analysis | | | |
|-------------------------------------|----------|----------|----------|
| Mean / % Coefficient of variation | | | |
| | DISTAL | MIDDLE | PROXIMAL |
| latex Condom | 496.2/4% | 389.8/5% | 297.1/7% |
| polyurethane. Condom | 412.2/7% | 427.2/4% | 400.7/6% |

Table 1. Results show variation within intact device.

| Intact Material Characterization | | | |
|---|-----------------------------------|----------|----------|
| Implant | Mean / % Coefficient of variation | | |
| Thickness | .019 | .030 | .036 |
| modulus | 74.0/1% | 122.5/3% | 147.1/4% |

Table 2. * Structural modulus (stiffness or compliance)

| In-Vivo Linear Incision Wound Healing | | |
|--|-----------|-----------|
| Mean / % Coefficient of variation | | |
| | Day3 | Day5 |
| carrier control | 102.3/10% | 155.0/12% |
| growth factor | 106.4/11% | 197.9/11% |

Table 3. Methodology reveals enhanced healing (Day5)

DISCUSSION

This technology and methodology represent a breakthrough in mechanical testing as materials and tissues no longer have to be excised prior to measurement. The ability to characterize a material without excision injects unlimited opportunity into future research & development of biomaterials. One obvious next step includes non-destructive testing of soft tissues and linear incision wounds in humans. In materials characterization, this technology will expand our knowledge as non-destructive analysis may be used as a predicting factor of product performance prior to field distribution. Additionally, evaluation of materials under stresses which are analogous to the real world conditions will provide for more reliable results.