HEMOFILTER FOR IN VIVO BLOOD FILTRATION

CROSS-REFERENCE

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 62/523,131, filed June 21, 2017, which application is incorporated herein by reference in its entirety.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

[0002] This invention was made with government support under grant no. U01 EB021214 awarded by the National Institutes of Health. The government has certain rights in the invention.

INTRODUCTION

[0003] End Stage Renal Disease (ESRD) remains a major public health problem in the United States, afflicting over 615,000 people with nearly 116,000 new patients initiating treatment each year. Due to the shortfall in organ availability, the majority of ESRD patients in the United States undergo in-center, 3-4 hour, thrice weekly dialysis, such as hemodialysis or peritoneal dialysis.

[0004] Hemodialysis involves passing a patient's blood against a synthetic or semisynthetic membrane and inducing diffusive transport of toxins from the blood into a bath of dialysate on the other side of the membrane. In peritoneal dialysis, the patient's parietal peritoneal epithelium performs the function of the dialysis membrane.

SUMMARY

[0005] According to a first aspect of the present invention, there is provided a hemofilter for use in filtering blood in vivo. The hemofilter includes an extended inlet manifold; a plurality of filtration channels; and an extended outlet manifold, the extended inlet manifold comprising a first region comprising a circular inlet configured for connection to a blood vessel of an individual; and a transition section in which lumen of the extended inlet manifold transitions from having a circular cross-section to having a rectangular cross-section; and a second region comprising a U-shaped turn and followed by a linear tapered section, the linear tapered section comprising a plurality of openings in fluid communication with the plurality of filtration channels, wherein the plurality of filtration channels are arranged in a spaced-apart stacked

configuration and are in fluid communication with a plurality of openings in a first region of the outlet manifold, wherein the first region of the outlet manifold is parallel to the linear tapered section of the extended inlet manifold and is reverse-tapered with reference to the linear tapered section of the extended inlet manifold and wherein the outlet manifold comprises a second region comprising a transition section in which lumen of the outlet manifold transitions from having a rectangular cross-section to having a circular cross-section; and a circular outlet defined by the circular cross-section of the outlet manifold, and wherein the hemofilter is configured for entry of blood through the inlet and for transporting the blood through the transition section of the extended inlet manifold to the tapered linear section, into the plurality of filtration channels to the first region of the outlet manifold, into the transition section of the outlet manifold, and exit via the circular outlet.

[0006] In certain embodiments, the plurality of filtration channels are substantially rectangular (e.g., with a length longer than width and substantially rounded corners) and are stacked in a parallel configuration.

[0007] In certain embodiments, the transition section in extended inlet manifold includes a turn which changes direction of blood flow with reference to the direction in the inlet by 60º -120º.

[0008] In certain embodiments, the U-shaped turn in the second region of the extended inlet manifold changes the direction of blood flow with reference to the direction in the transition section by 150º and 210º.

[0009] In certain embodiments, the tapered section of the extended inlet manifold decreases in height. In certain embodiments, the tapered section of the extended inlet manifold decreases in width.

[0010] In certain embodiments, the plurality of filtration channels comprises 2-50 channels, e.g., 6-30 channels.

[0011] In certain embodiments, the plurality of filtration channels comprises a first curved region connected to the tapered section of the extended inlet manifold, a linear section, and a second curved region connected to the reverse-tapered section of the outlet manifold, wherein the curvature of the first curved region is opposite to the curvature of the second curved region.

[0012] In certain embodiments, the plurality of channels each define a rectangular channel lumen enclosed by a top surface, a bottom surface, and side walls connecting the top and bottom surfaces.

[0013] In certain embodiments, the top surface comprises a membrane for filtration of blood in the channel lumen. In certain embodiments, the bottom surface comprises a membrane for filtration of blood in the channel lumen.

[0014] In certain embodiments, the tapered section of the extended inlet manifold and the reverse-tapered section of the outlet manifold and a top channel of the plurality of channels and a bottom channel of the plurality of channels are arranged in shape of a parallelogram. In some embodiments, the acute angles of the parallelogram shape defined by the configuration of the hemofilter may range from 75-25 degree, such as, 70-30 degree, 65-30 degree, 65-35 degree, or 50-40 degree and the obtuse angles of the parallelogram shape defined by the configuration of the hemofilter may range from 105-155 degree, such as, 110-150 degree, 115-150 degree, 115-145 degree, or 130-140 degree, respectively.

[0015] In certain embodiments, the plurality of channels are shaped and dimensioned to provide a volumetric flow rate of 20-100 ml/min, e.g., 25-100 ml/min for blood flowing through each of the channels and wherein the hemofilter provides a volumetric flow rate of 750-2000 ml/min for blood flowing through the hemofilter.

[0016] In certain embodiments, each of the plurality of channels has a length of 10 mm-200 mm, e.g., 40 mm - 100 mm. In certain embodiments, each of the plurality of channels has a width of 5 mm-100 mm, e.g., 10 mm - 40 mm. In certain embodiments, each of the plurality of channels has a height of 0.5 mm – 2.5 mm.

[0017] According to a second aspect of the present invention, there is provided a hemofilter for use in filtering blood in vivo, the hemofilter comprising: an extended inlet conduit; a single serpentine filtration channel; and an outlet conduit; the extended inlet conduit comprising: a first region comprising: an inlet having a circular cross section geometry configured for connection to a blood vessel of an individual; and a transition region in which lumen enclosed by the first region transitions from the circular cross section shape into a rectangular cross section shape; a second region comprising a rectangular cross section and a curved region connected to the serpentine filtration channel; the serpentine filtration channel comprising: a plurality of filtration sections arranged in a spaced-apart stacked configuration wherein the plurality of filtration sections are connected via turnaround sections; and the outlet comprising: first region having a rectangular cross-section; and a second region that transitions from rectangular to a circular cross section and terminates in a circular outlet configured for connection to a blood vessel of the individual.
According to a third aspect of the present invention, there is provided a hemofilter for use in filtering blood in vivo, the hemofilter comprising: an extended inlet conduit; a single serpentine filtration channel; and an outlet conduit; the extended inlet conduit comprising: an inlet; a first transition region; a first turnaround section; a second transition region; a second