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Abstract. The best way to assess fetal condition is to observe the oxygen status of the fetus (as well as to assess the condition of infants, children, and adults). Previously, several fetal oximeters have been developed; however, no instrument has been utilized in clinical practice because of the low-capturing rate of the fetal oxygen saturation. To overcome the problem, we developed a doctor's finger-mounted fetal tissue oximeter, whose sensor volume is one hundredth of the conventional one. Additionally, we prepared transparent gloves. The calculation algorithm of the hemoglobin concentration was derived from the light propagation analysis based on the transport theory. We measured neonatal and fetal oxygen saturation (StO₂) with the new tissue oximeter. Neonatal StO₂ was measured at any position of the head regardless of amount of hair. Neonatal StO₂ was found to be around 77%. Fetal StO₂ was detected in every position of the fetal head during labor regardless of the presence of labor pain. Fetal StO₂ without labor pain was around 70% in the first stage of labor and around 60% in the second stage of labor. We concluded that our new concept of fetal tissue oximetry would be useful for detecting fetal StO₂ in any condition of the fetus. © The Authors. Published by SPIE under a Creative Commons Attribution 3.0 Unported License. Distribution or reproduction of this work in whole or in part requires full attribution of the original publication, including its DOI. [DOI: 10.1117/1.JBO.19.6.067008]

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1 Introduction

Fetal heart rate (FHR) monitoring is a popular worldwide method to evaluate the condition of the fetus. The best approach to diagnose the fetal condition is to measure the fetal blood pressure and oxygen status, which at the moment, cannot be achieved noninvasively. The FHR is the gold standard in evaluating the fetal condition, however, the FHR monitoring has shown low false-negative and high-false positive rates. Thus, obstetricians have attempted to measure the fetal oxygen status instead of or in addition to the FHR monitoring. As a result, there have been many reports on the development and clinical trials of the fetal pulse oximetry.

The pulse oximetry enables us to determine the degree of oxygen saturation both noninvasively and continuously by measuring pulsating wave absorbance in the peripheral tissues, such as fingertips. Some researchers have reported that the oxygen dynamics can be measured over the course of delivery using a pulse oximetry probe applied transvaginally to the fetal head.¹⁻³ Moreover, the intravaginal optical probe for tissue oximetry using the near-infrared spectroscopy (NIRS) has been developed.^{4,5} However, the sensor volume of 4 cm³ (diameter 1 cm, length 5 cm) was too large to apply during delivery. The dimensions of the commercially available small optical probes for the brain (NIRO-200NX, Hamamatsu Photonics, Hamamatsu, Japan) and the muscle (Hb-14, ASTEM, Kawasaki, Japan) were 1 × 3 × 0.5 cm (width, length, and thickness). The sensors' volume of 1.5 cm³ was too large for monitoring the fetus directly. Additionally, the significantly low data capturing rate is one of

the biggest drawbacks to these procedures. East et al. have reported that during the active phase of labor, every method has a significant rate of signal loss and the loss of sensor contact occurred up to 64% of time with oximetry.⁶ Another drawback of this transvaginal procedure is that the probe often moves away from the fetal head during delivery, which may lead to an intrauterine infection caused by rupture of the gestational sac. Furthermore, these methods are essentially invasive, as the probe is inserted into the uterine cervix only after the rupture of the gestational sac. In addition to these problems, many patients feel discomforted by the intravaginal sensor. Obstetricians also feel that there is interference with the cervical examination by the sensor. Although many clinical trials of the fetal pulse oximetry have been performed, its clinical usefulness has been controversial. Thus, there are no established methods for detecting the fetal hypoxia during parturition yet. At present, many obstetricians look forward to further improvement of oximetry and a better understanding of clinical management.

We changed the conventional placement of sensors to overcome those problems. We proposed an idea of moving the sensor attachment from the fetus to the examiner. Namely, we attached an NIRS probe to the doctor's finger, instead of the fetal head or cheek. The obstetricians and midwives need to perform a cervical examination to understand the progress of delivery. They need to touch the fetal head to detect any cervical dilatation and the fetal position during delivery. Therefore, we hypothesized that if an NIRS probe was placed on the examiner's finger pulp and the appropriate calculation algorithms on the near field of the light source were developed, we could obtain the fetal oxygen status noninvasively. With this concept, we succeeded in attaching an NIRS probe to the examiner's finger pulp. Here, we report our instruments and preliminary clinical data.

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2 Instrumentation

An NIRS probe consists of near-infrared light emitting diodes (LEDs) and photodiodes. The source-detector distance was 4.0 cm in accordance with the Nellcor's fetal pulse oximetry (Nellcor N-400 system), which has been used in many clinical trials. We considered that if the distance could be shortened to around 1 cm, it would be possible to place the sensor on the examiner's finger. Our previous study showed that the strong signals of the arteries in the fetal scalp and brain surface were obtained at the point of 10 mm of the source-detector separation.⁷ Therefore, we thought that the miniaturized sensor would detect a fetal oxygenation signal by (1) deriving the calculation algorithm of the hemoglobin concentration satisfied in the near field of the light source, (2) blocking light propagation to the examiner's finger to prevent it from mixing with the unwanted finger oxygenation, and (3) manufacturing an ultrathin optical probe which fits to the finger pulp. Fortunately, we successfully developed a new small volume sensor with a polyimide-based flexible substrate. The wavelengths of the light sources were 770 and 810 nm, and sensitivity of the photodiodes (PD2501, Kyoto, Epitex) was high in the near-infrared band. The bare chips of the LEDs and photodiodes were mounted on the substrate with a wire bonding. The detectors were located 6 and 8 mm away from the LEDs in order to determine an absolute value of the hemoglobin concentration using the spatially resolved NIRS [Fig 1(a)], which was created based on a laboratory-made low noise instrument.

We placed a 1-mm thick black rubber sheet between the optical probe and finger pulp to block the light scattered through

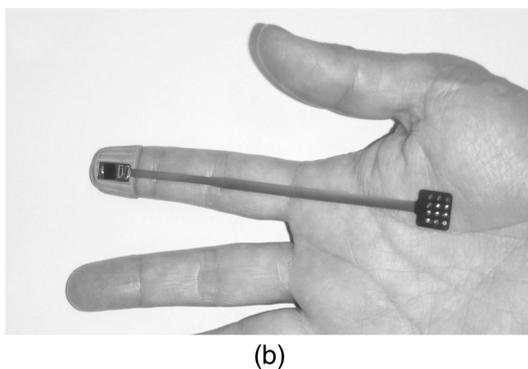
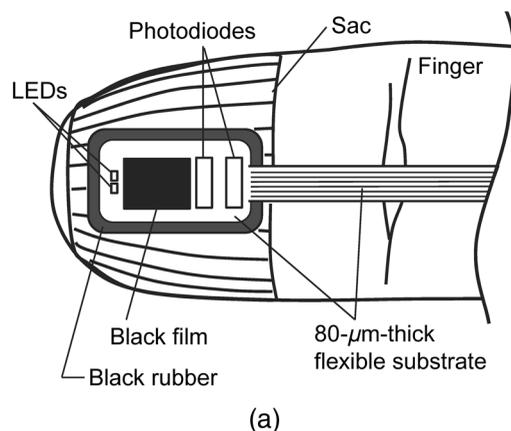


Fig. 1 Scheme (a) and photograph (b) of the oximeter probe attached to the examiner's finger pulp. Flexible substrate mounted two LEDs and two photodiodes are adhered to a black rubber sheet.

the examiner's finger. Then, the probe was fixed with an adhesive sheet on the black-colored finger sac. The optical elements integrated with a flexible cable (80- μm thick, 100-mm long) were connected to a soft shield cable on the examiner's palm. A 1.5-m long shield line was connected to the microcomputer unit in the examiner's breast pocket. In order to reduce external noise, the unit was battery powered and had a 2.4 GHz wireless module. The measured data were wirelessly transmitted into the computer. The trend of the hemoglobin concentration processed⁸ and calculated by the computer was shown on the screen in real time.

We prepared transparent vinyl gloves in collaboration with Utsunomiya Seisaku Co., Ltd. (Higashi Osaka-shi, Japan). The same amount of scattered light as without gloves was detected with the gloves. Figure 1(b) shows the examiner's finger with the developed optical probe.

3 Theoretical Analysis

We examined the light propagation in the fetal head model. The simulation model consists of the fetal scalp, skull, cerebrospinal fluid (CSF), brain, optical block, and examiner's finger. Table 1 shows the scattering coefficient, absorption coefficient, and thickness, which were set based on the literature data.⁹⁻¹¹

The anisotropic factors for each layer were 0.95.¹² The propagation of photons in the simulation was based on the transport theory with the Monte Carlo method. The model was divided into small cubes, and the optical path lengths in each cube were calculated to examine the measurement sensitivity. Figure 2 presents the sensitivity distribution obtained from the simulation results.

The results suggest that the light propagated to the finger does not contribute to the detected light intensity. In the simulation, the absorption coefficient of the optical block attached to the finger was 10 mm^{-1} . The optical absorber of the actual probe was easily realized because a typical colored adhesive tape has an absorption coefficient from 1 to 20 mm^{-1} . The changes in spatial intensity slope were examined to reveal the measurement sensitivity for the brain and the scalp. The slope values of S_0 , S_{brain} , and S_{scalp} represent an initial state ($\mu_{a_{\text{brain}}} = 0.02 \text{ mm}^{-1}$, $\mu_{a_{\text{scalp}}} = 0.02 \text{ mm}^{-1}$), a state where only the brain has changed ($\mu_{a_{\text{brain}}} = 0.025 \text{ mm}^{-1}$, $\mu_{a_{\text{scalp}}} = 0.02 \text{ mm}^{-1}$), and a state where only the scalp has changed ($\mu_{a_{\text{brain}}} = 0.02 \text{ mm}^{-1}$, $\mu_{a_{\text{scalp}}} = 0.025 \text{ mm}^{-1}$), respectively.

Table 1 Optical properties and thickness of each layer for Monte Carlo analysis.

Tissue	Scattering coefficient $\mu_s \text{ (mm}^{-1}\text{)}$	Absorption coefficient $\mu_a \text{ (mm}^{-1}\text{)}$	Thickness (mm)
Scalp	26	0.00–0.050	1.5
Skull	40	0.010	1.5
Cerebrospinal fluid	8	0.002	0.4
Brain	32	0.00–0.050	100.0
Finger	26	0.020	10.0
Optical block	20	10.0	0.4

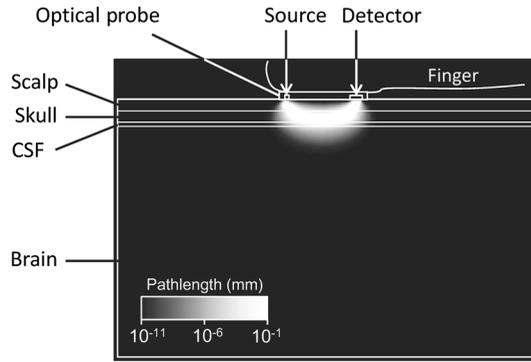


Fig. 2 Model for the Monte Carlo analysis and the sensitivity distribution obtained by the simulation.

The changes in slope were calculated as follows: $\Delta S_{\text{brain}} = S_{\text{brain}} - S_0$ and $\Delta S_{\text{scalp}} = S_{\text{scalp}} - S_0$. The sensitivity ratio was defined as $\Delta S_{\text{brain}} / \Delta S_{\text{scalp}}$. The ratio became high due to an increase in the source-detector distance, as shown in Fig. 3. When the detectors were located 6 and 8 mm from the light source, the sensitivities for the brain and the scalp were comparable. If the hemoglobin concentration of the brain is higher than that of the scalp, the values of the oxygen saturation and blood volume would contain more information about the brain than the scalp. Although the long source-detector distance was preferable in order to focus on measuring the cerebral tissue, we adopted the length of the 6 and 8 mm pair, considering convenience due to the size reduction.

In this study, the hemoglobin concentrations of both brain and scalp were measured. Therefore, we simultaneously varied the values of $\mu_{a_{\text{brain}}}$ and $\mu_{a_{\text{scalp}}}$ from 0.00 to 0.05 mm^{-1} . Then, we made a lookup table of the relationship between the value of μ_a and the spatial slope. In the measurement, the value of μ_a was calculated from the spatial slope of the measured light intensity using the lookup table. The following equations were used to calculate the concentrations of oxyhemoglobin [O_2Hb] and deoxyhemoglobin [HHb]:

$$[\text{O}_2\text{Hb}] = \frac{\epsilon_{\text{Hb}}^{\lambda_2} \mu_a^{\lambda_1} - \epsilon_{\text{Hb}}^{\lambda_1} \mu_a^{\lambda_2}}{\epsilon_{\text{HbO}_2}^{\lambda_1} \epsilon_{\text{Hb}}^{\lambda_2} - \epsilon_{\text{HbO}_2}^{\lambda_2} \epsilon_{\text{Hb}}^{\lambda_1}}, \quad (1)$$

$$[\text{HHb}] = -\frac{\epsilon_{\text{HbO}_2}^{\lambda_2} \mu_a^{\lambda_1} - \epsilon_{\text{HbO}_2}^{\lambda_1} \mu_a^{\lambda_2}}{\epsilon_{\text{HbO}_2}^{\lambda_1} \epsilon_{\text{Hb}}^{\lambda_2} - \epsilon_{\text{HbO}_2}^{\lambda_2} \epsilon_{\text{Hb}}^{\lambda_1}}, \quad (2)$$

where $\epsilon_{\text{HHb}}^{\lambda_{1,2}}$ and $\epsilon_{\text{O}_2\text{Hb}}^{\lambda_{1,2}}$ are the extinction coefficients of HHb and O_2Hb , respectively, at the wavelengths λ_1 and λ_2 .¹³ Tissue oxygen saturation StO_2 was calculated by $[\text{O}_2\text{Hb}] / ([\text{O}_2\text{Hb}] + [\text{HHb}])$.

4 Clinical Experiments

To determine whether our tissue oximetry obtained the fetal oxygenation, we measured StO_2 of three just delivered newborns at first. All the neonates were born in spontaneous vaginal delivery from 39 to 40 weeks of gestation. The FHR monitored during labor showed a reassuring fetal status pattern in all cases. The Apgar scores of the neonates were 9, 9, 10 at 1 min and 10, 10, 10 at 5 min. We attached the probe on the front hair, parietal, and occiput of head just after delivery. Each measurement lasted at least 10 s.

Second, we measured fetal StO_2 during labor, as shown in Fig. 4. We measured StO_2 for one parturient at the first and the second stages of labor after the rupture of membranes. The parturient was in her 39th week of pregnancy. The course of delivery was normal. The probe was attached to the fetus head during delivery. We examined the results for 2 min during the first and second stages of labor. We continued the measurement for 10 min after delivery. Informed consent was obtained from the subjects, and all measurements were approved by the ethical committee of Hamamatsu University School of Medicine.

The StO_2 values of the parietal region in the three newborns were $78.5 \pm 2.6\%$, $78.4 \pm 3.2\%$, and $75.8 \pm 2.3\%$, respectively. The values of front and occiput were similar to those of the parietal region in each newborn (data not shown). We could obtain the StO_2 easily in any condition of the neonate head, such as wetness or color of the hair.

The intrapartum fetal StO_2 was detected through the whole delivery (Fig. 5).

The fetal StO_2 was detected even during labor pains and the bearing down effort. We obtained the StO_2 data smoothly and quickly. The doctor got the fetal StO_2 as well as the cervical findings at the same time. Furthermore, the patient felt neither pain nor discomfort during the measurement. The fetal StO_2 in

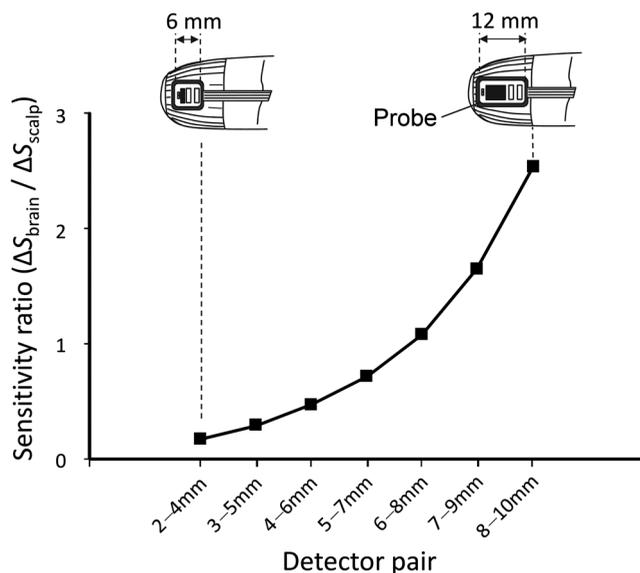


Fig. 3 Relationship between the brain-scalp sensitivity ratio and the pair of source-detector distances.

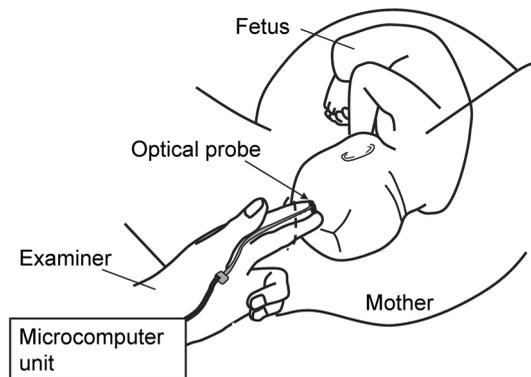


Fig. 4 Outlook of the measurement with an oximeter attached to the examiner's finger during labor.

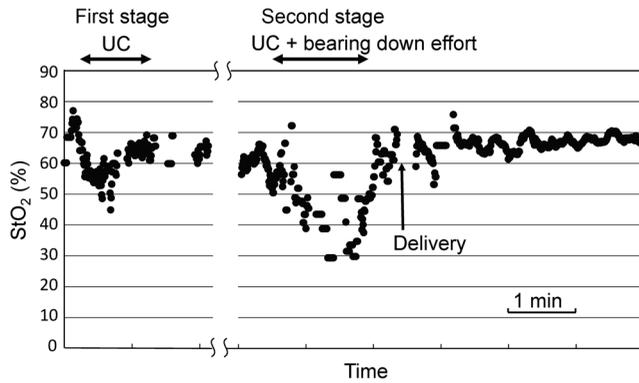


Fig. 5 The actual chart of the fetal StO_2 during labor. Left and right parts correspond to the first and the second stages of labor, respectively. UC denotes uterine contraction.

the first stage of labor was about 70% without labor pains and about 60% in a presence of labor pains. In the second stage of labor, the fetal SpO_2 was 60% without labor pains, and it decreased during labor pains and the bearing down effort. The lowest level of the fetal StO_2 was around 30%. After delivery, the neonate StO_2 increased rapidly up to 70%.

5 Discussion

All previous oximeter sensors were attached to the fetus. We have recognized the accidental possibility of the movement of the sensor and its slip during labor. Poor data capture was observed in some pregnant women due to the detachment of the sensor caused by frequent changes of the body position during labor.

Our oximetry system is able to detect the fetal StO_2 in the first and the second stages of labor very precisely regardless of the presence of labor pains. As the examiner can touch suitable sites during the internal examination, it is possible to measure the fetal StO_2 very naturally. Our fetal StO_2 measurements can be performed at the same time and in the same manner as obstetrical examinations during delivery. We recognized the fetal head promptly and obtained the fetal StO_2 precisely, because the pressure for an ultrathin probe propagated to the finger and the finger pulp was very sensitive. Furthermore, our sensor never touches the fetus directly because the sensor is inside the transparent sterilized gloves. We think that our measurement system is safer and more noninvasive than the previous one. Moreover, the parturient does not feel discomfort during the measurement.

As for the clinical analysis, the fetal StO_2 in the first stage of labor was about 70% without labor pains and about 60% in the presence of labor pains. The fetal oxygen saturation SpO_2 with a pulse oximeter is $59 \pm 10\%$ in the first stage of labor, and $53 \pm 10\%$ in the second stage.² The measurements of low saturation were estimated at 33% as two standard deviations below the mean. Since the decrease in arterial oxygenation rapidly results in low tissue oxygenation, the value of StO_2 would be correlated to SpO_2 strongly. Chipchase et al. have reported that the cerebral StO_2 for a fetus was $59 \pm 12\%$ using an optical fiber-based NIRS instrument.¹⁴ The oxygen saturation values in this study were the same or slightly higher compared to the previous studies. One of the reasons would be that the value of StO_2 was a mixed measurement of the scalp and the brain. If the sensitivity of the scalp was suppressed by using a long separation probe, the values may be close to the cerebral oxygen saturation values

previously reported. The comparison of results suggests that our new concept of oximetry could be applicable to clinical practice.

In this study, there was no caput succedaneum in the fetal head. When the thickness of the caput succedaneum layer is thick, the cerebral sensitivity (the ratio of $\Delta S_{\text{brain}}/\Delta S_{\text{scalp}}$) would decrease. In the future, we may solve the problem of the swelling layer by squeezing the subcutaneous fluid and by measuring the surface layer thickness with an ultrasound apparatus.

As for neonatal monitoring, the values of cerebral StO_2 for a child and a neonate have been reported to range from 65% to 85%¹⁵ and from 67% to 80%,^{16,17} respectively. The oxygen saturation values in this study (75%–78%) were similar to that reported in the literature.

Fouzas et al. described that SpO_2 with a pulse oximeter might not be measured or might be inaccurate in low-perfusion states, such as low cardiac output, shock, hypothermia, vasoconstriction, and arterial occlusion.¹⁸ They also stated that a continuous oxygen saturation monitoring is essentially needed for the safety of the newborn. Rapid measurements of several sites of StO_2 are needed in the case of neonatal asphyxia. But the commercially available sensor is set on one site of the skin of the neonate. Our sensor can be set on any site of the newborn where doctors want to measure. In addition, the spatially resolved NIRS system can detect the tissue oxygenation in a low-perfusion condition, because the StO_2 measurements require only the spatial intensity slope and do not require the weak pulsation signals on a pulse oximetry. Our system could be useful in practice for such cases. To assure the usefulness of this oximetry, we must accumulate more data. At the moment, we are planning a multicenter study to confirm the usefulness of our system.

In conclusion, we developed an oximeter with the sensors attached to the fingers of an obstetrician or a midwife, in contrast to conventional oximeters whose sensors were attached to the fetus. We successfully detected the fetal oxygenation smoothly and certainly. We are sure that our system could become a new fetal monitoring approach.

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