

Novel technology for the prevention of preterm birth

Shashar DS, Kees SK, Kabiri DK, Amsalem HA, Ofir KO, Tsur AT, Mazaki SM, Achiron RA, Schiff ES, Sivan ES
Sheba medical center, Tel Hashomer, Israel

Objective

Preterm birth (PTB) is the most common, catastrophic, and costly pregnancy complication. One in ten babies is born preterm, amounting to approximately fifteen million babies annually worldwide, of which one million will not survive past infancy. PTB is the global leading cause of morbidity in infants and the leading cause of disability in children up to the age of five. All existing solutions, including progesterone, tocolytic drugs, cerclage, and pessaries, are unsatisfactory, which is why rates have not changed for decades. Therefore, there is an essential need for an innovative solution to prevent preterm birth.

Methods

We have developed a novel and non-surgical device for the prevention of PTB called Lioness. Lioness is an elastic, smartly structured silicone ring, anchored high around the uterine cervix at the site of the Shirodkar cerclage. It is designed to reduce the load off the cervix and keep it elongated despite pressure and premature contractions, thus delaying the biomechanical cascade leading to PTB. Lioness is placed by the doctor, in their clinic, through the speculum, with intended application tools in a procedure taking only a few minutes. Placement is between the 12th and 18th week of gestation, and removal is conducted at term. The Lioness has a self-release safety mechanism allowing it to detach in active labor.

Results

After completing a First in Human safety study, Lioness is currently undergoing a pilot safety and feasibility study among pregnant women at high risk of PTB with twin pregnancies or a history of PTB. The study is conducted in two leading medical centers in Israel. Up to April 2023, the Lioness has been placed among twelve pregnant women. So far, we have accumulated over 1200 days of experience without significant side effects, four deliveries at term, and one delivery at 36w+3d in which the device disconnected as expected during active labor before its intended removal. In all participants, Lioness placement led to elongation of the cervix and kept it elongated until reaching term.

Conclusion

Due to these encouraging results and after completing the ongoing pilot study, we plan to conduct a large pivotal randomized multicenter study to demonstrate the statistically significant efficacy of the Lioness in reducing PTB. Full disclosure: The presenter is the co-inventor and CEO of PregnanTech - the start-up company that develops Lioness. In the presentation, we would like to present the Lioness, the results of the pilot study obtained until June 2023, and a video of about 10 minutes explaining the functionality and the placement procedure.