BIOCYBERNETICS AND BIOMEDICAL ENGINEERING 36 (2016) 138–144

Available online at www.sciencedirect.com

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Original Research Article

A biomechanical comparison between tissue stiffness meter and shore type 00 durometer using fresh human fetal membrane cadavers

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ARTICLE INFO

Article history:
Received 3 January 2015
Received in revised form
22 July 2015
Accepted 7 October 2015
Available online 25 October 2015

Keywords:
Stiffness
Palpation
Biomechanics
Biomedical engineering
Biomedical device design

ABSTRACT

A manual palpation is traditionally used on soft tissue stiffness evaluation in clinical practices. However, the palpation is a subjective technique, so quantitative tissue stiffness measurement would be a more reliable method on diagnosing disorders instead of a palpation in medicine. The purpose of this study was to emphasize a new medical device that was capable of measuring soft tissue stiffness.

An in vitro investigation with a soft tissue stiffness meter (STSM) was presented and it is compared with a shore type 00 durometer in this study. Soft materials were needed for in vitro experiments to show feasibility of the STSM, so fetal membranes were decided to use on experiments. Five fetal membranes undergoing normal birth (NB) (35 samples, 105 measurements) and four fetal membranes undergoing pre-term birth (PRB) (20 samples, 60 measurements) were collected immediately after delivery. Samples were examined on custom designed tissue holder.

Resu*lts of the STSM were in correlation with results of the durometer for NB and PRB ($r^2 = 0.995$ and $r^2 = 0.996$ respectively). Moreover, a tissue stiffness difference between NB and PRB was statistically significant by using STSM ($p \leq 0.001$), whereas it was not statistically significant by using durometer ($p = 0.360$).

In conclusion, newly produced device, STSM is more sensitive than durometer even for very small stiffness differences as between NB and PRB fetal membranes.

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1. Introduction

A manual palpation is a subjective method that is traditionally used on soft tissue stiffness evaluation in clinical practices [1]. There are two ways to perform this method: (i) a physician uses a fingertip to push into the tissue until a certain amount of displacement is observed, (ii) a physician uses a fingertip to push into the tissue until a certain level of force is sensed [2]. However, a manual palpation technique is not completely

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http://dx.doi.org/10.1016/j.bbe.2015.10.007

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reliable because it is subjective to human interpretation and not repeatable. To solve that problem, several devices have been designed to objectively quantify tissue stiffness, but none of them is used routinely in clinics. For instance, Aroskoski et al. described a soft tissue stiffness meter that was used on muscle areas, but that device did not take a place in clinics [1]. It is believed that if a quantitative method to measure tissue consistency was available, the clinical care of patients with spasticity, lymphedema and neck–shoulder problems would be more definitive [1].

If any biomedical device is existed in place of the palpation technique, then it would be helpful also in gynecology. It may be used in prediction of the preterm birth by evaluation of cervical stiffness through transvaginal route. As it is understood, changes in soft tissues consistency is really important and, a new biomedical device is needed to measure stiffness of soft tissues [3].

Newborns are defined as a ''preterm'' when the gestational age is younger than 37 weeks, and ''full-term'' stands for births taking place between 37 and 42 weeks of gestation [4]. A birth occurring at full-term without any pre-labor rupture is called normal birth (NB). Similarly, if the birth occurs at preterm without any pre-labor rupture, it is called preterm birth (PRB) [5]. PRB is the major cause of perinatal and neonatal mortality [6]. Shorter gestation period results as higher mortality and morbidity rates. [6] However, the etiology of PRB remains inadequately understood.

The fetal membrane (FM) is a bilayer thin membrane, but remarkably tough and it holds a developing embryo and serves as a barrier [7]. The FM contains amniotic fluid inside, which serves several important functions including: providing a medium in which the fetus can readily move, cushioning the fetus against possible injury, helping to maintain an even temperature, and providing useful information concerning the health and maturity of the fetus [8]. Resting amniotic pressure varies between 1.1 mmHg (0.15 kPa) to 13.1 mmHg (1.75 kPa) and an intra-amniotic pressure (IAP) can increase maximum up to 2.66–3.99 kPa when Braxton-Hicks contractions occur in uterus [9,10]. A complete structure that is formed by the fetal membrane itself and the amniotic fluid might be considered as a single piece of soft tissue structure, and the birth types might be distinguished respect to stiffness of that structure. Because that structure has its own mechanics and stiffness. Maybe those properties are changed according to gastational ages, so fetal membranes in different type were decided to use on this study.

As it is mentioned above, biomechanical properties of human fetal membrane is variable, so the stiffness of that structure might be important since it is thought that features are not stable between birth types. If the STSM is reliable on fetal membranes and if it distinguishes birth types, it may gain one more symptom in prediction of preterm delivery on gynecology. Because, we know that biomechanical properties of FM as stiffness are also important to understand its sophisticated structure for interpretation of preterm deliveries. In this study, in vitro stiffness of fetal membranes were studied and tried to be distinguished between birth types according to the stiffness. A soft tissue stiffness meter (STSM) was used in in vitro stiffness measurements of the FMs and results were compared with results of the durometer that is shore type 00 scales of soft plastics in industry [11].

Although it is known that the STSM will not be possible to use in clinics for determining birth types just according to the stiffness of the FM, the idea of this study was to use a soft tissue stiffness meter (STSM) [11] in distinguishing any soft tissues between each other's and compare two different kinds of FM to emphasize stiffness features if there is.

Aim of this study was to acquire preliminary data regarding tissue stiffness measurement performance of STMS and to compare it with durometer with this respect.

2. Materials and methods

2.1. *Sample collection*

Total 9 fetal membranes, 5 NBs (>39 WOG) and 4 PRBs (<36 WOG), were examined in this study. Pregnancies were at between 30 and 35 years old they were selected randomly, tested for human immunodeficiency, hepatitis B, C viruses, *Streptococcus* infection, *Rubella*, and Toxoplasmosis, and confirmed that were negative. Selected women had no history of diabetes, connective tissue disorders or hypertension. Membranes were stored at 4 °C following sample preparation, and tested the same day.

2.2. *Sample preparation*

Fetal membranes (Fig. 1a) were collected from the Department of Obstetrics and Gynecology, Faculty of Medicine, University of Cologne, Germany, and transported to the Laboratory for Medical and Molecular Biology, the Institute for Bioengineering at Aachen University of Applied Sciences. Those membranes were collected for another project in Germany [4]; however, residual ones or pieces of FMs were used in the current study. Those residual membranes were too much for the going on the project (ZIM, Germany), so they were evaluated on the current study. Before measurements, the placenta was removed (Fig. 1b), then the rest of the fetal membranes including amnion and chorion was washed with an isotonic saline solution (0.9% NaCl) for a few seconds just to get rid of from blood clot and dirts on them. Afterwards, the fetal membrane was prepared for mapping. The round form of the membrane was made flat by cutting the connecting parts as shown in Fig. 1c. In the next step, small samples of fetal membranes were prepared (8 cm × 8 cm) in accordance with the size limits of the tissue chamber (Fig. 1d). Finally, the fetal membranes were mapped and potentially damaged parts of the membrane were not included in the mapping and measurements, as they might distort the results because of their weak biomechanical features. Totally 55 samples, 35 NB and 20 PRB were obtained after the mapping procedure.

2.3. *Soft tissue stiffness meter (STSM)*

The STSM, a compact device, is capable of measuring the resistance force (N) of soft materials that are subjected to deformations with its indentation rod [11]. That indentation rod serves as a link between the sample and the measurement component of the STSM. The STSM, hand-held medical device, which contains the force transducer (CLS-50NA Load cell, TML,

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