Physiology-Based Stretchable Electronics Design Method for Accurate Surface Electromyography Evaluation

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Stretchable electronics-based surface electromyography (sEMG) evaluation devices are expected to play a big role in clinical diagnosis. However, the stability and quality of the signals collected by existing stretchable electronics are too poor, especially when muscle movement is involved, making them inappropriate for high standard clinical diagnosis. Here, a physiology-based design method for stretchable electronics and a novel airbag-type stretchable electrode array (ASEA) device for assessment of the complex female pelvic floor muscle (PFM) is proposed. Clinical trials show that the ASEA device is able to provide stable contact interface and multi-channel accurate data acquisition. The stability and quality of the sEMG signal are much better than those obtained by the existing stretchable electronics-based PFM electrode devices. Furthermore, a muscle-unit evaluation method (MUEM) to assess the PFM complex state is proposed, especially its cross-interaction between muscles. Clinical trials show that MUEM can accurately and comprehensively assess PFM state and the correlations between main muscles, which unveils the mechanisms of some special muscle states that are not possible using traditional methods. This proof of concept research holds the promise for the development of new diagnostic strategies for muscle pathological research, and has the potential for clinical application and general implication.

1. Introduction

Great mechanical compatibility and biological adaptability of stretchable/deformable electronic devices have made them being widely used in the field of medical research and clinical diagnosis,[1–5] and their corresponding evaluation methods have revolutionized some medical technologies and diagnosis.[6–9]

Stretchable electronics-based surface electromyography (sEMG) sensors are one type of these devices, and have been used not only for detecting neuromuscular diseases, but also for providing supports for fundamental disease research, diagnosis and rehabilitation.[10–12] Recently, they have also been applied to evaluate complex muscles related to swallowing, urination, defecation, and have achieved some encouraging results.[13–15] However, the stability and quality of signals collected by existing stretchable electronics are too poor, making them not suitable for high standard clinical diagnosis application, and the technical bottlenecks mainly have: 1) Poor rigorous bonding interface strategy. Current stretchable devices generally utilize simple tapes or hydrogel films to adhere to skin,[16,17] which is unable to make stable and tight contacting interfaces due to small contacting areas, movement of muscles/organs and liquid mucosal environment, hence introducing large artifacts and interference signals.[18] 2) Oversimplified electrode distribution. Most of the high-density electrode arrays and contact pads are distributed uniformly, which often obtain mixed signals from different muscles when the contact pads are at the cross points of muscles.[19–21] 3) Lack of proper and accurate evaluation method. Due to poor signal quality and simple distribution of detection point (contact pads), it is difficult to obtain accurate state of the muscles under specific conditions. Combination of these makes it impossible to evaluate...
electrophysiological signal and intermuscular correlation for disease/illness analysis. Hence, it is of great significance to develop high stable and precise stretchable electronics design method.

To break through the technical bottlenecks for stretchable electronics application, we intend to explore new concepts for the technologies in the following areas. First, we will design an innovative inflatable device for accurate sEMG signal collection by utilizing its unique confocal deformability for stable contact interfaces.

The inflatable electronics could also reduce the contact impedance instability caused by sweating, muscle movement etc., hence improve the signal quality. Second, we will utilize a large number of bipolar electrodes along the direction of the muscle fibers or at the key muscle locations to contact with every key muscle, for accurate sEMG signal acquisition. Finally, we will develop a multi-characteristics and their correlations based muscle-unit model to evaluate the results, which is helpful to explore the causes of problems in clinical diagnosis, and could provide useful information for accurate pathological analysis.

In order to achieve these, we select female pelvic floor muscle (PFM) as the research object as it has the most complex anatomical structure among the numerous muscles of a human body and the prior studies have showed the above mentioned shortages. Moreover, abnormal PFM function is the inducement of pelvic floor dysfunction (PFD), which has a stronger influence on quality of life, and the number of patients worldwide has exceeded 30 million each year. PFD involves multiple functional defects of different parts of PFM. For example, the deficiency of urinary sphincter results in stress urinary incontinence (SUI), the damage of anal sphincter caused by obstetric factors is the commonest inducement of anal incontinence, the pubococcygeus (PC), ilioococcygeus (IC), and cauda situs make up the levator ani muscle, whose avulsion and hiatus area expansion are associated with pelvic organ prolapse. Therefore, accurate evaluation of sEMG of the special targeted PFM is very useful and important to identify the causes of diseases, and could enhance the effectiveness of rehabilitation. With these regards, this work is essential and of great significance.

Compared with skeletal muscles in other parts of human body, PFM also has some other special characteristics: irregular shape, elastic folded wall, and wet environment of vagina. These require high deformability of the probe and ability to collect electrophysiological signals in wet environment. Moreover, the complex structure, small individual muscle sizes and the synergistic effect of the muscles in exercise make the evaluation of PFM extremely complicated, thus requires innovative evaluation methods. Certainly, the existing sEMG probe devices cannot meet these requirements as they used rigid materials, and the probes have a fixed shape with uniformly distributed contact pads; also their assessment methods are not suitable for full assessment of the PFM characteristics due to the limited number simple time-domain parameters.

Therefore, the successful development of the inflatable device and its evaluation method for the PFM assessment would have much broader implication, allow them to be simply applied for various muscles of human body.

Here, we propose a novel airbag-type stretchable/inflatable electrode array (ASEA) device for sEMG signal acquisition for PFM analysis. The ASEA probe integrates a large number of contact pads distributed along the direction of muscle fibers, which is able to provide stable contact interface following the muscle movement, ensure in-suit stable acquisition of multi-channel data and obtain details and fine sEMG signals. Clinical trial shows that the accuracy and stability of ASEA is far superior to existing PFM electrode devices. Benefited from the high-quality sEMG signal collection by ASEA, we further design a muscle-unit evaluation method (MUEM), which is able to show accurate PFM state based on multi-characteristics, allowing the cross-interaction evaluation of target muscles. Clinical trial shows the MUEM is able to unveil the mechanisms of some special muscle states, which could be extended to analysis of pathological mechanism. The feasibility of new design methodology holds the promise for the development of new diagnostic strategies for muscle pathological research, and has the potential for solving some technique bottlenecks of stretchable electronics for clinical application.

2. Results and Discussion

2.1. Bionics Acquisition Device

2.1.1. Structure of ASEA Device

The innovative ASEA device combines the concepts of inflatable probe, and the PFM structure-based electrode distribution and correlation of multi physiological parameter measurement. Figure 1a–c shows the schematic of the whole ASEA device, a bipolar electrode unit array, and layers of the serpentine conductive wires (or tracks) and contact pads. The ASEA device consists of an inflatable airbag with a ten-stretchable serpentine electrode array integrated on its surface. The airbag is made of silicone with a thickness of 0.75 mm and a height of ≈65 mm before inflation, which is able to expand up to 35.6% in volume without breaking the electrode array, and to change its shape according to different physiological conditions of the users. The pear-shaped airbag inflated can stay in vagina firmly, suppressing or minimizing artifacts and interferences caused by muscle movement during tests.

Each bipolar electrode unit consists of 2 or 4 even number conductive tracks to link the contact pads with the interconnector of the measurement unit outside. There are 32 contact pads specifically distributed on the surface of the ASEA device as will be discussed later, so that they can collect sufficient sEMG signals for all major muscles to construct 2D contour maps of muscle potentials and other characteristics for PFM assessment and PFD diagnosis. Wide conductive tracks will increase the possibility of twisting up during deformation and cause pain and discomfort. To minimize the electrode width, two layers of conductive tracks are placed upper and lower in symmetry which is able to withstand deformations more than 10%.

Details of the double layer symmetry distribution are shown in Figure 1c and Figure S1, Supporting Information. Each bipolar electrode unit composes of multiple layers: a bottom insulating layer (polyimide, PI) on the airbag, a bottom conductive layer (copper, Cu), a middle PI insulating layer, a top Cu conductive layer, a top PI insulating layer, a gold-plated conductive layer (contact pad) and a PDMS insulating layer, with a total thickness of ≈120 µm. The thickness of the middle PI layers is 25 µm, and that of the top and bottom PI insulating layers is 12.5 µm. Copper was chosen as the conductive layers with a thickness of 13.5 µm. For
Figure 1. Structure and configuration of the ASEA probe. a) The ASEA structure model and electrode array stress distribution of an inflated state at a 2 atm internal pressure obtained by numerical simulation. b) Stress distribution in an electrode unit at 2 atm pressure. c) Details of the double-layer electrode unit. Two layers of conductive metal tracks are placed upper and lower in symmetry for each electrode unit to reduce the conductive track width (Red: Cu, Yellow: Au). d) A section of PFM obtained by TUI image (Measurement in the transverse plane, located at a depth of 2.5 cm from the vaginal opening). The V-shaped muscle is the PR muscles. e) The schematic model of an electrode of the ASEA device located between the PR muscles; the electrode unit has two contact pads. The electrode unit distribution direction is consistent with the direction of muscle fibers as indicated by the arrows. f) Ultrasound image of the corresponding position of the single electrode unit with two contact pads and the PR muscle. g) Distribution of main pelvic muscles in a 2D format and locations of the contact pads of ASEA (black dots) that are distributed according to the major muscle distribution and muscle fiber directions and unit (arrow). Each muscle is marked with specific color for better distinction. Grey colored dots are shown for those muscle overlapping areas, where the contact pads are shared by two muscles. Details on how to obtain the 2D map can be found in Figure S4, Supporting Information.

The exposed contact pads, gold was used to ensure the biocompatibility with skin and was obtained by electroplating on top of the copper layer with a thickness of 26.5 µm. The electrode array, manufactured by Desheng Electronics Co., Ltd. (Shenzhen, China) with traditional flexible printed circuit (FPC) manufacturing process, was then assembled on the airbag surface by ourselves. A layer of PDMS film was then coated on surface of the electrode array, except for the contact pads exposed for acquiring sEMG signals, with a thickness of ≈150 µm as the encapsulation layer owing to its non-toxicity, good biocompatibility and smoothness of the surface. As the PDMS has low Young’s modulus\(^{[39]}\) and high extendibility, the ASEA possesses excellent stretchability and deformability.

2.1.2. Bionic Electrode Unit Design

Due to dynamic deformation process of PFM motions involved, the electrode tracks and pads will experience localized stress,
which may fail the device in operation, therefore, it is necessary to analyze stress distribution of the electrodes, pads, and conductive tracks on the airbag during inflation, and to design better shaped electrodes and contact pads for accurate/sensitive measurement of sEMG signals. During test, it was found that the main stress imposed on the airbag and electrodes was from the outward pressure from the inside of the airbag during inflation, though the contraction of the PFM during test may induce a small inward pressure and deformation.

The ABAQUS software was used to analyze stress during inflation and to optimize the direction, curvature, etc. of the serpentine tracks and shape of the contact pads. Through the simulation, serpentine metal tracks with different curvatures at different locations and a four-petal flower shaped contact pads were selected for the electrode units to minimize the stress imposed on the metal tracks and pads. Figure 1a shows the simulated stress distribution of ASEA during expansion. The radius of the serpentine curves is varied from 0.75 to 1.8 mm to adapt to the shape of the airbag at different locations. Under a 2 atm internal pressure, the maximum stress on the serpentine tracks at the curvatures (Figure 1b) is \( \approx 210 \text{ MPa} \), which is much smaller than the yield strength of 350 MPa of the copper layer. The simulation showed that the outward pressure induces more deformation in the latitudinal direction with relatively small expansion in the longitudinal direction, thus the electrode array is arranged longitudinally with the serpentine curve structures in the latitudinal direction as shown in Figure 1a.

For ordinary circular contact pads, the stresses on edges are normally greater than that at the center due to the edge effect, which may cause the stress to be irregularly scattered across the boundary. To ensure the stability of the device structure, a four-petal flower-shaped pad was designed to ensure a stable and uniform distribution of stress induced on pads. Details of simulations of stresses and their distributions can be found in Figure S2, Supporting Information. The direction of each electrode unit and locations of contact pads on the ASEA device were determined by the major muscle fiber directions as will be discussed later.

Although PFM contraction during test may also induce some stresses on the electrode unit, it is much smaller compared to that imposed by the inflation, and it also reduces the stress imposed by the inflation, thus it has no significant effect on electrode unit.

### 2.1.3. Optimization of Contact Pad Distribution

For direct and visible evidences based clinical diagnosis and pathological analysis, MUEM will construct contour maps of muscle characteristics extracted from the sEMG signal by multiple contact pads. The ASEA device with 32 contact pads was designed to obtain the electrical potential distribution and the corresponding frequency information etc. for all the major muscles in vagina. In order to collect precise sEMG signals from the main muscles related to PFD, it is necessary to design the locations of the electrode array and contact pads to match muscle fiber structures and distribution in the pelvic floor. To assist the design, tomography ultrasound imaging (TUI) technology (Resona 8S, Mindray, Shenzhen, China) was utilized to acquire images of anatomical structures of PFM as shown in Figure 1d, for identifying major muscle fiber directions and locations for the contact pads. Details of TUI detection and corresponding anatomical model reconstruction can be found in Figure S3 and Note S1, Supporting Information. To be more accurate for the model, 30 people participated in TUI image measurements, and the average dimensions were used to reconstruct the PFM. In this study, urethral sphincter (US), vaginal sphincter, external anal sphincter (EAS), puborectalis (PR), IC, and PC muscles were selected for the investigation as these muscles are most likely related to PFD.

The TUI technique can also be used to confirm if the electrodes and contact pads designed are in the right locations or not. As noted in Figure 1d, taking the V-shaped PR as an example, Figure 1e,f present the schematic and TUI image of the ASEA device inside the PR. The TUI image clearly shows the electrode unit with two contact pads and the muscles. With the help of the TUI images, all the key locations of the main muscles and their coverage areas were identified. With these, the contact pads were confirmed to be allocated for the specific muscles and locations in the middle of these muscles for better and strongest sEMG signal acquisition. Since the PFMs are symmetrical round a near-cylinder shape vagina, they can be presented on a X-Y plane (2D format) for convenience. Figure 1g shows the distributions of main PFMs identified and the corresponding pad locations designed in 2D format with symmetry. It should be noted that some contact pads are shared by two muscles due to the overlapping of the muscles in the same places, as indicated by the grey dots in Figure 1g. Further information of the construction of 2D format muscle distribution and the electrode array can be found in Figure S4 and Note S2, Supporting Information.

### 2.1.4. Reliability and Stability of ASEA

Electrical and mechanical stabilities of the electrode array under deformations were investigated in detail. A tensile test machine (HSV-500, Decca Precision Measuring Instruments (Shenzhen) Co., Ltd.) was used to test the ASEA device as shown in Figure 2a. A syringe pump was used to slowly inflate it from the initial 1 atm pressure to 2 atm. Figure 2b are comparison of the un-inflated ASEA (1 atm, before inflation) and that being inflated to 2 atm, respectively. With the elongation under a 2 atm internal pressure, ASEA is inflated by 35.6% in volume with the expansions in both the latitudinal and longitudinal directions. The length in the longitudinal direction is extended from 6.9 to 10 mm, and the maximum perimeter in the latitudinal direction is extended from 31.3 to 38.9 mm. Meanwhile the electrode array is expanded by 32.2% in the longitudinal direction and less than 10% in the latitudinal direction as shown in Figure 2c. No visible damage to the electrode array and contact pads is observed, consistent with the simulation results. The airbag was made by a model with an initial volume of 36 mL, experiments showed that an average of additional 10.8 mL of inflation air is needed to make the pads of ASEA to contact with PFM tightly, which corresponds to a maximum circumference of 32.1 mm, length of 7.23 mm in the longitudinal direction, an internal pressure of 1.07 atm and a 9.5% elongation in the longitudinal direction, well within the extension value of 32.2% tested above, therefore it can be concluded that the ASEA device would be safe for practical operation.
Figure 2. Mechanical and electrical properties of the ASEA device. a) A photo image for the tensile test of the ASEA device, a tube is connected at the bottom of ASEA for pumping in air. b) Volume change of ASEA before and after inflation from 1 to 2 atm pressure, an initial state (0%, left) and an inflated state (35.6%, right). The whole device maintains the integrity without being broken. c) Change of the serpentine-shaped electrode array before and after inflation in the longitudinal direction, at the initial state (0%, left) and an inflated state (32.2%, right); the change in the latitudinal direction is less than 10%. d) Contact impedance variation of ASEA during cyclic inflation/deflation on a pig stomach, the impedance remains stable, and it becomes smaller when the device is inflated owing to the better contact under force. e,f) Comparison of the contact impedance and its phase for the three kinds of electrodes on a pig stomach at the same location. Our ASEA device has lower contact impedance and small phase of the contact impedance compared to the other two types of devices.

The electrode-skin surface contact impedance is another important factor, influencing the quality of the sEMG signal severely. Low contact impedance ensures a high signal-to-noise ratio, hence good quality of biopotential signals. In order to evaluate the change of contact impedance before and after expansion and repeatability of the measurements, we assessed the contact impedance of the ASEA probe for 100 repeated inflations. The experiments were conducted on a pig stomach with mucosa to mimic the environment of the pelvic floor. Contact impedance of one electrode unit was investigated using a TH2827A digital electric bridge module (TONGHUI Technology, Changzhou, China) at 1000 Hz frequency, and the airbag was inflated from the initial state to 62 mL, corresponding to an internal pressure increase from 1 to 2 atm. The unit was placed along the muscle fiber direction with a 10 mm distance between the two contact pads, each measurement was repeated for ten times to ensure the repeatability of the data. Figure 2d is typical variation of the contact impedance of the electrode unit as a function of cyclic inflation. The contact impedance before inflation is $1.03 \text{k} \Omega$ and drops by 11.3% after inflation. Overall the contact impedances before and after inflation remain stable with changes less than 2% after 100 cyclic inflation. The impedance becomes smaller after inflation owing to the tight contact under pressure, which could improve the accuracy of signal acquisition. From all the results shown above, it thus can be concluded that the ASEA device has excellent stability in mechanical and electrical properties; the serpentine metal tracks and contact pads can withstand the practical stresses imposed during measurements and maintain good contact with muscles.

In addition, an experiment was conducted to compare the contact impedance at different frequencies of our ASEA with other two types of commercial electrodes: the standard electrocardiogram (ECG) electrodes and electroencephalogram disc-shaped electrodes at the same positions in the same environment. The experiments details are shown in Figure S5, Supporting Information. Ultrasonic lubricant was applied on all the electrode pads to simulate real clinical conditions. Figure 2e,f show contact impedance and phase as a function of frequency for these three types of electrodes. The impedance of our stretchable electrode unit is lower than those obtained by other two types of commercial electrodes at frequencies lower than $300 \text{ Hz}$, and slightly higher at high frequencies. The phase curves show similar trends with our electrode unit close to zero in a broader frequency range, which appears only the electrode-skin contact equivalent circuit with a low parasitic capacitance. Overall, the impedance of our electrode changes less with frequency compared with those of other two types of electrodes, indicating that the stretchable electrode array has excellent low contact impedance and better stability in different frequency domains in the mucosa environment.
2.1.5. Clinical Verification of ASEA

To demonstrate the feasibility and superiority of the ASEA probe, clinical sEMG signal acquisition comparison experiments were conducted using the inflatable ASEA and two traditional stretchable high-density probe devices. The clinical trials in this work were approved by the Ethics Committee of the Women’s Hospital, School of Medicine, Zhejiang University, Hangzhou, China, ID: No. 067 (2019), and written informed consent was obtained from all the participants. Due to the special clinical application environment of ASEA equipment, the research selected the Glazer protocols as the standard assessment actions, which consists of a rest, a rapid contraction, a tonic contraction of 5–10 s, and an endurance contraction of 30–60 s.[44] The rapid contraction was used to assess functions of the fast-twitch muscle fibers, while the tonic and endurance contraction were used to assess functions of the slow-twitch muscle fibers. Details of the standard Glazer protocol procedure can be found in the Experimental Section.

To mimic the rigid probe and the probe with uniformly distributed contact pads, we fabricated two additional ASEA-like devices, one has rigid material inside to represent the shape-fixed probe, and the other one is a similar inflatable airbag probe but has a uniformly distributed array and contact pads as shown in Figure 3a–c. Four symmetrical channels as indicated by the different color bands were chosen for measurement comparison. A healthy 30-year-old postpartum woman participated in the tests. The volunteer was asked to use three probes to perform five rapid contractions, respectively, under guidance. The test interval for each probe-based test was 1 h, and the tests were repeated two times for each electrode probe. A signal acquisition system named ZJUEMG, consisting of 4 ADS1299 with a graphical user interface (GUI), was used to collect sEMG signal, with details of the acquisition system shown in Note S3 and Figure S6, Supporting Information. The typical sEMG signals collected by the three types of probes are summarized in Figure 3d–f, respectively, all the potentials were filtered and converted to RMS values. Figure 3g shows the RMS amplitude comparison of each channel for the three types of probes. There are significant differences between channel 1 and channel 2 (p = 0.006), and between channel 3 and channel 4 (p = 0.002) for the inflatable ASEA probe. For the rigid probe, interference signals are observed because partial contact pads do not make tight contact with the vaginal wall as indicated by the error bar of channel 3 in Figure 3g. For the channel 4, this probe is even unable to collect the sEMG signal, this is possibly because the pads do not contacted with the muscles. The rigid ASEA shows similar results for channel 1 and channel 2 (p = 0.031) to those of the ASEA device, but channel 3 and channel 4 cannot be included in the statistics due to the interference signals and missing signals.

For the inflatable probe with uniform pad distribution, although it is able to eliminate most of the artifact signal caused by the improper fit, the collected sEMG signals of adjacent channels show a high degree of similarity because the adjacent channels are too close and the contact pads are not placed along the muscle fibers. There is no significant statistical difference between channel 1 and channel 2 (p = 0.809), and between channel 3 and channel 4 (p = 0.813) as shown in Figure 3f,g, that make the evaluation of muscles extremely difficult. On the other hand, our ASEA device has superior performance as compared with other two types of the probes, it can make tight contact with human body, and the contact pads are distributed on the right places for proper and accurate sEMG signal acquisition, showing its excellent potential for clinical application.

To further investigate if the stretchable/flexible electrode unit can acquire sEMG signals in vagina as other electrodes or not, an experiment was also carried out using both the flexible electrode array and rigid needle electrodes on a rat model. This part of research was approved by Animal Ethical and Welfare Committee of ZCMI, ID IACUC-20190708-06. In addition, another experiment was conducted to compare the performance of our ASEA device with a commercial rigid electrode device, V2 (VISHEE Medical Technology, Nanjing, China) to verify the suitability of the stretchable electrode array developed for tests in human, again both of the experiments exhibited the superior performance of our ASEA device as compared to the commercial probes. Details of experimental results can be found in Note S4, Figures S7–S9, and Tables S1 and S2, Supporting Information.

2.2. Muscle-Unit Evaluation Method

2.2.1. Characteristic Contour Maps-Based PFM Clinical Assessment

MUEM is composed of two parts: muscle clinical assessment based on contour maps of characteristic parameters and physiological analysis-based muscle correlation. Detailed parameters of muscles on the pelvic floor can be measured using the 32 contact pads of ASEA, and their characteristic contour maps can be constructed, that provide the basis for doctor’s principle analysis and diagnosis. In this work, we selected SUI, a common PFD disease, as the research object. Our previous study showed that the resting and contraction potentials of PFM for women with SUI are much weaker than those of healthy women.[45] US (located at 1–4 and 8–11 o’clock positions with a depth of 1.6–2.4 cm) is one of PFM which controls the outflow of urine by contraction and is highly related to SUI. Vaginal delivery may cause a varying degree of damages to pelvic support tissues, decrease pelvic floor myoelectrical activity and PFM strength as compared to cesarean population,[30,46] and may especially induce dysfunction of the US area.[47] Our ASEA device and MUEM were then used to study the effects of childbirth on PFM-related SUI.

Twelve women of similar healthy condition, age, height, and weight participated in the clinical trials. They were divided into three groups: nulliparous (Group A), vaginal delivery (Group B), and cesarean section (Group C), with four people in each group. Figure S10, Supporting Information, shows sEMG signals of 4 tonic contraction potentials of the muscles in the US area (9–11 o’clock position, 2.4 cm depth) and EAS area (4–8 o’clock position, 2.4 cm depth), respectively, from one volunteer of Group B. The amplitude plateaus[48] during contraction can be clearly seen in the sEMG signals from the EAS region, but not from the US region where it decreases with time continuously, indicating deterioration of the muscle continuous contraction function in this region for this volunteer.

Muscle characteristics were evaluated in terms of strength, tension, and coordination. RMS-processed potential amplitudes of three different contraction actions are characteristics of
Figure 3. Comparison of clinical trial signal acquisition between ASEA and traditional stretchable electronic PFM probes. a–c) Physical appearance of the probes and distribution of the electrode array and contact pads. From left to right: inflatable ASEA, rigid version ASEA to mimic traditional shape-fixed probe, and inflatable probe with uniformly distributed electrodes and contact pads. Different channels are marked with different colors. d–f) RMS of sEMG signals of five rapid contraction potentials collected by each probe. All data were from the same volunteer, and the test interval is 1 h. g) Comparison of max potential amplitudes obtained by the three probes in the clinical experiments with the repeatability test samples of N = 10. *p < 0.05, between two adjacent channels (chn1 and chn2, chn3 and chn4). All potential amplitudes were processed by RMS.
muscle strength, and the resting potential (RP) is correlated to muscle tension, rise in RP is the indication of an increased muscle tension.\[45\] In addition, when the fatigue degree increases, the spectrogram of the muscle will move toward low frequency; the median frequency (MF) and mean power frequency (MPF) were chosen to characterize muscle coordination.\[49\] Coefficient of variation (CV) used for assessment is as follows:

\[
CV = \frac{sd}{mean} \times 100\% \tag{1}
\]

where mean and sd are the average and standard deviation (SD) of the RMS amplitude of potentials recorded by each subject in trial.

**Figure 4** shows the averaged RP distribution of muscles around the US area for the three groups. The RP of Group B is \(\approx 0.5 \mu V\), much lower than those (\(\approx 3 \mu V\)) of Groups A and C in the same area, consistent with general clinical observation. The potentials of rapid contraction and endurance contraction CVs of three groups are shown in Figure 4b,c, respectively, presenting different characteristics of the local muscles. In addition, for Group B, it is clear that the rapid contraction potential of the left side in US area (\(\approx 3 \mu V\)) is weaker than that of the right side (\(\approx 8 \mu V\)), indicating weaker muscle strength of the left side as compared to the right side of the US area. For clinical diagnosis and treatment of PFD, when similar asymmetry occurs, targeted treatment options should be considered. The contour maps of the tonic contraction and endurance contraction are shown in Figure S11a,b. Supporting Information, respectively, for clarity.

**Figure 4d** is the summary of potential amplitudes for the resting, rapid contraction, and tonic contraction in the US area. It is clear that the potential amplitudes of the resting and rapid contraction potentials for Group B are lower than those of the other two groups, indicating that the functions of the muscles in this area for Group B are more severely damaged. Combined with general clinical observation, it can be concluded that Group B volunteers have weaker muscle strength in the US area and tend to suffer from SUI in lateral age, and SUI prevention measures or muscle exercise for US may be necessary. Figure 4d also shows that the contraction potentials for Group B and C are remarkably lower than that of Group A, clearly indicating that childbirth indeed has drastic impacts on the US area. However, it can also be noted that the contraction potential of Group C varies greatly, much more than those of Group A and B, implying there is still strong instability in this US area even among the nulliparous.

For Group C, by visually comparing the color of muscle areas in the contour maps of different contraction potentials, a similar muscle strength state between tonic contraction and endurance contraction can be observed. Comparing the two contractions with rapid contraction, slightly different muscle strength distribution is found in some areas, such as EAS area (4–8 o’clock position, 2.4 cm depth) and part of iliococcygeal area (5 and 7 o’clock position, 3.6 cm depth). But in Group A and B, the distribution of muscle strength for each contraction is similar, which shows that for the individuals in Group A and B, the contraction dominated by different types of muscle fibers exhibits a consistent muscle strength state, it is inconsistent in Group C. These phenomena indicate that, according to different physiological conditions of the person, the contour maps of different contractions might present different muscle parameter distributions. Thus, we speculate that for populations with different PFDs, the difference in muscle characteristic contour maps between different contractions might be more obvious than those of healthy women.

The results have clearly demonstrated that the ASEA device is very useful in obtaining sEMG signals from muscles on the pelvic floor, and the obtained muscle potential contour maps and potential strength parameters are very useful for the diagnosis of PFD and identification of damaged muscles intuitively, and even provide a guidance for preventing future SUI for healthy women with different conditions. As for different PFDs, according to their principles, through comparative analysis of contour maps among different contractions, it is able to provide a more accurate auxiliary diagnosis. A detailed experimental analysis method for the contour conjecture remains to be developed in the future. The potential contour maps are particularly useful for diagnosis of PFD owing to its obvious evidences of damaged muscles visualized. Combined with the contour maps, the state of muscles can be analyzed comprehensively, and a specific plan can be formulated based on these results. To our knowledge, there is no report yet on potential and characteristic contour maps for major muscles of pelvic floor for muscle assessment.

### 2.2.2. Correlation Analysis of Target Muscles

Human body activities are a result of coordinated and collective complex muscle actions.\[50\] For example, during normal urination, PC facilitates urethral closure and inhibits bladder contraction, while bulbocavernous (BC) and ischiocavernosus muscle (ISC) prevent urethral contraction and promote bladder contraction.\[51\] In this action, BC and ISC show a cooperative relationship, while PB and BC show an opposite relationship. Both cooperative contraction and opposite function of muscles may appear in daily activities frequently. Analysis of the muscle correlation of each movement is helpful for clinipathological research and formulation of targeted treatment plans for related symptoms.\[52\] During the tests using ASEA, characteristic contour maps of a few other muscle areas that contain abnormal characteristics were obtained. **Figure 5a** shows the RMS potentials at the intersection of the PC and IC muscles (located at 3–5 o’clock and 7–9 o’clock positions at a depth of 3.2–3.6 cm). The multiple parameters are summarized in Table S3, Supporting Information, and detailed information of frequency domain parameters for the evaluation and analysis can be found in Note S5 and Figure S11c,d. Supporting Information. It can be seen that Group C has significantly high resting and contraction potentials compared with those of other two groups, which are a clinical phenomenon of increased muscle tension and muscle strength for the areas. However, the scattering of the RP and endurance contraction potential for Group C are also very high as shown in Figure 5b, which may be caused by high tension and instability of the muscles.

To analyze the reason for this situation, we apply the Pearson coefficient method to explore the effect of muscle coordination in the Glazer protocols via the intraclass correlation coefficient (ICC)\[27\] of parameters of PC and IC muscles with other muscles, the detailed information of muscle division can be found in...
Figure 4. 2D potential contour maps of PFM. Volunteers were divided into three groups: Nulliparous, Group A; Vaginal delivery, Group B; Cesarean section, Group C, with each group test samples of $N = 4$. a) RP contour map of the three groups. Left: Nulliparous (Group A); Middle: Vaginal delivery (Group B); Right: Cesarean section (Group C). b) Rapid contraction potential contour map of the same three groups. c) CV of endurance contraction contour map of the same three groups. The contour maps clearly show asymmetric potential distribution, abnormal muscle areas, and extremely weak muscle potential, etc., provide direct evidences for diagnosis of PFD or damaged muscle areas. d) Muscle strength characteristic values at the US area between the three groups. *$p < 0.05$, between three groups (group A, group B, group C).
Figure 5. Judgment of abnormal parameters and analysis of ICCs. Volunteers were divided into three groups. Nulliparous, Group A; Vaginal delivery, Group B; Cesarean section, Group C, with each group test samples of $N = 4$. a) Muscle strength characteristic values at the intersection of the PC and IC muscles area between the three groups. *$p < 0.05$, between three groups (group A, group B, group C). b) Tension and coordination difference in the intersection area of the PC and IC areas. Resting CV represents the tension of muscle. The endurance contraction CV, MF, and MPF shows the coordination of muscle. The ratio of MF and MPF is the ratio of the corresponding data between 5 s before the end of the contraction and 5 s before the start of the contraction. *$p < 0.05$, between three groups (group A, group B, group C). c) The ICC of RP between PC & IC muscle and other muscles. 

Figure S12, Supporting Information. When the value of ICC is positive and close to the value of 1, it indicates the two muscles are in close positive cooperation; when the ICC value is close to −1, it means that muscles are in negative cooperation. Figure 5c–e, respectively, shows the ICC between the PC and IC muscles with other muscles for Group C. The amplitudes of the RP, rapid contraction potential, and endurance contraction CV are used to investigate the cooperative relationship of muscle tension, muscle strength, and coordination. The results are divided into left and right parts for consistency comparison, and it can be seen
that the left and right parts of the muscle basically maintain the same cooperative/opposite characteristics, and the muscle tension characteristics at rest, obvious regional connections are presented. The muscles close to the PC and IC areas have the highest cooperative relationship, and the high muscle tension of Group C in these areas may be caused by the high tension between the aforementioned muscles. The dividing line in the EAS in Figure 5c shows the distinction between cooperation and opposition. The superficial muscles do not show cooperation with the PC and IC muscles at this time, therefore the potential is normal. Regarding the muscle strength in the fast contraction state, the superficial US and EAS junctions are considered to be the demarcation. The muscles cooperation with PC&IC muscles may greatly increase the potential amplitude due to the effect of high muscle tension, which is consistent with the above speculation. In the steady state of continuous contraction, all muscles show consistent cooperation. Therefore, the potential difference between the muscles for Group C during the long-term contraction test are smaller than those of the resting and rigid contraction state, as shown in Figure S11a,b, Supporting Information. The results have clearly demonstrated that the MUEM is able to assist the diagnosis of symptoms and find the pathological causes. These allow the establishment of a complete clinical analysis, including: 1) ASEA clinical assessment based on high-quality sEMG signal acquisition. 2) Multi-parameter contour map observation for finding the target muscle. 3) Correlation analysis for exploring the mechanisms of some muscle states. Our bionic device and evaluation method have successfully detected the problem muscles and explained it from a principle point of view, showing its great application potential.

3. Conclusion

The physiology-based design method is an innovative concept for the stretchable electronics-based clinical assessment, and has delivered the merits of excellent sEMG signal acquisition and accurate PFM state assessment. The ASEA device has 32 contact pads distributed along the major muscles, and has the capability to deform confocally to fit the pelvic muscles, thus, it can precisely acquire myopotentials of the major muscles for the construction of contour maps of the characteristic parameters. The multi-parameter contour map method allows to evaluate the characteristic distribution of individual muscles and correlation of the muscles, providing the direct evidences for damaged muscles and lost functions of the muscles, the basis for pathological research and diagnosis. The physiology-based device and evidence-based assessment method allow doctors to obtain real-time muscle state and to select specific muscles for analysis according to the pathology of different diseases, further assisting the related research more accurately, locally and objectively.

The method is also able to provide a range of possible related applications in research that requires accurate muscle property evaluation, involving characteristics of specific muscular activity, such as regular postoperative tracking of the targeted muscle group for rehabilitation, and matching of postoperative abnormalities to pathology. The precise requirements for detection, diagnosis and rehabilitation of complex muscle groups predict a wide range of opportunities for this new concept. Other potential clinical applications of the device include electrical stimulation therapy for specific muscles after accurate assessment, regional muscle tone assessment with integrated pressure modules, and local muscle health state assessment with integrated lactate, blood oxygen, pH, and other physiological parameters modules, demonstrated great potential for applications.

4. Experimental Section

**Fabrication of ASEA Device:** The electrode array was fabricated by a FPC manufacturer. Details of the manufacturing process could not be shown due to the commercial secrecy, a brief introduction for the process is as follows: 1) drilling & plating through holes: Plating a conductive layer (Cu) on the surface of the drilled holes. 2) Filming: Laminating a photoresist layer on the cleaned substrate (PI with double Cu layers). 3) Exposure & Develop: Expose the film with a metal mask using ultraviolet light, and develop the patterns. 4) Etching: Etching Cu with the photoresist as the etching mask. 5) Removal: peel off the photoresist. 6) Coating layer: Paste protective insulating material on the surface of Cu layer and heat press. 7) Surface treatment: chemical immersion gold in the contact pad part.

After the electrode array was fabricated, it was assembled on the airbag to form the inflatable airbag probe with the integrated electrode array. The assembly process is as follows. 1) Place the electrode arrays on locations required of the airbag. After distributing the electrode arrays and marking the positions, the electrode array was glued to the surface of the airbag by medical grade glue (3311, LOCTITE, China) one by one. 2) Contact pad covering film. A polyethylene terephthalate (PET) film of 1 mm thickness was used to cover the contact pads so that they are not coated with the PDMS insulating layer. The PET film was cut into the same size as the gold-plated part of the contact pads, and then was applied on the gold-plated parts one by one. 3) Surface coating layer. A PDMS resin and curing agent were mixed at a ratio of 10:1 to form a PDMS solution, and it was degassed in a vacuum oven for 40 min. Then, a PDMS layer of ≈100 µm was applied on the ASEA surface evenly, and baked in an oven at 120 °C for 40 min with 0.2 rad s⁻¹ axis rotation for better uniformity. After curing, the electrode-covering PET films were peeled off to expose the contact pad areas. All materials used in the manufacturing process were safe to the human body.

**Standardized Operation Process of Glazer Protocols:** Subjects were asked to position supine with 45° of hip and knee relaxed. ASEA was cleaned and disinfected in advance. Then, ASEA with uninflated state was placed in the vagina of the testers in a specific direction. A standard ECG electrode was placed on the abdomen bony area (unilateral anterior superior iliac spine) of subjects, as a reference electrode. Another pair of standard ECG electrodes was placed in the region of abdominal rectus muscles (one on the right side and the other on the left side) to monitor crosstalk of contraction of the abdominal muscles.

The airbag was then filled with air, and the air pressure inside the airbag was monitored through the GUI till the air pressure reaches the required value and the subjects felt that the ASEA device had been closely attached to the muscles. Then, the surface contact impedances were assessed by the impedance detection module in the GUI. If all the channels appeared normal, the test by the standard actions of the Glazer protocol was initiated. The sEMG for PFM evaluation using Glazer protocol consists of a five-segment assessment sequence: pre-rest baseline test for 1 min; five rapid contractions with 10 s rest between each contraction; five 10 s contractions with a 10 s interval between two contractions; endurance test of a single 60 s sustained contraction; finally, post baseline for 1 min rest. The subjects would be instructed to perform the training exercises first. If it was found that the contraction is not standard or the abdominal muscles exert too much force, the subjects would be given the guidance. After the training test was completed, the formal test started following the above-mentioned test sequence. After the test, the airbag was restored to its uninflated state and removed from the human body.

**Statistical Analysis:** Continuous data were expressed as mean ± SD and analyzed by one-way ANOVA among three groups. Correlation
between multiple groups was performed by Pearson correlation analysis. The star (*) indicates the level of statistical significance (p < 0.05 tested at a 2-tailed. All data statistics were analyzed by SPSS (Version 12.5).

### Supporting Information
Supporting Information is available from the Wiley Online Library or from the author.

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### Conflict of Interest
The authors declare no conflict of interest.

### Data Availability Statement
Research data are not shared.

### Keywords
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