Bioabsorbable materials for use in vena cava filters

Inferior vena cava (IVC) filters are used to prevent a blood clot from blocking the pulmonary vein causing a pulmonary embolism (PE). The filter is placed in the large vein, vena cava, through a minimally invasive procedure. The filter today are made from various metal alloys. Due to their long-term complications, such as filter fracture, filter migration, caval wall perforation, recurring deep vein thrombosis (DVT) and post-thrombotic syndrome, there is currently a need for an alternative to these IVC filters. A way to overcome the complications is to create a bioabsorbable IVC filter which is the main objective in this project. The aim was to investigate potential bioabsorbable materials for use in a bioabsorbable IVC filter. Certain requirements for the filter were identified, and the aim was to choose and optimize a material which could function in a filter, exhibit adequate radial force to avoid migration while withstanding the constant external force on the vena cava causing it to collapse continuously. Through investigation of the literature and performance of initial experiments on different bioabsorbable polymers, poly(L-lactide) (PLLA) was chosen as a possible material candidate and further investigated. It was hypothesized that PLLA could be optimized through strain-induced crystallization and was extruded into small tubes, which underwent a biaxial strain during an expansion process. The mechanical properties, such as stiffness and strength, were improved through the processing. Several optimal processing parameters, such as high straining temperature, fast axial processing strain and a large degree of strain in the radial direction proved to improve the properties further. The mechanical properties were shown not to be related to the crystal orientation obtained during straining but related to the alignment of amorphous chains. The biaxially strained tubes were laser cut into either appropriate filter designs or the body part of the filter (stent-base) and expanded to 27 mm during a heat treatment. The effect of processing, heat treatment and sterilization were evaluated under in vitro Conditions. The radial force of the stent-base proved to correlate with the circumferential stiffness of the biaxially strained tubes. The fatigue properties of the stent-base were improved when tested under in vitro conditions. Based on these results the stent-bases were implanted in vivo in an ovine model for 2 and 3 1/2 weeks using three sheep. Two stent-bases were implanted per sheep, one cranially and one caudally. After merely 2 weeks the stent-bases showed multiple fractures in the circumferential direction caused by the continuous cyclic compression. The fragments from the caudal device remained in the caval wall, whereas little remained of the cranial device. Histology showed that the PLLA fragments were embedded in neointima to a degree that fragmented pieces did not migrate. It also showed mild fibrosis around the struts caused by the radial force of the stent. It was concluded that PLLA did not exhibit the adequate flexibility in such a filter design to withstand the cyclic compression of the vein over the course of 2 weeks. To achieve the goal of creating a bioabsorbable IVC filter, the stent-base must be made from a different polymer.