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Development of a new tissue-equivalent material applied to optimizing surgical accuracy ☆

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ABSTRACT

The precision of orientation to target placement during invasive therapy is mainly influenced by tool–tissue interaction. In this study, we aim to investigate a transparent Poly (vinyl alcohol) (PVA) hydrogel as tissue-equivalent material which is used in accurate surgical insertion research. The PVA hydrogel with specified formula was prepared by means of physical and chemical crosslink. The effects of chemical composition and synthesis technique on the biomechanical property, density and micro-structure morphology of PVA materials have been investigated in detail. It can be concluded that when PVA concentration is 8 g/dl, the NaCl concentration is 4 wt.%, with mix water/DMSO solvent, prepared under 7 freeze/thaw cycles, the material has the most similar properties with kidney tissue. Experimental results demonstrate that this tissue-equivalent material could be used in the ex vivo insertion accuracy test for robot-assisted percutaneous intervention and surgical training in minimally invasive surgery (MIS).

1. Introduction

In the last decades, the patients with inoperable renal pelvis carcinoma have shifted their attentions from the traditional surgery to the use of minimally invasive therapy, such as brachytherapy and percutaneous nephrolithotomy. The chief feature of these minimally invasive surgeries is to penetrate the surgical tool (e.g. needle) into human body and then destroy diseased tissue. Additionally, the effectiveness of the percutaneous intervention surgery is highly dependent on the insertion accuracy. In clinical surgery, target displacement is most pronounced along the insertion axis and is caused by needle–tissue interaction forces [1]. Even a slight inaccurate placement of the needle can risk injuring the kidney and adjacent organs [2]. Therefore, for preoperative preparation and surgical training, the main purpose of the research on tissue-equivalent material is to improve insertion accuracy.

Preoperative CT or MR images, though they do yield three-dimensional information, are static and cannot reflect the changes in target position in real time that occur during surgery [3]. The developments of deformable equivalent models used in lab experiment can accurately simulate the mechanical properties of organs and the interactions with the insertion tool. Realistic tissue-equivalent materials can not only trace the movement of target position, but also model the geometric changes of organs accurately. In collaboration with soft-tissue equivalent material phantom, preliminary experiments can be designed to assess the performance characteristics of surgery system under realistic conditions [4]. The target displacement can be investigated and mitigated, so that the puncture needle can reach its intended accuracy in realistic surgical simulation.

Much work has been done in developing organ substitutes used in laboratory environment. Misra et al. [5] evaluated elasticity properties of plastisol and porcine gels, and calculated the deflection of a bevel-tipped needle insertion into a soft elastic medium. A very stiff artificial tissue was applied by Webster et al. [6] to obtain experimental data of flexible needle fitting the nonholonomic kinematic model. Crouch et al. [7] explained the correlation between force and needle deflection during insertion at various speeds. The tissue phantom was made of silica gel in their work. Yan et al. [8] carried out the experiment in a two-layer phantom, which was composed of PVC lumps and animal meat, simulating the multilayer insertion during surgery. Our work also requires the use of tissue-mimicking phantom, but the difference is that all of morphology characteristics, mechanical property and needle deflection have been analyzed to validate the substitutability in comparison with biological tissue.

This research focuses on developing a transparent tissue-equivalent material synthesized with PVA hydrogel. PVA, a hydrophilic, biodegradable and biocompatible synthetic polymer, has been widely used in different areas of the biomedical field [9]. Moreover, PVA is innoxious to people, it is an excellent cartilage tissue substitute material in the field of tissue engineering [10]. It has been utilized in tissue engineering for regeneration of artificial articular cartilage [11], hybrid-type artificial

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pancreas [12], and commonly used in medical research for phantom materials [13]. The gels formed by the repeated freezing/thawing method were reported to be stable at room temperature and highly elastic [14]. In order to investigate the substitutability of the transparent gel, different PVA materials were prepared to substitute for real tissues in vitro. A robot-assisted needle insertion system incorporating tissue-equivalent material has been built specifically to provide an experimental environment as close as possible to a real medical operation.

This paper presents the evaluation of resemblance between series of PVA materials and porcine kidney tissue. The effects of chemical composition and synthesis technique on the density, the micro-structure morphology and the biomechanical property have been investigated in detail. Special attention was paid to the NaCl concentration which is an important factor affecting the micro-structure morphology of PVA phantom. In addition, we constructed an ex vivo experimental platform of robot-assisted needle insertion system incorporating the transparent PVA phantom, so as to explore the target displacement and interaction force during insertion.

2. Materials and methods

2.1. Creatural sample

Due to the difficulty in obtaining human organ, the porcine kidney was selected as the substitute organ in this study which has obvious similarity in structure and function with human kidney. All of the fresh kidneys obtained from local Jinxin butchery were stored in the refrigerator (Haier Co., SD-332, Shanghai, China) at a temperature of 4 °C until the testing phase. In view of the creatural tissue stability, the storage time was limited within 12 h. The kidney tissue samples were comprised only by renal parenchyma tissue. To prevent dehydration of the tissues during the experiment, both of the organ and examining specimens were remained in a saline solution. To develop tissue-equivalent material of kidney tissue for measuring target displacement by high-speed cameras in laboratory, the PVA phantom should be transparent, as well as maintain corresponding biomechanical properties. Thus, several experimental methods were discussed in this paper to explore the transparency and biomechanical properties of PVA hydrogels. For each test, a minimum of 5 samples were prepared and tested at room temperature (23 °C) to eliminate experimental errors.

2.2. Preparation of PVA hydrogels

In contrast to kidney tissue, the PVA hydrogel phantom is geometrically regular, generally robust as a surgical model and can be used to measure the needle deflection directly. Furthermore, the production method of transparent PVA hydrogel can be mastered easily by the staff in lab. The PVA phantom used in the experiment has an average degree of polymerization of 2.009 and a degree of saponification of 97% (Shanghai Chemical Dispensing Factory, Shanghai, China). Analytical grade sodium chloride and dimethyl sulfoxide (Tianjin Xiwei Co., Tianjin, China), and de-ionized water were used in the preparation of the PVA solutions. Mixed solutions of dimethyl sulfoxide/de-ionized water/NaCl (DMSO/H_2O/NaCl) were prepared as the solvent. The mixing ratio of DMSO/H_2O was maintained at 20/80 by weight, which results in PVA hydrogel transparency greater than 90% [15]. Four different homogeneous PVA hydrogels were prepared with the same PVA content at 8 g/dl, and the NaCl concentration ranging from 1 wt.% to 4 wt.% respectively. PVA solutions were obtained by water bath heating the mixed solvents for 1 h at the constant temperature (95 °C). To allow the rising and dissolution of air bubbles in the solutions, the solutions should be rested for approximately 30 min at 40 °C. Subsequently, all of the solutions were poured into the appropriate perspex molds separately to shape solid phantoms. Each sample was frozen at −20 °C and maintained for 24 h. At the end of the freezing stage, the phantoms were required to thaw to room temperature over 2–5 h, completing one cross-linking cycle. Detailed studies about this physical method indicate that the number of crystallites formed and several other properties of PVA materials would be affected by the number of physical cross-linking cycle in the aqueous solution [16]. Thus, the same procedure has been repeated 3, 5 and 7 times for each featured composition respectively.

3. Experiments

3.1. Density measurement

The weights of kidney and PVA hydrogel samples were measured to determine their densities. Based on the measured data, we can find one PVA material similar to the kidney tissue at specific component ratio. An additional motivation of density measurements was to find a material with isodense image characteristics under MRI scanning environment. Surry et al. [17] demonstrated that regularly or irregularly shaped PVA tissues that were frozen a different number of times could be easily targeted with ultrasound or MR, for segmentation or biopsy. Density of the tissue was measured by the immersion method, and calculated dependent on the formula as follow:

$$\rho_s = \frac{\mathrm{m}_{s,a,} \times \rho_{\mathrm{w}}}{\mathrm{m}_{s,a} - m_{s,w}} \tag{1}$$

where $\mathrm{m}_{s,a}$ and $m_{s,w}$ represent the weights measured in air and in immersed water, respectively. The analytical balance (Ohaus, DV214C, Nanikon, Switzerland) was used for the weight measurement.

3.2. Morphology characterization

Morphology evaluation of kidney cortex tissue and PVA hydrogels was performed using scanning electron microscopy (SEM). Each specimen was sectioned to display the cross-sectional morphology structure. Firstly, microscope observation of transparent PVA hydrogels, with different NaCl concentrations but same physical cross-linking cycle, was performed. And then, according to the micro-structure, PVA specimens with a specific NaCl concentration but varying circulations were examined. Samples were sequentially placed on the cooling stage of SEM (Hitachi, X-650, Tokyo, Japan). The hydrated hydrogel samples (5 mm in thickness and 120 mm in diameter) were frozen overnight at −60 °C and then freeze–dried in a vacuum freeze drier (Labconco, FreeZone-1 L, Kansas City, America) for 10 h. The porcine kidney tissue samples of $5 * 5 * 5\ \mathrm{mm}^3$ were processed in the same way.

3.3. Biomechanical property testing

The biomechanical properties of PVA hydrogels were estimated in vitro by uniaxial tensile strength test. Due to the complicated geometrical and internal structure of porcine kidney, the main challenge is how to achieve regular dimensions of kidney cortex specimens. In this study, tissue samples were obtained from porcine kidney with the same shear knife along a standard dumbbell shape (see Fig. 1), so that the size of each specimen could be as same as possible. In order to employ the same protocol, the PVA samples were acquired in the same way. Both ends of each specimen were stuck to the clamp assistant units by rapid hardening gelatin. A tensile tester (Laizhou Electron Instrument, LLY-06B, Laizhou, China) was employed, with a resolution of ±1% and loading rate ranging from 0.5 to 60 mm/min. The test setup is shown in Fig. 2. Force and displacement were measured during the loading test in which the loading rate was set at 10 mm/min.