

A CANNULATION ASSEMBLY AND METHOD

Field of the Invention

- 5 The invention relates to the extraction of umbilical cord blood and, in particular, the apparatus and method to achieve this.

Background of Invention

- 10 It is well known that umbilical cord blood (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 carry oxygen to the brain, new white blood cells used in the body's immune system and new platelets which can assist in blood clotting. It is currently estimated that stem cells may be used for the treatment of over 45 malignant and non-malignant
- 15 diseases. Such diseases may include certain cancers such as leukemia, 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
- 20 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 while avoiding the risks associated with general anesthesia, which is required for the purposes of extracting bone marrow.

UCB is also readily available when needed, assuming an efficient and systematic collection and storage procedure. It has been found that UCB is also more often compatible with people undergoing transplants. Furthermore UCB has a lower procurement cost. It has also been demonstrated that UCB has broader potential clinical applications for improving neural repair, bone and tissue growth. As such, the importance of UCB is now widely recognized. Blood centres worldwide may collect and store UCB after delivery of a baby subject to the parents' consent or request.

However, a 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.

Summary of Invention

In a first aspect the invention provides a cannulation assembly comprising: a housing; a needle selectively extendable from a proximal end of said housing; a tube arranged to pass through the housing and through a bore of said needle such that an insertion end of said tube is arranged to selectively project from an insertion end of said needle; a slide mounted to the needle in sliding engagement with the housing and arranged to move the needle from a retracted position to an insertion position such that the needle projects from said housing; wherein said slide is further arranged to move the needle from the insertion position to a locked position such that the needle is fully retracted.

In a second aspect the invention provides A clamp for clamping an umbilical cord, the clamp comprising: two arms connected by a resilient hinge, said hinge arranged to bias said arms to an open position; one arm having a release lever at an end opposed to the hinge; the second arm having at least one ridge at an end opposed to the hinge; said lever and at least one ridge cooperatively shaped and arranged to engage on closing of said arms and, on activation of the lever, said arms are opened under the resilient biasing of said hinge; wherein said lever is arranged to activate on depressing a contact point on said lever.

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In a third aspect the invention provides a cannulation needle comprising a bevel proximate to a tip, said bevel including a reverse curve.

Accordingly, the invention provides for the needle to be used to insert the tube, and can then be removed to allow access for the tube. Further, by passing the tube through the housing, and importantly, through the needle the volume of blood extracted is maximized through having the larger bore of the needle during cannulation.

In one embodiment, the needle may also be locked in place after retraction so as to prevent multiple uses of the cannulation assembly. In this embodiment, the first lock may therefore prevent cross contamination through use with multiple patients.

Brief Description of Drawings

It will be convenient to further describe the present invention with respect to the accompanying drawings that illustrate possible arrangements of the invention. Other arrangements of the invention are possible and consequently, the particularity of the accompanying drawings is not to be understood as superseding the generality of the preceding description of the invention.

Figure 1 is an elevation view of a cannulation assembly according to one embodiment of the present invention;

Figure 2 is a sectional view of the cannulation assembly of Figure 1;

Figures 3A and 3B are plan views of the cannulation assembly according to a further embodiment of the present invention;

Figures 4 to 7 are sectional views of the cannulation assembly of Figures 3A and 3B;

Figure 8 provides various views of an umbilical cord clamp according to one embodiment of the present invention;

Figure 9 provides various sectional views of the cannulation assembly of Figure 3A;

Figures 10 and 11 are exploded views of the cannulation assembly of Figure 1.

Figures 12A, 12B, 13A and 13B are isometric views of a cannulation procedure according to one embodiment of the present invention;

Figure 14 is a schematic view of a full cannulation arrangement according to a further
5 embodiment of the present invention;

Figures 15A to 15C are various views of a needle for a cannulation assembly according to a further embodiment of the present invention.

10 Detailed Description

Figure 1 shows one embodiment where the cannula itself is a length of flexible plastic tubing 4 of suitable composition for the safe transfer and storage of blood. The distal end, or tube insertion end, is spherically tipped 5 whilst the proximal end 6 is connected
15 to the tube set; providing in-utero collection of blood into a removable blood bag 7 and thereafter, redirection and ex-utero collection via a second removable blood bag 8. The cannula slides through the inside diameter of a surgical stainless steel needle 9 or trocar; the push/pull force being characteristic of a transition fit. The needle has a distal taper point, or needle insertion end, 10 (Figure 4 and 5), the proximal end 11 being square and
20 perpendicular and bonded to the carriage tube 13. The length of the needle is sufficient to allow adequate extension 12 from the cannula housing to perforate the umbilical vein. The proximal end of the needle is inserted into the carriage tube 13 which is assembled within a two piece plastic housing, the upper 14a and the lower 14b; suitably bonded together in a manner that prevents disassembly. The carriage tube 13 is guided and

restrained laterally within the lower housing 14b by a combination of ribs 15 and raised projections 16; allowing the carriage to extend and retract with minimal frictional contact. Extending posteriorly with proximal bias from the carriage tube is the carriage lever 17. A slot 18 in the upper housing allows the carriage lever to protrude. In doing
5 so, the carriage is guided linearly and prevented from rotation.

In the as packaged configuration, the spherical tip of the cannula 5 is positioned slightly proximal to the distal opening of the needle, whilst the needle is positioned within the housing; the distal taper point 10 being concealed within the housing. An external
10 adhesive label 19, wraps over the lower to upper housing joint and the carriage lever (Figure 1, 10 and 11). The label maintains the as packaged position of the distal taper point of the needle relative to the housing. It must be peeled off and removed prior to use. Once removed, the cannula shall be considered as used and non-sterile.

15 Immediately posterior to the label, on the inside of the upper housing 14a and either side of the slot 18, a row of raised projections 20 accommodate two small cylindrical spigots 21 projecting from either side of the carriage lever (Figure 7 and 10). The two rows of raised projections 20, immediately adjacent to the edge of the slot and along the entire length of the slot, present a cylindrical contour 22 with minimal clearance to the outer
20 diameter of the carriage tube 13. When the carriage tube is assembled inside the housing it has a single degree of freedom, able to move linearly i.e. extend and retract. The position of the spigots 21 on the carriage lever 17, relative to the central axis of the needle (and carriage tube), creates a cantilever whose bending moment is a maximum where the carriage lever extends from the carriage tube 23. The opposing force

resisting this bending moment ensures contact between the spigots and each row of raised projections; in a manner similar to a rack and pinion gear. This functionality enables the slider & needle to be selectively temporarily locked in place at any desired position along the length of the feature such that it allows for an inherently stable

5 deployment of the needle in a partially retracted position or partially/fully extended position when the thumb grip is not depressed. Attached to the posterior of the lever, external to the housing, is the thumb grip 24. Pressing the thumb grip disengages the spigots. Held within the palm of the user's hand and with moderate pressure applied to the thumb grip simultaneous with distally biased pressure, the needle extends from the

10 housing; the heel 25 of the lever compressing and clamping the flexible tube to move in unison with the needle. With sufficient extension of the needle, the cannula housing can then be manipulated ready for use together with the cord clamp. The plurality of ridges on the cord clamp are included so as to enable varying clamping force

15 The cord clamp 26 is placed over the umbilical cord distal to the desired point of cannulation. It is intended to provide temporary occlusion of the umbilical vein, reducing the potential for blood loss, at that moment when the needle taper point 10 perforates the umbilical vein. The spherical tip 5 of the flexible cannula tubing, having a locally increased outside diameter, creates an annular seal 27 against the inside diameter

20 of the needle (Figure 9); preventing leakage of cord blood past the spherical tip, where it may collect between the outside diameter of the flexible cannula tube and the inside diameter of the needle. Using the quick release lever 28 (Figure 8), the hook 28a rotates locally around a reduced cross section area 28b allowing the cord clamp to be removed

and repositioned so that the cylindrical aperture 29 in the clamp jaws 30 is aligned with and allowed to clamp the umbilical cord over the needle 9.

Thereafter, the user can grip the cannula housing in one hand whilst guiding the
5 proximal flexible cannula tube 30 through the cannula housing 14 with the other hand;
the spherical tip 5 smoothly negotiating the inside of the umbilical vein.

With the flexible cannula sufficiently extended into the umbilical vein, the cord clamp is
once again released and then repositioned so that the cylindrical aperture 29 in the
10 clamp jaws 30 is aligned with and allowed to clamp the umbilical cord over the flexible
cannula tube 4; the diameter of the cylindrical aperture being sufficiently large to
prevent occlusion. Compressing the thumb grip 24 and applying a proximally biased
pressure retracts the needle back to the initial position whereupon tactile feedback to the
user will suggest resistance to any further retraction. Two (2) spherical protrusions 31
15 on the inside of the lower housing, posterior to the carriage tube 13, engage with the
leading edge of the carriage tube. If the cannula is being used for in-utero collection
and immediately thereafter, ex-utero collection, additional proximally biased pressure
retracts the needle fully. However, if used for ex-utero this partial retraction creates a
needle safe environment for assessing cord blood collection prior to a deliberate re-
20 extension and re-cannulation.

In the partial retraction position, the two (2) spherical protrusions 31 on the lower
housing, engage with the leading edge of the carriage tube. By applying sufficient
proximal biased pressure to the thumb grip, the leading edge of the carriage will rise

over the spherical projections; which offer a minimal contact area of interference 32 to the carriage tube. With continued proximally biased pressure all resistance is overcome and the needle will retract until the carriage lever stops against the proximal extremity of the slot 18.

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There are two methods of preventing the needle from being extended for re-use. Firstly, two (2) spherical depressions 33 in the carriage tube 13 will align with the aforementioned spherical projections 31 in the lower housing 14b. The position of alignment will coincide with the taper point of the needle coming to rest proximal to a longitudinal rib 34 in the upper housing (Figure 6). Due to the interference of these spherical protrusions against the carriage tube, combined with resistance to the compression of the carriage lever creating a moment around the contact point 32 of the spherical protrusions, the distal taper point now assumes an angular deflection 35 relative to the central axis of the needle i.e. when the needle was extended or partially retracted. Any attempt to re-extend the needle will result in the needle taper point colliding with the proximal side of this rib 34. Secondly and further proximally, a rectangular protrusion 36 from the inside of the lower housing aligns with an anterior slot 37 in the carriage tube, configured parallel to the centre axis (Figure 5 and 10). Distally biased pressure applied to the carriage lever 17 will force the proximal end of this slot 37 against the rectangular protrusion 36, ensuring the carriage remains fully retracted. With the needle fully retracted and locked, the cannula housing can be slid over the cannula tube and taped to the umbilical cord as required. In-utero cord blood collection can proceed followed by ex-utero should it be necessary.

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Figures 12A and 12B show the first step for the collection of cord blood. Here at placenta 38 has umbilical cord 42 attached from which the cord blood is to be harvested. A cannulation assembly 44 according to one embodiment of the present invention has the needle 46 extended outside the housing for penetration of the cord. The needle has a bore through which a tube 48 is placed. The tube 48 extends through the housing and through the bore of the needle 46 ready for insertion in the cord.

Figures 13A and 13B show the next step by which the needle having penetrated the cord 42 then allows the tube 48 to be inserted into the cord. The tube 48 is then pushed further into the cord so as to be well within the cord in order for harvesting. The needle is then retracted into the housing and locked in place so as to prevent further use of the cannulation assembly. This then leads to the image shown in Figures 13A and 13B whereby the needle has now been retracted. The tube 48 is inserted into the cord and the cord and indirectly the tube are then clamped by a clamp 49 at the cannulation site 52 so as to hold the tube and cord in place.

Figure 14 shows a possible arrangement of a full cannulation assembly kit. Here, a pair of cannulation assemblies 40 is connected by valves 45 and 50 to supply bags 55. It would be appreciated that in a full arrangement the cannulation assembly 40 will need to drain the harvested blood into a blood bag 55 with Figure 14 showing a full arrangement under optimal conditions. The dual arrangement shown in Figure 14 allows for multiple harvesting points and so accommodates multiple cannulation sites. Further, to ensure that no time is wasted in the critical few minutes from pre-delivery to post-delivery by having multiple blood bags 55 connected to the multiple cannulation assemblies, the

volume of harvested blood can then be maximized. It would be appreciated that such an arrangement may have a single cannulation assembly, a single blood bag, or various combinations thereof. It would further be appreciated that multiple cannulation assemblies, that is, more than two may also be used. Further still, multiple blood bags 55
5 may also be attached in anticipation of a high supply of cord blood harvested.

Figure 15A to 15C shows a side profile of a needle 65 for a cannula according to one embodiment of the present invention. In this embodiment, the bevel 60 of the needle is a reverse curve having a greater steepness 80 at the middle section of a spline profile. In
10 the present embodiment, the reverse curve is a "S" spline shaped needle bevel design which is designed with a smooth and continuously varying bevel gradient 70, 75.

The primary advantage of the proposed design is the shallow proximal tip and reduced bevel length. The advantage of a shallow 90 and narrow proximal needle tip 95 is that it will greatly reduce the initial penetration force required. The reduced bevel length helps
15 to prevent puncturing through the cord as it enables the needle bevel to be fully enclosed by the umbilical cord with minimal depth of insertion of the needle.

The proximal tip 95 of the needle has a shallow gradient 90 (drawn as approximately 14 degrees in Figure 15 for the purposes of a non-limiting example). The mid-section of the
20 bevel has a much steeper gradient 80 (drawn as 48 degrees as a non-limiting example). The final section of the needle bevel resumes to a shallow gradient. The proximal tip 95 is also suitably narrowed (drawn as 60 degree V shaped wedge 100 for the purposes of a non-limiting example).

The steep mid-section creates a tangible increased resistance to insertion such that the operator has a haptic “notch” to indicate that the needle is mid-way into the cord. This will help the operator to differentiate the depth of insertion, and prevent the operator from puncturing right through the cord

Claims

1. A cannulation assembly comprising
a housing;
5 a needle selectively extendable from a proximal end of said housing;
a tube arranged to pass through the housing and through a bore of said needle
such that an insertion end of said tube is arranged to selectively project from an
insertion end of said needle;
a slide mounted to the needle in sliding engagement with the housing and
10 arranged to move the needle from a retracted position to an insertion position
such that the needle projects from said housing;
wherein said slide is further arranged to move the needle from the insertion
position to a locked position such that the needle is fully retracted.
- 15 2. The cannulation assembly according to claim 1, wherein said housing includes a
first lock arranged to irrevocably lock the needle inside the housing whilst in the
locked position.
3. The cannulation assembly according to claim 2, wherein the first lock includes
20 corresponding lugs on the slide and the housing, said lugs arranged to permit the
slide to retract into the locked position but prevent the slide from moving from
the locked position through an interference between the respective lugs.

4. The cannulation assembly according to any one of claims 1 to 3, wherein the
needle is arranged to penetrate an umbilical cord, said external diameter of said
needle corresponding to the bore of said umbilical cord.
- 5 5. The cannulation assembly according to any one of claims 1 to 4, wherein said
insertion end of said tube is enlarged so as to seal an interstitial space between the
needle bore and tube.
6. The cannulation assembly according to any one of claims 1 to 5, wherein the
10 insertion end is spherical in shape.
7. The cannulation assembly according to any one of claims 2 to 6, wherein said
housing includes a second lock intermediate the locked position and the proximal
15 position, said second lock arranged to selectively release the needle on
engagement.
8. The cannulation assembly according to any one of claims 1 to 7, wherein a bevel
of said needle includes a reverse curve.
- 20 9. The cannulation assembly according to claim 8, wherein the reverse curve is a
“S” shaped spline.

10. A method of cannulating an umbilical cord comprising the steps of:
- projecting a needle from a housing;
 - inserting the needle into the umbilical cord at a cannulation site;
 - passing a tube through a bore of said needle;
 - 5 projecting the tube from the needle into the umbilical cord;
 - retracting the needle into the housing.
11. The method according to claim 10, further including the step, after the retracting step, of clamping the tube at the cannulation site.
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12. The method according to claim 10 or 9, further including the step after the retracting step of locking the needle within the housing.
13. A clamp for clamping an umbilical cord, the clamp comprising:
- 15 two arms connected by a resilient hinge, said hinge arranged to bias said arms to an open position;
 - one arm having a release lever at an end opposed to the hinge;
 - the second arm having at least one ridge at an end opposed to the hinge;
 - said lever and at least one ridge cooperatively shaped and arranged to engage on
 - 20 closing of said arms and, on activation of the lever, said arms are opened under the resilient biasing of said hinge;
 - wherein said lever is arranged to activate on depressing a contact point on said lever.

14. The clamp according to claim 11, wherein the second arm includes a plurality of ridges spaced so as to provide a varying clamping force to the umbilical cord on engagement of the lever with any one of said ridges.

5 15. The clamp according to claim 11 or 12, wherein said arms are shaped intermediate the hinge end and opposed ends to form an aperture on closing of said arms.

10 16. The clamp according to any one of claims 11 to 13, wherein the clamp is molded as a single unit.

17. A cannulation kit comprising a cannulation assembly according to any one of claims 1 to 7 and a clamp according to any one of claims 11 to 14.

15 18. A cannulation needle comprising a bevel proximate to a tip, said bevel including a reverse curve.

19. The cannulation needle according to claim 18, wherein the reverse curve is an “S” shaped spline.

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