# A Study on the Design and Development of Vascular Stents


## ABSTRACT

Heart attacks and strokes account for more than 85% of all cardiovascular disease (17.9 million) related deaths worldwide. Atherosclerosis is the primary mechanism leading to the build-up of plaque on the coronary artery's inner wall, restricting the blood flow and causing a heart attack. Coronary artery stenting has emerged as the preferred treatment technique to restore normal blood flow, where a metallic or polymeric stent is used to expand the plaqued artery and then they are left inside the lumen to provide the support until the remodeling is complete.

The research work is taken to develop the bioresorbable polymeric scaffold under the IMPRINT program of the MHRD/ICMR-GOI. Design, fabrication and testing are performed, resulting in a novel polymeric stent design.

Coronary artery disease has been studied to identify the factors related to a stent design, limiting coronary stenting's clinical success. Stents have been classified based on stent technique, design, manufacturing form and fabrication method. Several performance characteristics of stent design, such as radial strength, recoil, dogboning and foreshortening are expressed in engineering terms. The effect of stent design parameters on stent performance is studied using computational (finite element model) and experimental (fabrication and testing) methods.

The influence of stent design variables such as ring amplitude, strut length, strut width and strut thickness on the performance characteristics have been shown through simulation and confirmed through testing. Optimization of any stent design is required due to conflicting requirements. Two polymeric scaffold design variables such as crown radius, amplitude and strut width (Open and closed cell) are optimized to reduce the failure (breakage) during the loading cycle and maximize the radial strength. The scaffold designs are fabricated by laser cutting on the tube and in-vitro testing is performed as per ISO/ASTM standard.

A finite element analysis validated with physical testing is proven to be very efficient and effective in studying and optimizing any stent design compared to costly experiments requiring material, machine and testing apparatus.

The balloon-expandable polymeric scaffold and metallic stent is finally designed and developed as part of the IMPRINT project for an animal trials in the immediate future.



*Keywords: Bioresorbable stent, CoCr stent, FEM, Crimping, Expansion, Radial Strength.*