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Research Paper

Evaluating temperature and duration in arterial tissue fusion to maximize bond strength

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ABSTRACT

Tissue fusion is a growing area of medical research that enables mechanical closure of tissues without the need of foreign bodies such as sutures or staples. Utilizing heat and pressure applied for a specified time, a bond can be formed between adjacent tissues. The success or failure of tissue fusion is contingent upon the strength of the bond it creates between opposing tissues, yet little characterization has been done to measure the strength of this interface as a function of the input parameters, such as heat and pressure. Previous studies have examined the strength of tissue fusion using clinically relevant outcomes such as bursting pressure or tearing strength, but none have explored metrics more appropriate for determining the mechanics of the actual bond such as peel or shear strengths. The goal of this study is to establish methodology for T-peel and lap shear testing of fused tissues and measure the fusion bonding strength as a function of temperature and time using the ConMed Altrus® laparoscopic thermal fusion device. Across five temperatures (120, 140, 150, 160, 170 °C) and four time durations (500, 1000, 1800, 3000 ms) the mean peeling strength, ultimate shear strength, and bursting pressure of fused porcine splenic arteries were measured. The shear strength increased with increasing temperature and time with an ultimate shear strength at 160 °C and 3000 ms equal to 290 ± 99 Pa. No trend was observed between the input parameters of time and applied temperature and the mean peeling force, although there were significant differences between groups. The bursting pressure increased significantly with increasing durations, but no trend was noted between temperature and bursting pressure. The shear strength data suggest there is some physical or chemical reaction which occurs in the tissue between 120 °C and 150 °C which provides a stronger bond. The shear and peel results also reveal that the fusion bond undergoes brittle failure. This study suggests that the tissue fusion bond is maximized at temperatures over 150 °C and at a time of 3000 ms using the ConMed Altrus® and that input parameters can be tuned to optimize the strength of the bonded region.

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1. Introduction

Tissue fusion is a method of mechanically joining tissues through the application of heat and pressure over time. This type of closure has been developed for clinical use over the last couple decades. Currently, there are several devices, which perform vessel ligation via tissue fusion being used in surgery (hysterectomy (Smith and Pasic, 2008), cholecystectomy (Schulze et al., 2010), and colorectal surgery (Lorenzo et al., 2012)). Tissue fusion takes less time and dexterity to perform than traditional closures (sutures, staples, and clips), which makes tissue fusion devices ideal for laparoscopic surgery (Talmor et al., 2001). Additionally, tissue fusion does not leave behind foreign bodies and exhibits reduced scarring and infection rates in comparison to traditional closures (Alimova et al., 2009; Hambley et al., 1988).

Tissue fusion devices use various modalities to deliver energy to the tissue. Bipolar current (Person et al., 2008; Lamberton et al., 2008; Hruby et al., 2007; Newcomb et al., 2009; Carbonell et al., 2003; Harold et al., 2003; Landman et al., 2003; Richter et al., 2006), direct heating (Cezo et al., 2012, 2013a, 2013bReyes et al., 2012), and ultrasonic devices (Person et al., 2008; Lamberton et al., 2008; Hruby et al., 2007; Newcomb et al., 2009) have been designed for the purpose of vessel ligation or sealing. These devices function by clamping the vessel between two jaws and then applying energy to the tissue clamped between the jaws. This applied energy will heat the tissue, evaporate water from the tissue, and cause the bond to form. Laser tissue fusion has also been studied, but has yet to be incorporated into a commercially available fusion device (Talmor et al., 2001; Hambley et al., 1988; Hruby et al., 2007; Newcomb et al., 2009; Carbonell et al., 2003; Harold et al., 2003; Landman et al., 2003). Laser tissue fusion works by irradiating the tissue with specific wavelengths of light. The light is either directly absorbed by a component of the tissue (generally water) or added chromophores. Laser tissue fusion has not yet seen commercial success due to high implementation costs and amount of training needed for proficiency with laser tissue fusion. The bond created during tissue fusion is thermally driven as there are no photo-chemical or electrochemical reactions which take place to create the bond. Therefore the difference between any of the methods used to perform tissue fusion is tied to the inputs of heat, pressure, and time.

The mechanisms for tissue fusion are still unknown, although several theories exist. In the case of vessel sealing, the extracellular matrix (ECM) of the artery is primarily collagen and elastin. The general consensus in the literature is that denaturation of collagen in the ECM is responsible for the formation of the tissue fusion bond (Bass et al., 1992; Bass et al., 1991; McKenzie, 1990; Guthrie et al., 1991; Murray et al., 1989; Aksan et al., 2005; Wright and Humphrey, 2002; Weadock et al., 1996; Fenner et al., 1992). Collagen found in arterial tissue consists of a triple helix structure held together by crosslinking. The temperatures reached in the tissue during fusion ($>100\ ^{\circ}C$) are sufficient to denature collagen and break the crosslinks which hold the helix together, causing the structure to undergo a conformal change. It is theorized that these denatured collagen molecules then entangle, crosslink with adjacent proteins, or a combination of both (Bass et al., 1992; Bass et al., 1991; McKenzie, 1990; Guthrie et al., 1991; Murray et al., 1989; Aksan et al., 2005; Wright and Humphrey, 2002; Weadock et al., 1996; Scherer et al., 2010). Another theory points to the heat-induced water loss from the hydrated proteins in the tissue (Cezo et al., 2013; Fenner et al., 1992). Water bound through dipole interactions or hydrogen bonding to the ECM molecules will be driven off during tissue fusion. The absence of water from these dipoles will create a site which can then bond to adjacent proteins. While these theories exist, there is no definitive justification for any or all of these mechanisms creating the bond in tissue fusion.

In order to study the robustness of the bond formed in tissue fusion, three mechanical tests (bursting pressure, T-peel, and lap shear) were used in this research to assess the strength of fused tissues. Of these three tests, bursting pressure is the only widely used method to evaluate tissue fusion bonding strength, while the other two tests were developed from standardized engineering methods. Additionally, to elucidate the conditions required for bond formation, tissue fusion was performed at a range of temperatures (120–170 °C) and durations (500–3000 ms), derived from specifications for clinical use of the ConMed Altrus®.

2. Background

The study of tissue fusion revolves around two clinically important measurements: bursting pressure of fused vessels and thermal spread to adjacent tissue. While both of these measurements are critical in understanding the acute and chronic viability of tissue fusion in surgeries, they do not fully illustrate what is happening in the bond itself. This study serves to develop methodologies for testing tissue fusion bond strength using standard engineering methods and compare them to the existing state of the art methodology (burst pressure). Through this analysis we aim to ascertain which strength measurement is best able to measure variation in bond strength, which fusion parameters combine to create the strongest bond, and understand how the fusion bond fails under each of the three mechanical tests.

The most common measurement to determine the efficacy of a tissue fusion device is bursting pressure. The vessel is sealed via clamping and heating by a tissue fusion device. The vessel is then cannulated and the internal pressure of the vessel is increased until rupture. The maximum pressure achieved is the recorded bursting pressure and is used to determine whether the fusion created would withstand physiologic blood pressures. While burst pressure is a clinically relevant metric, it is difficult to determine the bond mechanics from these tests. The way in which the fusion site is ruptured during bursting pressure testing is not only a matter of bond strength, but also the vessel geometry, vessel structure, native vessel mechanics, and mechanical load on the tissues. Bursting pressure is also limited to testing tubular structures which are sealed closed. There is one study in which burst pressure has been measured to compare the effects of fusion temperature, duration, and apposition pressure using a purposed built research tissue fusion device (Reyes et al., 2012). Reyes et al. determined that bursting pressure of fused ovine carotid arteries increased significantly with increasing temperature, duration, and apposition pressure,