Biomedical Innovation Competitor #3

The FB Stent

Presented and authored by Dr. Alim P. Mitha, MD

Video: https://w21cinnovationacademy.com/competitors/#Competitor7

An aneurysm is a balloon off a blood vessel in the brain that could potentially bleed, resulting in devastating consequences for the patient. Brain aneurysms are common, and are present in up to 7% of the general population. Traditional treatment of complex brain aneurysms involves placing a metal "flow-diverting" stent across the neck of the aneurysm, leading to redirection of blood flow away from the aneurysm dome. Bioabsorbable flow-diverting stents have recently been developed by Fluid Biotech Inc. as a novel way to treat brain aneurysms.

Metal stents are permanent, they cannot be removed, and remain in the patient long after their purpose is served. Because of the perpetual risk of clot formation on the metal, patients require lifelong blood thinning medications. Furthermore, the metal can interfere with imaging studies (such as CT and MRI scans), and instead requires more invasive testing called angiograms, which are riskier for the patient and costly for the health care system. The FB Stent allows for imaging with CT and MRI scans, and patients can discontinue their blood thinners once the aneurysm is healed and after the stent dissolves.

The FB stent was developed in the Mitha Lab and has undergone numerous in vitro and in vivo studies to validate its properties. The stent was designed to be a self-expanding stent, similar to existing metal flow-diverting stents, in order to avoid any difference for the neuro-interventionalist in terms of how the stent is delivered to the target lesion. Using the parallel plate test, we have demonstrated the stent to have a similar radial force to existing metal stents, which could otherwise have negative implications on the long-term complication rate. The FB stent has also been deployed in flow models and imaged using MRI, revealing significantly reduced imaging artifacts compared with existing metal stents. Through a collaboration with the University of Toronto and the Toronto Western Hospital, we have also studied the flow diverting properties by deployment of the stent into silastic aneurysm models in pulsatile conditions and imaging the models using high frame rate digital subtraction angiography (DSA). The results of these studies were consistent with aneurysm occlusion over a three month period, which is better than the leading commercially available metal stent. We are also in the process of validating the flow diverting properties using laser particle imaging velocimetry (PIV) through a collaboration with the University of Washington in Seattle. The FB stent has also been implanted into the aorta of rabbits, showing persistent patency of side branches covered by the stent, which is an important indicator of safety. These studies also revealed excellent biocompatibility of our stent, as evidenced by endothelial cell coverage over the stent at one month follow-up. Furthermore, the FB stent has been placed in aneurysm models in both rabbits and pigs demonstrating contrast stagnation within the aneurysm, an indicator of stagnation of blood flow within the aneurysm and a sign of future aneurysm occlusion. Ongoing studies include determination of the in vitro and in vivo absorption pattern, in order to predict the required duration of blood thinner use in patients treated by the stent.

The FB stent is unique in that it is the only dissolvable flow-diverting stent for aneurysms and, to our knowledge, there is no similar stent in the process of being developed. The value proposition of avoiding long-term blood thinning medications, allowing for non-invasive imaging, and restoring the ability of the blood vessel to expand and contract are simply not possible with metal stents; a market opening for a stent with these unique features was confirmed with an international study of neuro-interventionalists and thought leaders in the space. Furthermore, Fluid Biotech has patents pending on this technology, with more being filed.