UMBILICAL CORD BLOOD COLLECTION APPARATUS

FIELD OF THE INVENTION

The present invention relates to an umbilical cord blood collection apparatus. In particular although not solely the invention generally relates to an electro-mechanical device for the purposes of collecting umbilical cord blood which yield useful volumes of blood from a delivered placenta.

BACKGROUND

It is well known that umbilical cord blood or UCB, is an increasingly important and rich source of stem cells. It is known that stem cells can divide to create new red blood cells which may for example carry oxygen to the brain, new white blood cells which may be used in a bodies immune system and new platelets which can assist in blood clotting. It is currently estimated that stem cells can be used for the treatment of over 45 malignant and non-malignant diseases. Such may include certain cancers such as leukaemia and immune and genetic disorders. UCB may also provide a readily available source of stem cells for transplantation in many situations where bone marrow is currently used. Hence the use of UCB instead of other sources of stem cells such as for example bone marrow and peripheral blood has many advantages. Such may include for example the reduction or elimination of risk involved in the collection of UCB. UCB is also easier to collect and harvest without the risks associated with general anaesthesia required for the purposes of extracting bone marrow. UCB is also readily available when needed if it is properly collected and stored at birth. It has been found that UCB is also more often compatible to a person when used in transplants. Furthermore UCB has a lower procurement cost. It has also been demonstrated that UCB has broader potential clinical applications for improving neural repair and bone and tissue growth. As such the importance of UCB is now widely recognised. Blood centres worldwide may collect and store UCB after delivery of a baby subject to the parents consent or request. The UCB may become extremely useful and indispensable at a later stage

in life in saving the life of the new born baby. However one problem associated with UCB is that its collection appears to be a one time possibility and the amount of blood that can be collected is limited using current blood collection technology. Such current blood collection technology may include syringe assisted and gravity assisted methods. A few studies have been conducted including for example that published by Bertolini F., Lazzari L., Lauri E. et al. *Comparative study of different procedures for the collection and banking of umbilical cord blood.* J Hematother 1995:4:29-36. Such methods are manually carried out. As well as the task being tedious and difficult to achieve the current ways of extracting the blood also creates inherent risk of unnecessary contamination.

According to McCullough J., Herr G., Lennon S. et al. *Factors influencing the availability of umbilical cord blood for banking and transplantation.* Transfusion 1998:38:508-510, the current ways of UCB collection typically recovers 20-40ml. Apart from obstetric factors such as infant weight and time of collection, the procedure involved and the equipment used to perform the collection influence the final yield.

It is accordingly an object of the present invention to provide an umbilical cord blood collection apparatus which can effectively and automatically yield an increased volume of blood from a delivered placenta when compared to some of the prior art known or to at least provide the public with a useful choice.

This invention aims to provide an umbilical cord blood collection apparatus which is designed to improve the existing UCB collection technology and process. Another of the objects may be to provide a system which fulfils the objective of providing an automated and efficient collection of a larger volume of UCB from the delivered placentas, and/or to provide modularity in design, ease of use and reduction in the risks of contamination when compared to the prior art, or to at least provide the public with a useful choice.

BRIEF DESCRIPTION OF THE INVENTION

In a first aspect the present invention consists in a device for extracting and collecting blood from a delivered placenta comprising:

a means to define a compartment to locate and support a delivered placenta and umbilical cord said compartment including a flexible membrane which can be displaced (preferably under the influence of a fluid (preferably gas) pressure differential between the compartment side and non compartment side of said membrane) to impart onto at least the placenta a pressure to encourage the displacement of fluid carried by said placenta towards the umbilical cord, said compartment including at least one outlet opening via which said umbilical cord can extend (preferably in a sealed manner) to allow the flexible membrane pressure induced flow of fluid carried by said placenta to at least in part displace from said compartment for external to the compartment collection of said fluid.

Preferably said compartment includes a tray like region by which (directly or indirectly) said placenta can be supported in a manner to allow said umbilical cord to extent to said outlet opening.

Preferably said flexible membrane is provided in a lidding like manner to said tray like region to define said compartment.

Preferably said compartment is a pressurisable compartment.

Preferably a pressure cap is able to locate over said flexible membrane in a manner to establish diaphragm pump like relationship with said compartment, the pressure cap forming a pressurisable enclosure to the opposite side of said flexible membrane to said tray side of said flexible membrane.

Preferably said pressure cap is a rigid cap.

Preferably said tray is a rigid tray.

Preferably device includes further components or detailed aspects as herein described.

In a further aspect the present invention consists in a UCB system including a device as hereinabove described, said system further including a control means as herein described.

In a further aspect the present invention consists in a UCB system as herein described with reference to the accompanying drawings.

In a further aspect the present invention consists in a device as herein above described and as described with reference to the accompanying drawings.

In a further aspect the present invention consists in a novel UCB collection system for collection of blood from a delivered placenta, including

(a) means for placenta and umbilical cord placement,

(b) means for air-sealant and holding the placenta in place,

(c) means for the application of a uniform and distributed pneumatic air pressure across the maternal surface of the placenta according to a desired pressure profile,

(d) means for generating vibration of (a), (b) and (c), and

(e) means for overall control of the system.

Preferably said placenta placement means comprises of a preferably mildly cone-shaped modular element on which the placenta sits and a ventura which preferably uses a plastic component to direct the umbilical cord to a collection point.

Preferably it also acts as a hard mechanical filter against contaminated blood from the surface of the placenta.

Preferably said air-sealant and placenta holding means comprises of a silicon pressure pad preferably of a varying thickness. It preferably has an integral sealing ring snapped into position above the placenta, the holding means seals the air chamber, keeps the placenta in position and evenly distributes pneumatic pressure on the placenta from the periphery towards the umbilical cord at the centre.

Preferably said pneumatic pressure application means comprises of an air-tight chamber into which air from a compressed air source is able to be admitted in a controlled manner, thus inducing a pneumatic pressure on the pressure pad;

Preferably said vibration generation means comprises of a vibrator attached to a structure holding or supporting (a) and (b) and (c), to induce a high frequency

vibration therein, thus keeping placenta in a natural positioning and reducing bottlenecks and clots to blood flow;

Preferably said control means comprises an open-architecture software control system which generates desired pressure profiles, controls the chamber pressures to track these profiles precisely and which may provide alarm and relief measures.

This invention may also be said broadly to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or collectively, and any or all combinations of any two or more of said parts, elements or features, and where specific integers are mentioned herein which have known equivalents in the art to which this invention relates, such known equivalents are deemed to be incorporated herein as if individually set forth.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a representation of the blood collection unit in fluid communication with a controller,

Figure 2 is a partial sectional perspective view of the blood collection unit,

Figure 3 is a representation of the placenta tray engaged in fluid communication with the controller,

Figure 4 is a partial sectional perspective and exploded view of the blood collection unit of Figure 2,

Figure 5 is a perspective view of the placenta tray with its lid removed,

Figure 6A is a perspective view of the placenta tray umbilical cord positioner and wrapper,

Figure 6B is a diagrammatic view of a placenta and the umbilical cord positioner and wrapper,

Figure 7 is a perspective representation of the tray with its lid removed but with a silicon like cover or pressure pad located over the interior cavity of the tray,

Figure 8 is a schematic drawing of the umbilical cord blood collection apparatus including the blood collection unit as shown in Figure 1, the controller and the electrical controller of the device such as for example provide by way of APC,

Figure 9 is a partial perspective view of a silicon pressure pad,

Figure 10 is another perspective view of Figure 9,

Figure 11 shows a user interface for the control system, and

Figure 12 is a sectional view through the silicone pressure pad showing the preferred variation in thickness across the diameter of the pressure pad wherein the thicker part of the pressure region is provided at the circumference of the pad.

DETAILED DESCRIPTION OF THE INVENTION

The invention includes the following four primary components,

a placenta tray with umbilical cord positioner,

an air-tight chamber with a controlled and distributed pneumatic pressure application system,

an adjustable and integrated vibratory structure, and

an open-architecture software control system fulfilling the functionalities of the overall system.

The Components

Placenta tray and umbilical cord positioner

The placenta tray 1 is preferably a modular slightly-reverse sloping (cone-shaped) component. It forms part of the overall (preferably stainless steel) support structure 2. It serves as the support base for the placenta, with the maternal side facing upward, the fetal side facing downward. The umbilical cord, originating from the fetal side, passes through a ventura as shown in Figure 6B of the funnel-shaped element which is formed by a plastic umbilical cord positioner 3. The placenta can be wrapped in a UV sterilised wrapper 4 prior to being placed in the tray to reduce the possibility of contamination. The umbilical cord positioner 3 is

preferably walled with a disposable absorbent. The umbilical positioner includes or is walled with a disposable absorbent material to allow for any fluids running from the placenta onto the umbilical cord positioner, to be absorbed rather than having these flow onto other parts of and through the ventura. The absorbent material therefore allows for the device to be kept cleaner than should their not have been any absorbent material provided. The positioner acts as a mechanical filter against contaminated blood from the surfaces of the placenta dripping through the ventura by the absorbent material absorbing the blood.

A variable thickness silicon pressure pad 7 with an integral sealing ring 8 can be snapped into position above the maternal side of the placenta to capture the placenta in the placenta tray in cavity 9. This pad fulfils a three-fold function. It serves to keep the slippery placenta in place, air-seals the gap between the pressure application lid 9 and the placenta tray base 10, and its deliberate varying thickness design will evenly distribute pneumatic pressure radially across the maternal side of the placenta from the periphery of the placenta towards the umbilical cord at the centre, when the pneumatic pressure is applied. With reference to Figure 12, it can be seen that the silicone pressure pad has a thicker wall thickness at the circumference of the pressure portion of the pad than at and towards the middle of the pressure pad. It is also not of a planar shape but has a slight double concave surface to its downward or inward side across the diameter of the pad.

Pneumatic pressure application system

The pneumatic pressure application system comprises of a pressure application lid 9 which is snapped onto the placenta tray 1. Together with the placenta tray 1 and positioner 3, they form an air-tight chamber 13. The sealing ring 8 which is an integral part of the pressure pad 7 is used to eliminate air-leakage. The lid 9 houses three interfaces to standard air tubings. One interface 14 is connected to an air tubing via a servo valve from a compressed air source which can be an air cylinder or an air compressor (not shown). The second interface 15 is connected to a pressure sensor inside the box 17 to yield chamber pressure measurements and to complete the control loop. The actual chamber pressure can be varied to follow a

desired profile by manipulating directly the valve opening via a pressure controller. In this way, a massaging action is delivered to the placenta to induce a faster and smoother flow of blood from the placenta. The third interface 16 is connected to a vacuum pump to speed up the exhaust process.

Vibratory structure

The stainless steel structure is integrated with a vibrator 20 which can generate high frequency vibration to the entire structure. In this way, the placenta is kept in a naturally-inclined position at all time. In other words when the placenta is placed from the lowest energy natural position, the vibration of the device can move the placenta into the appropriate position to ensure efficient extraction of blood. Bottlenecks and clots impeding blood flow can be reduced. The amount of vibration is adjustable via a vibration controller.

Open-architecture software control system

The integrated full system is shown in Figure 8 in schematic diagram form. An open-architecture software control system fulfils the overall functions of the system. It can be programmed to give different chamber pressure profiles. Closed-loop control ensures the pressure is precisely controlled to track desired profiles. Alarm and safety features can be implemented to maintain the chamber pressure within acceptable thresholds. The user interface to operate the system is shown in Figure 11.

Test Results

The apparatus has been tested on six delivered placentas. The average total volume of UCB collected was 58.25ml. The device was also tested for incremental improvement. It was applied after the syringe-assisted collection procedure is exhausted. The average device yield was 28.6%, representing the incremental volume over total volume collected.

Further Advantages

These four primary components are modular in nature so that each can be modified or replaced, while the other components remain in use. This feature facilitates repeated operations using the same device. Collectively, the four

components form an electro-mechanical apparatus which is able to manipulate the placenta via a combination of high frequency vibration and controlled pneumatic pressure, to maximise the flow of blood from the placenta to a collection tube. In addition, all the key components which may be directly or indirectly in contact with the placenta can be readily sterilised and are also designed to filter contaminants from the collected blood.

The foregoing description of the preferred embodiment of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed, since many modifications or variations thereof are possible in the light of the above teaching. All such modifications and variations are within the scope of the invention. The embodiments described herein were chosen and described in order best to explain the principles of the invention and its practical application, thereby to enable others skilled in the art to utilise the invention in various embodiments and with various modifications as are suited to the particular use contemplated thereof. It is intended that the scope of the invention be defined by the claims appended hereto, when interpreted in accordance with the full breadth to which they are legally and equitably suited.

What we provisionally claim is:

1. A device for extracting and collecting blood from a delivered placenta comprising:

a means to define a compartment to locate and support a delivered placenta and umbilical cord said compartment including a flexible membrane which can be displaced (preferably under the influence of a fluid (preferably gas) pressure differential between the compartment side and non compartment side of said membrane) to impart onto at least the placenta a pressure to encourage the displacement of fluid carried by said placenta towards the umbilical cord, said compartment including at least one outlet opening via which said umbilical cord can extend (preferably in a sealed manner) to allow the flexible membrane pressure induced flow of fluid carried by said placenta to at least in part displace from said compartment for external to the compartment collection of said fluid.

2. A device as claimed in claim 1 wherein said compartment includes a tray like region by which (directly or indirectly) said placenta can be supported in a manner to allow said umbilical cord to extent to said outlet opening.

3. A device as claimed in claim 1 wherein said flexible membrane is provided in a lidding like manner to said tray like region to define said compartment.

4. A device as claimed in claim 1 wherein said compartment is a pressurisable compartment.

5. A device as claimed in claim 1 wherein a pressure cap is able to locate over said flexible membrane in a manner to establish diaphragm pump like relationship with said compartment, the pressure cap forming a pressurisable enclosure to the opposite side of said flexible membrane to said tray side of said flexible membrane.

6. A device as claimed in claim 5 wherein said pressure cap is a rigid cap.

7. A device as claimed in claim 1 wherein said tray is a rigid tray.

8. A device as claimed in claim 1 wherein the device includes further components or detailed aspects as herein described.

9. A UCB system including a device as hereinabove described, said system further including a control means as herein described.

10. A UCB system as herein described with reference to the accompanying drawings.

11. A device as herein above described and as described with reference to the accompanying drawings.

12. A UCB collection system for collection of blood from a delivered placenta, including

(a) means for placenta and umbilical cord placement,

(b) means for air-sealant and holding the placenta in place,

(c) means for the application of a uniform and distributed pneumatic air pressure across the maternal surface of the placenta according to a desired pressure profile,

(d) means for generating vibration of (a), (b) and (c), and

(e) means for overall control of the system.

13. A system as claimed in claim 12 wherein said placenta placement means comprises of a preferably mildly cone-shaped modular element on which the placenta sits and a ventura which preferably uses a plastic component to direct the umbilical cord to a collection point.

14. A system as claimed in claim 12 wherein it also acts as a hard mechanical filter against contaminated blood from the surface of the placenta.

15. A system as claimed in claim 12 wherein said air-sealant and placenta holding means comprises of a silicon pressure pad preferably of a varying thickness

16. A system as claimed in claim 15 wherein said air sealant and placenta holding means has an integral sealing ring snapped into position above the placenta, the holding means seals the air chamber, keeps the

placenta in position and evenly distributes pneumatic pressure on the placenta from the periphery towards the umbilical cord at the centre.

17. A system as claimed in claim 12 wherein said pneumatic pressure application means comprises of an air-tight chamber into which air from a compressed air source is able to be admitted in a controlled manner, thus inducing a pneumatic pressure on the pressure pad.

18. A system as claimed in claim 12 wherein said vibration generation means comprises of a vibrator attached to a structure holding or supporting (a) and (b) and (c), to induce a high frequency vibration therein, thus keeping placenta in a natural positioning and reducing bottlenecks and clots to blood flow.

19. A system as claimed in claim 12 wherein said control means comprises an open-architecture software control system which generates desired pressure profiles, controls the chamber pressures to track these profiles precisely and which may provide alarm and relief measures.