External Scaffolding for Rapid Use of Arteriovenous Fistulas

Product Design Specification

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Function:

Patients who undergo hemodialysis often require the placement of an arteriovenous (AV) fistula, a surgical connection between an artery and a vein typically in the arm. Currently, AV fistulas are successful only 45% of the time that they are surgically inserted. If the fistula does mature, it serves as an access point for the large hemodialysis needles. However, maturation can take 1-3 months and during this time the patient must rely on less ideal access points, such as a catheter, for hemodialysis. Our clients believe that external scaffolding to prevent fistula collapse during dialysis will enable more rapid use of AV fistulas in dialysis patients. We will work to design an external scaffolding of appropriate biomaterials that will adhere to the outer surface of the vein and tether it to the surrounding tissue, thereby supporting the vessel as it matures while making it immediately available for use in hemodialysis.

Client Requirements

- The designed material must adhere to the outer surface of the vasculature and tether to surrounding structures.
- The material must be injectable into the tissue surrounding the fistula.
- The material must be polymerizable *in situ.*
- The material must support the vessel during canulation without separation of the scaffolding and vascular wall.

Design Requirements:

I. Physical and Operational Characteristics

a. *Performance requirements:* To provide for more rapid use of arteriovenous fistulas, the designed biomaterial must adhere to the outer surface of the vascular connection to thicken the wall of the developing vein while allowing for natural maturation. To avoid additional surgery for the patient, the material should be injectable into the tissue surrounding the fistula and then polymerizable *in situ*. Once polymerized, the material should support the vessel

without losing contact with the vasculature during insertion of the hemodialysis needles and self-sealing upon removal. Additionally, it would be ideal if the material biodegraded at a rate similar to the development of the arterialized vein.

b. *Safety:* This material is to be adhered outside the venous wall in the human arm, therefore, it is critical that the materials used in its design do not cause harm to the body. Testing in a pig model and FDA approval are necessary prior to use in humans.

c. *Accuracy and Reliability:* The material needs to be able to be localized to a specific area on the exterior of a vein. Ideally, the material will improve the success rate of AV fistulas from 45% to 100%.

d. *Life in Service:* Currently, arterio-venous (AV) fistulas take 1 to 3 months to mature. Ideally, the scaffold will biodegrade at the same rate the fistula develops and, therefore, will last between 1 to 3 months.

e. *Shelf Life:* The material needs to remain in a liquid form long enough for a surgeon to inject the material into the arm after connecting the vein and artery.

f. *Operating Environment*: The material will be made outside the body and will be injected into the human arm where it will polymerize and remain for the rest of its life in service.

g. *Ergonomics:* The material should have good fluidity so that it encapsulates the desired tissue (vein) before it polymerizes. This lowers the chance of creating the scaffold around the undesired region on the patient, which could potentially cause further problems. Moreover, the encapsulation material should not cause pressure or stress on the patient's operation area. The injected material should not be felt by the patient even when suppressing the scaffolding location.

h. *Size:* The size of the material after being applied to the patient should be exactly encapsulating the vein of the patient. This should be no more than 2mm in diameter for the vein on the forearm. The length of the material encapsulating the vein may vary from patient to patient due to arm length differences. The size of the pre-polymerized material container should be approximately 5~10ml.

i. *Weight:* After the material encapsulates the vein, the weight of this material should not be felt or sensed by the patient. Ideally, it will be a weightless membrane that wraps around the vein.

j. *Materials:* Material that does not adhere to a vessel, stiffens too quickly, has no elasticity, is not self-sealing, and/or has no strengthening properties should be avoided. A gel-like polymerizable material is preferred. Materials such as Pluronics F127, Alginate, and PEG-diacrylate are potentially suitable materials. Thermal gelling (gelling by body temperature) is also a characteristic to consider.

k. *Aesthetics:* The material itself does not have to be aesthetically pleasing, but the finished scaffold should not bulge out from the skin surface (the scaffold should not be visible from the external skin surface).

II. Production Characteristics

a. *Quantity*: Design of a single material is required for proof-of-concept. Material production must be conducive to widespread use in patient treatment.

b. *Target Product Cost*: Material production must be cost- and resource-efficient to allow for widespread use. Cost minimization would increase the accessibility of this treatment to hospitals and patients.

III. Miscellaneous

a. *Standards and Specifications*: FDA approval of this class III medical device would be required, as the material is intended to support life and failure would be life threatening. As a medical device, the material must be manufactured under a quality assurance program, be suitable for the intended use, be adequately packaged and properly labeled, and have establishment registration and device listing forms on file with the FDA.

b. *Customer*: Ease of use is required so that health professionals may effectively use the material.

c. *Patient-related concerns*: The material must not present danger, discomfort, or additional inconvenience neither when the material is surgically placed in the body nor when the patient is undergoing hemodialysis.

d. *Competition*: Numerous patents exist to improve the implementation of arterio-venous fistulas. However, these patents focus primarily on the design of a stent for implantation into the lumen of canulated veins. No other attempt to provide external biomaterial support to the canulated vein is known to exist. Thus, the approach of this project is believed to be novel.