The importance of developing or formulating a most suitable material in the success of a project cannot be overemphasized. Plasticised poly (vinyl chloride) (pPVC), the most important material in the biomedical field, is at the crossroads. Migration of plasticizer into the body fluids from pPVC during its service life and the environmental pollution after its service life has prompted the scientific community to look for other materials to replace pPVC. This study has been undertaken in this context.

The first part of the study has been to reduce the plasticizer (DEHP) extraction and thus to make plasticized PVC less troublesome. For this end three polymeric plasticizers namely NBR, ENR and XNBR were tried to partially replace DEHP. PVC/NBR has been found to be the most promising material due to its good mechanical properties and reduced leaching of DEHP compared to PVC/ENR and PVC/XNBR. Further, PVC/NBR system was found to be nontoxic in the preliminary toxicity evaluation by in vitro cytotoxicity studies. But limitations of the system were the reduction in gas permeability and the increase in water vapour transmission rate. These limitations may affect the long-term storage of biological fluids especially the platelet concentrate in the system. However, PVC/NBR system is definitely superior to plasticized PVC for other applications like medical tubings where the permeability is not an important criterion.

The second part of the study has been to explore the possibility of completely replacing pPVC. For this, a novel polymer, metalloocene based polyethylene (mPO), was chosen as the base material. As per the literature, this class of materials has superior mechanical properties and better transparency than conventional polymers due to its narrow molecular weight distribution and has been projected as a potential candidate in the biomedical field. Even though many applications have been identified for these materials, its use in the medical field is not seriously explored. One potential polymer from this group was selected for our studies based on the mechanical properties. The material was evaluated by measuring properties like mechanical...
water and gas permeabilities, transparency, preliminary toxicity, blood clotting time test etc. mPO was found to be superior to pPVC and EVA (the conventional materials used for medical applications) in mechanical properties and resistance to water permeability. But mPO was found to be inferior to pPVC and EVA in gas permeability as well as compatibility with blood. In order to overcome these limitations mPO was modified with EVA. The modified material was found to be superior to pPVC in mechanical properties, resistance to water permeability and swelling, transparency and had almost comparable contact angle and oxygen and carbon dioxide permeability characteristics. To find the effect of sterilization, the modified material was subjected to gamma radiation. The effect of gamma ray sterilization on the blend was evaluated by comparing the technical properties before and after sterilization.

A mPO/EVA12 was found to be promising candidate for replacing pPVC and was subjected to the preliminary toxicity evaluation by in vitro cell culture cytotoxicity tests. The material mediated toxicity and the toxicity due to leachables were evaluated by the ‘direct contact’ and ‘test on extract’ test methods. The in vitro cell culture cytotoxicity studies using mouse fibroblasts cell line (L929) showed that the modified materials were non-cytotoxic to the L929 cell line. The modified material was further evaluated for its biological performance with blood. In vitro blood compatibility analyses like Haemolysis, Cell adhesion and Clotting time were performed according to the methods recommended as per ISO-10993 for blood-material interactions. The analysis for haemolysis showed that the modified material had low haemolytic potential compared to pPVC which indicates that the modified material causes less cell wall lysis or less damage to blood cells compared to pPVC. The clotting time test showed that the modification of mPO with EVA enhanced the clotting time. The increase in clotting time of the modified sample, AE1225 makes it superior to pPVC. The cell adhesion test was carried out as per the International Standard ISO-10993-4: 2002 using the blood from human volunteers. The percentage platelet count reduction in the medium was analysed. A higher platelet count reduction in the medium of mPO indicated higher adhesion of platelets on to mPO surface. But the modification of mPO with EVA reduced the adhesion of platelets onto the surface. Also the modified sample showed a less platelet adhesion compared to pPVC. In the case of leukocytes, red blood cells, the adhesion was found to be less on to the virgin as well as the modified sample surfaces compared to pPVC. So this system is found to be superior to pPVC in biological analysis also.

The study shows that PVC/NBR and mPO/EVA blend are suitable for short term blood contact applications and the latter for long term application too. mPO/EVA system can be used for the complete replacement of pPVC.