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Rapid prototyped sutureless anastomosis device from self-curing silk bio-ink

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Abstract: Sutureless anastomosis devices are designed to reduce surgical time and difficulty, which may lead to quicker and less invasive cardiovascular anastomosis. The implant uses a barb-and-seat compression fitting composed of one male and two female components. The implant body is resorbable and capable of eluting heparin. Custom robotic deposition equipment was designed to fabricate the implants from a self-curing silk solution. Curing did not require deleterious processing steps but devices demonstrated high crush resistance, retention strength, and leak resistance. Radial crush resistance is in the range of metal vascular implants. Insertion force and retention strength of the anastomosis was dependent on fit sizing of the male and female components and subsequent vessel wall compression. Anastomotic burst strength was dependent on the amount of vessel wall compression, and capable of maintaining higher than physiological pressures. In initial screening using a porcine implant, the devices remained intact for 28 days (the length of study). Histological sections revealed cellular infiltration within the laminar structure of the male component, as well as at the interface between the male and female components. Initial degradation and absorption of the implant wall were observed. The speed per anastomosis using this new device was much faster than current systems, providing significant clinical improvement. © 2014 Wiley Periodicals, Inc. J Biomed Mater Res Part B: Appl Biomater, 103B: 1333–1343, 2015.

Key Words: silk, sutureless anastomosis, resorbable implant, drug delivery, bio-ink

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INTRODUCTION

Manual suturing is the current gold standard for generating vascular anastomoses. Reconstitution of blood supply via vessel anastomosis remains a technically challenging and time-consuming procedure with a steep learning curve for surgeons. Suturing errors such as uneven spacing, inversion of suture walls, and misalignment of the vessel intima can lead to anastomotic leaks, thrombosis, prolonged hospital stays and death.[1,2] These and other factors have contributed to the persistent failure rates in 2–6% of cases, potential loss of reconstruction, and elevated healthcare costs.[3,4] There is increasing demand for an easy, time saving, less damaging but reliable procedure to form vascular anastomoses. This is particularly crucial in trauma, cardiac surgery, and organ transplant surgery where patient survival is dependent on clamp time or warm ischemia time. By decreasing the level of technical dexterity required for anastomosis, pathways to less invasive tool and robotic facilitated anastomosis may become available. Furthermore, development of anastomosis devices that do not require highly skilled hands or lengthy surgical times will allow the possibility of temporary peripheral vessel bypass by minimally trained respondents in times of emergency such as direct combat casualty care.

A variety of vascular anastomosis mechanisms and devices have been pursued.[5] Each anastomosis mechanism

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