CERVICAL STIFFNESS MEASUREMENTS TO PREDICT RISK OF SPONTANEOUS PRETERM BIRTH

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Background

- This study evaluates a novel bedside test measuring cervical stiffness (CS), the Pregnolia device
- Pilot data using Pregnolia device demonstrates reducing CS with advancing gestation[1]
- Reduced CS in 1st trimester using shear wave elastography associated with increased risk spontaneous preterm birth (sPTB) <34/40[2]

Objectives

- To collect CS measurements in women at high risk of sPTB
- To evaluate how CS measurements relate to clinical outcome/existing investigations (gestation at delivery, cervical length, fetal fibronectin)

Methods

- Women at high risk of sPTB recruited from St Thomas' preterm surveillance clinic
- Serial measurements taken at specified gestational timepoints (10-13+6, 14-15+6,16-19+6, 20-24+0,>24weeks')
- 3 measurements taken per visit
- Lowest value used
- Paired biomarker swabs
- Cervical surgery group prospectively excluded
- Results analysed using GraphPad prism V.9

Eligibility Criteria:
- 1 or more sPTB 16+0-36+6
- Cervical length <25mm in current pregnancy
- Uterine anomaly
- Multiple pregnancy
- History of:
  - cervical surgery
  - full dilatation caesarean section

Pregnolia measurements

- Device consists of control unit and single use probe (Figure 1)
- Small cup 0.5cm diameter on end of probe
- Placed on anterior lip of cervix during speculum examination
- Device uses negative pressure to aspirate cervical tissue to depth of 4mm
- Gives value of pressure required to do this (mbar)
- This is recorded as cervical stiffness value

Results

- Preliminary results
- 85 women recruited
- Cervical surgery group (n=23) prospectively excluded due to erroneous readings
- 29 women delivered, 3 sPTB
- Significantly lower values in preterm group, p=0.006 (Figure 2)
- Cervical stiffness shows correlation with cervical length, r=0.14, p=0.01 (figure 5). Correlation with quantitative fetal fibronectin, r=0.12, p=0.056 and gestation at delivery, r=0.03, p=0.18 (figure 4), is non-significant

- ROC curves for the performance of CS in the prediction of sPTB <37/40
  - AUC 0.94, 95% CI 0.84-1, p=0.12
- Comparison with cervical length (CL) and fetal fibronectin (fFN)
  - AUC CL 0.83, fFN 0.68
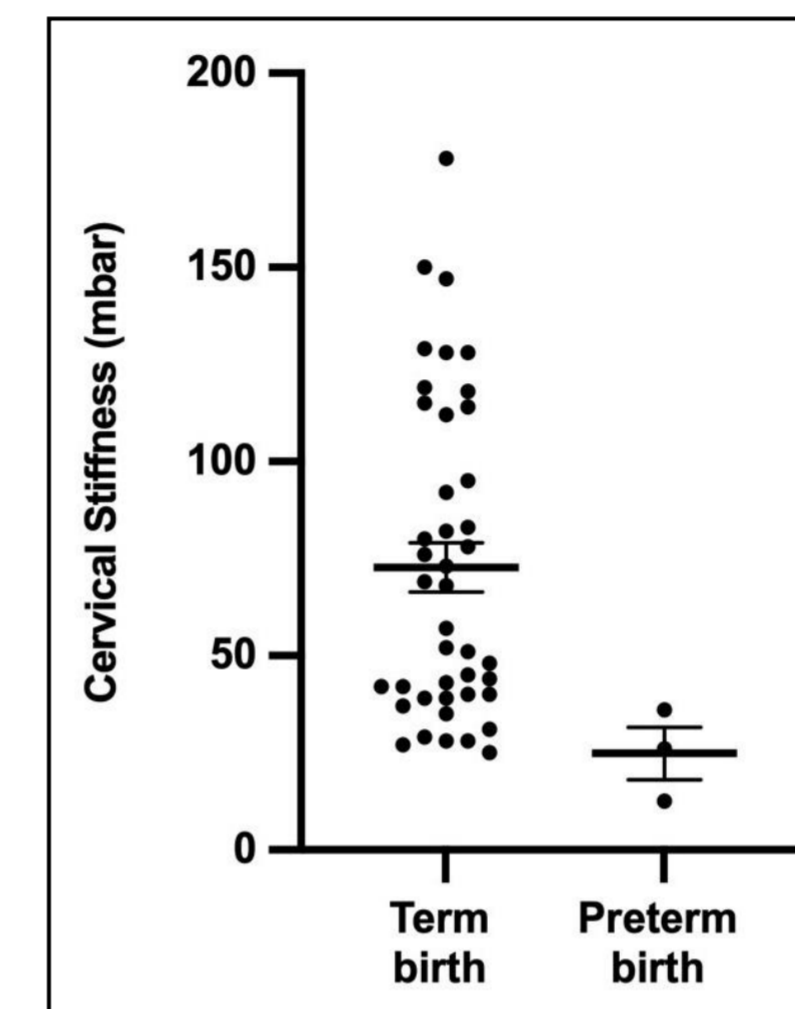

TERM VS PRETERM CERVICAL STIFFNESS VALUES
Figure 2 – Cervical stiffness values in term and preterm deliveries

ROC Curve sPTB <37/40
AUC = 0.94
Figure 5 – ROC curve for the performance of cervical stiffness in the prediction of preterm delivery <37 weeks gestation

ROC Curve sPTB <37/40
AUC: Cervical stiffness 0.937; Cervical length 0.829; Fetal fibronectin 0.680
Figure 6 – ROC curve for the performance of cervical stiffness, cervical length and fetal fibronectin in the prediction of preterm delivery <37 weeks gestation
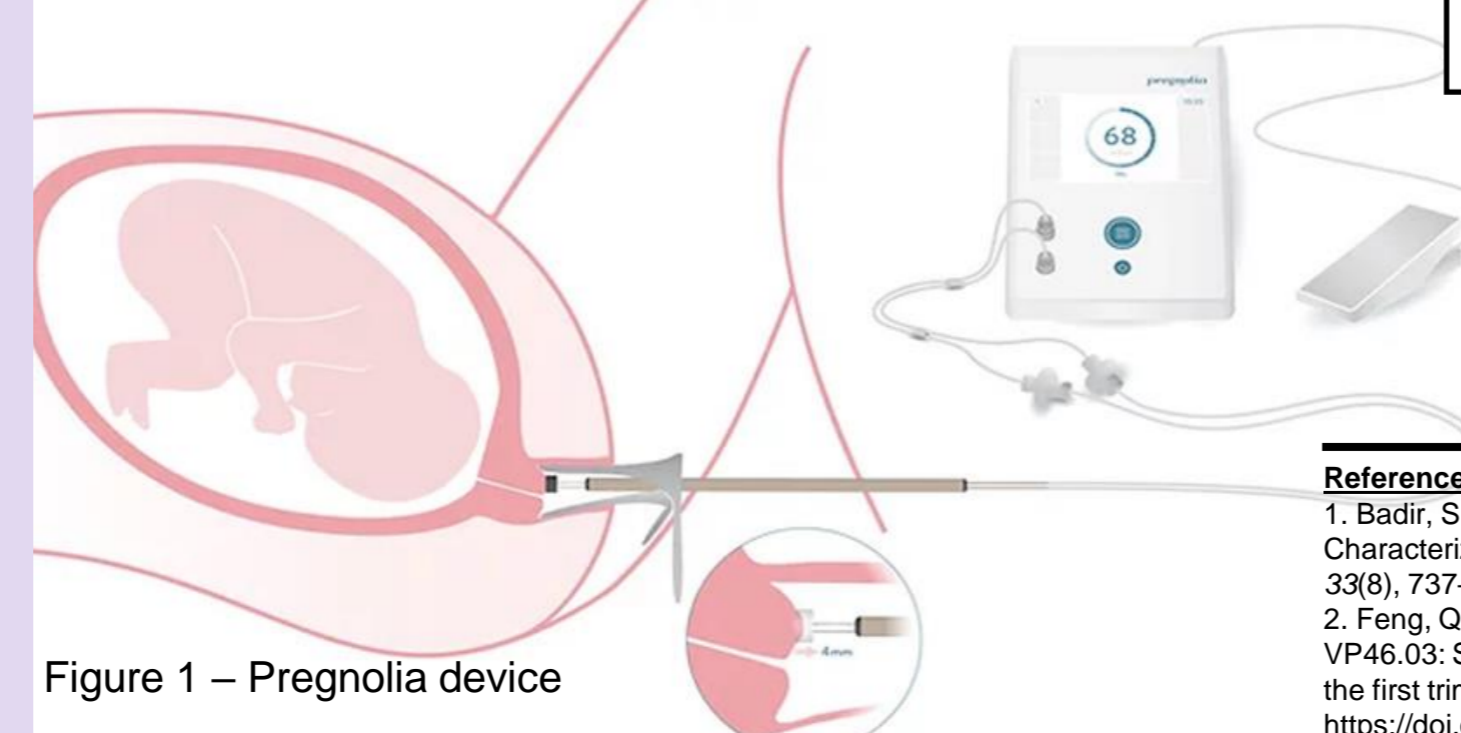
Figure 1 – Pregnolia device

References:
1. Badir, S., Mazza, E., Zimmermann, R., & Bajka, M. (2013). Cervical softening occurs early in pregnancy: Characterization of cervical stiffness in 100 healthy women using the aspiration technique. *Prenatal Diagnosis*, 33(8), 737–741. https://doi.org/10.1002/PD.4116
2. Feng, Q., Duan, H., Shen, L., Wang, X., Tai, Y., Chaemsaithong, P., Leung, T., & Poon, L. C. (2021). VP46.03: Screening for spontaneous preterm birth by cervical shear wave elastography and cervical length in the first trimester of pregnancy. *Ultrasound in Obstetrics & Gynecology*, 58(S1), 293. https://doi.org/https://doi.org/10.1002/uog.24678

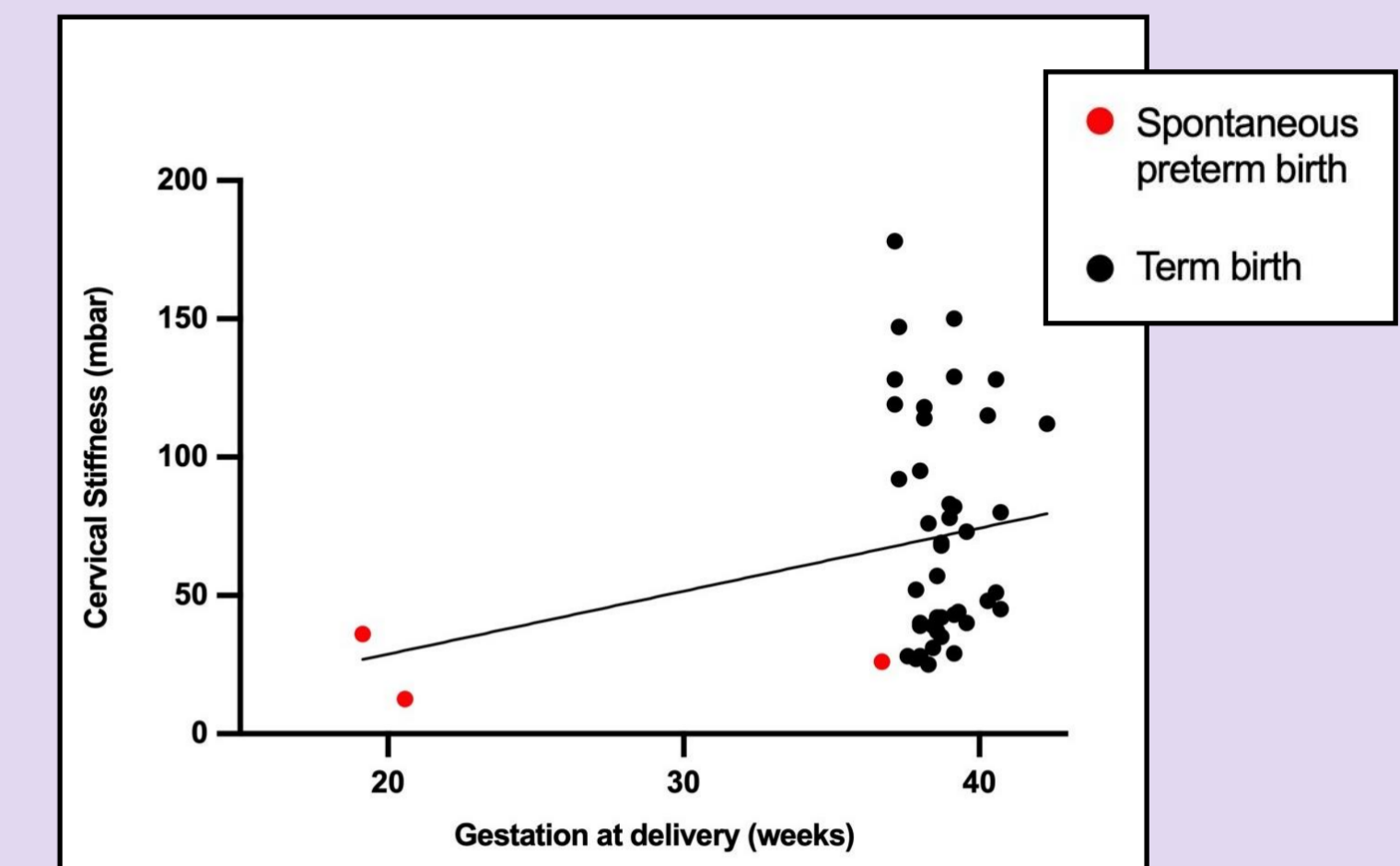## RELATIONSHIP BETWEEN CERVICAL STIFFNESS AND GESTATION AT DELIVERY

Figure 3 – Cervical stiffness and gestation at delivery

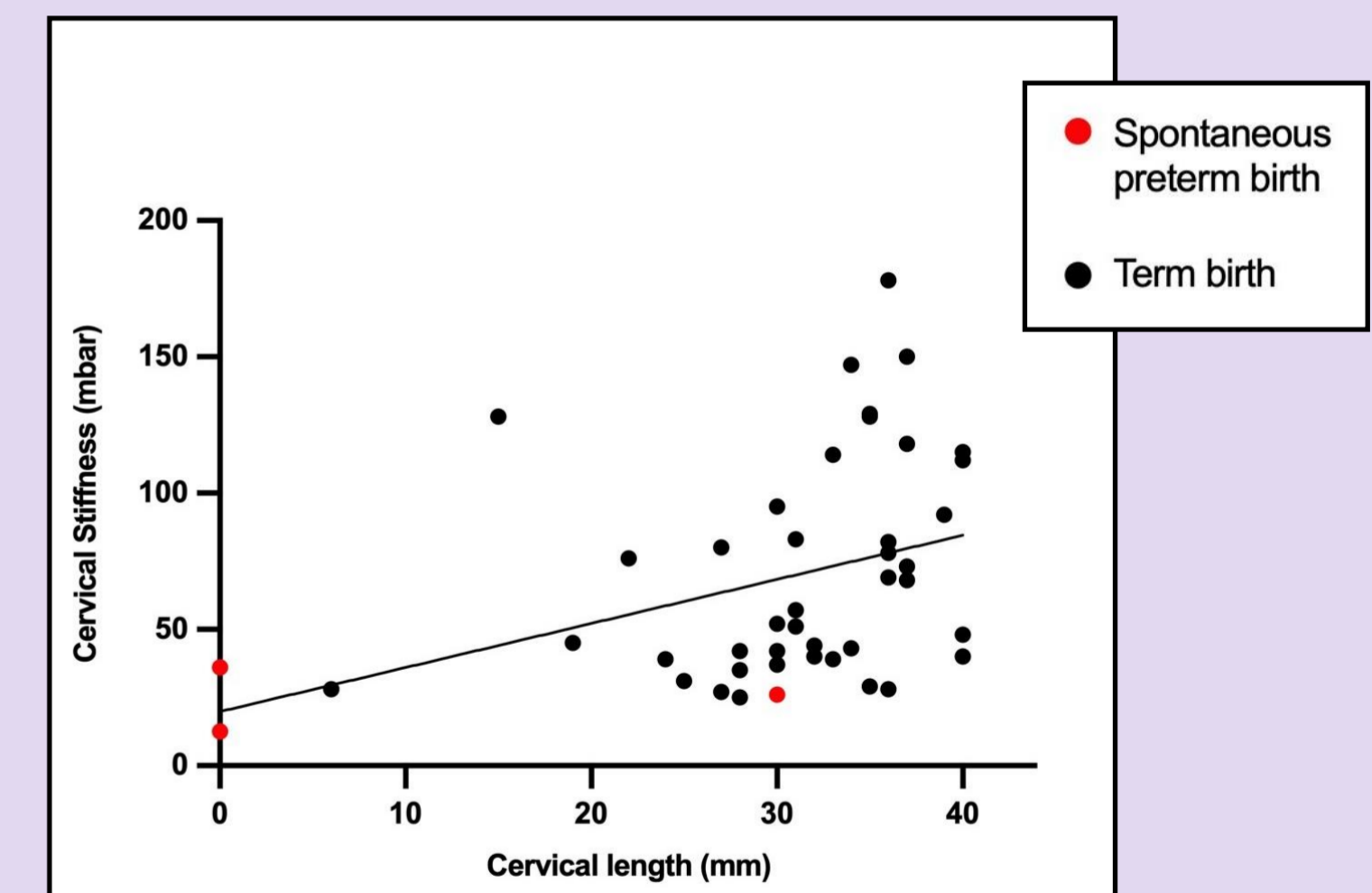## RELATIONSHIP BETWEEN CERVICAL STIFFNESS AND CERVICAL LENGTH

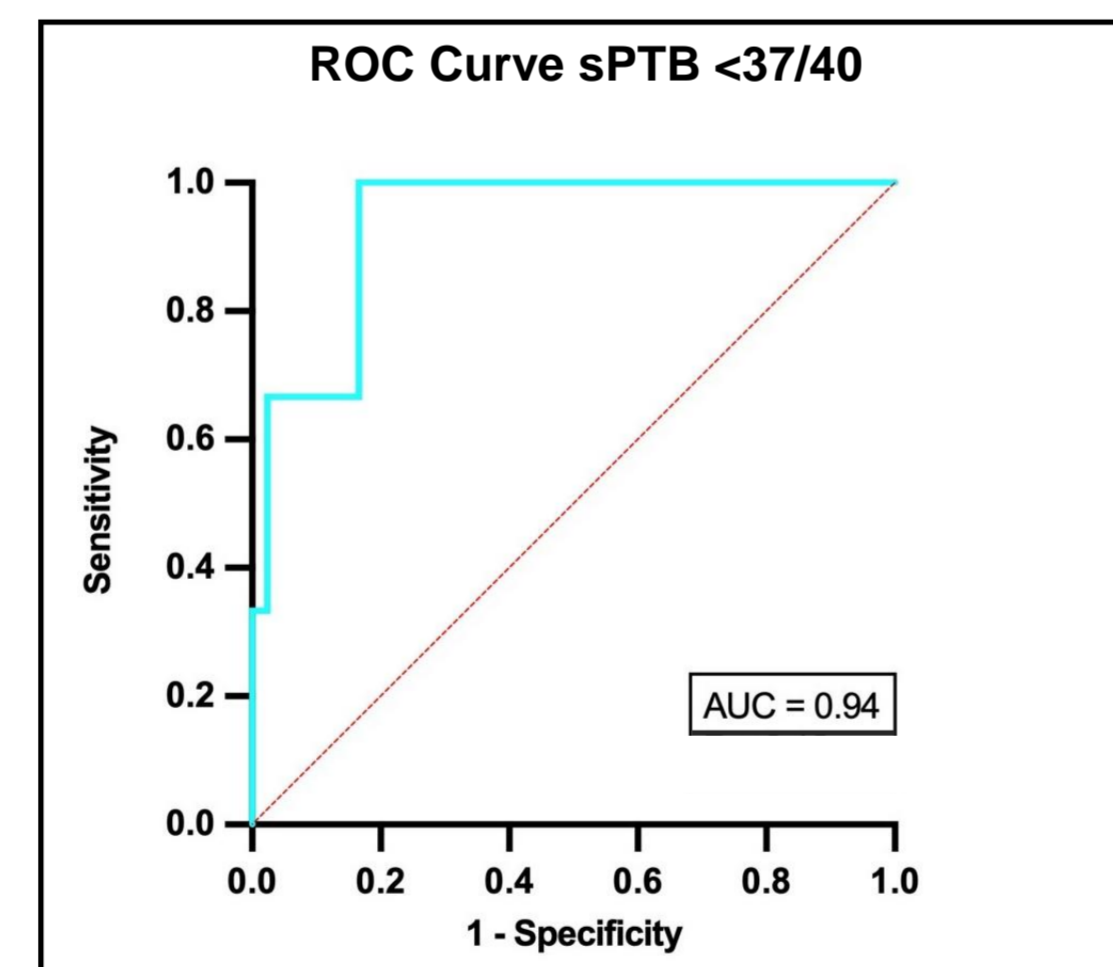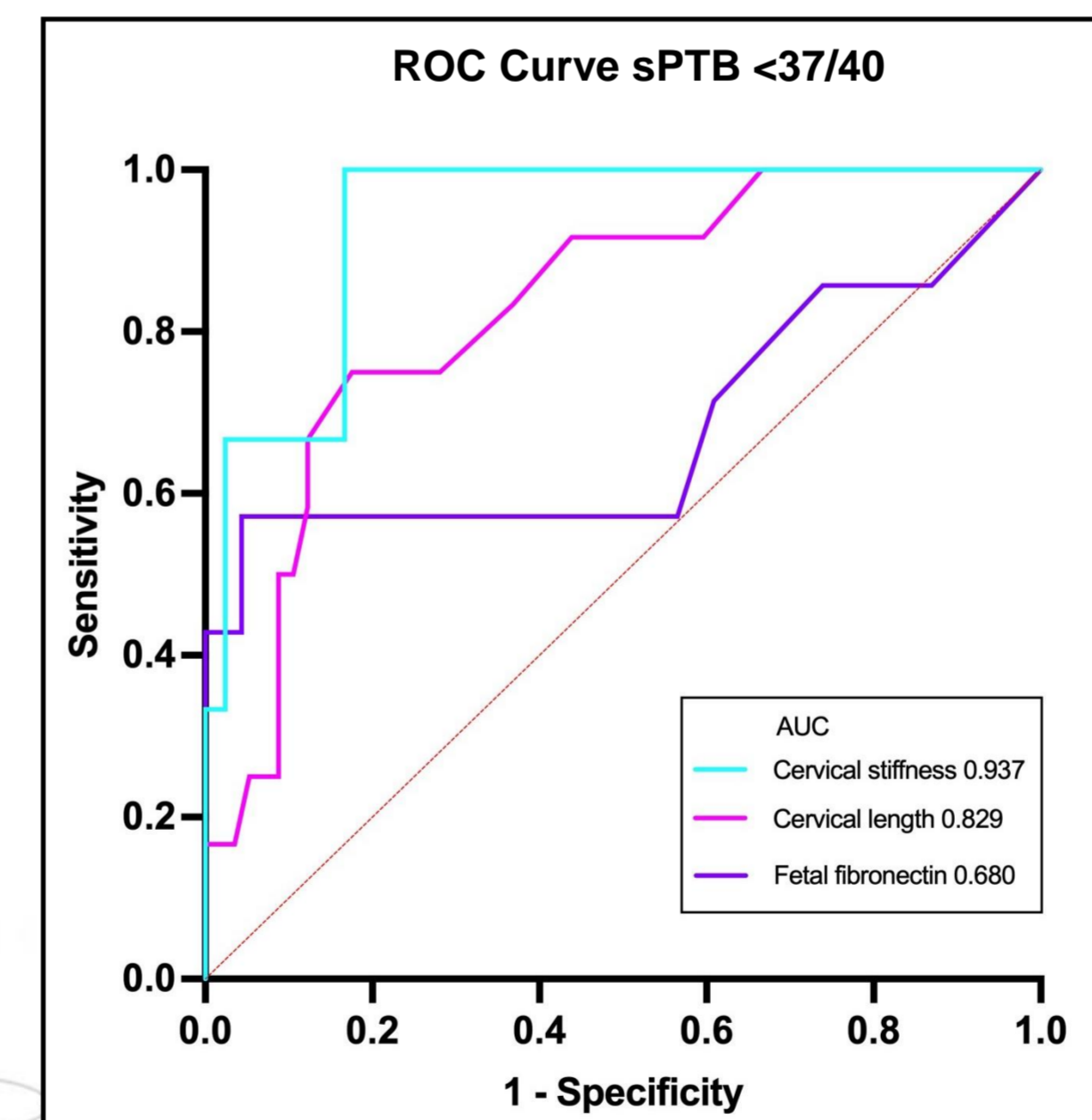Figure 4 – Cervical stiffness and cervical length measurements

Discussion

- CS shows promise as a predictive test, more data required
- Cervical surgery results could be secondary to scar tissue or differing mechanism of sPTB
- Expand testing to threatened preterm labour group
- Further understanding of interaction between cervical remodelling and other tests needed (fFN, CL)
- Addition of paired cervical remodelling biomarker project
- Results may further our understanding of mechanism of preterm cervical softening and subsequent sPTB in different risk groups