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Development and *in vivo* evaluation of a copper IUD coated with a biodegradable polymer

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Copper intra uterine devices represent an important contraceptive option for nearly 160 million women worldwide. The main attraction of copper IUD is that it is comparatively less expensive and highly effective (99%) over other long term methods of contraception. Major side effects related to a copper bearing IUD are increased menstrual bleeding, cramping and abdominal pain. Research results showed that this is due to the high corrosive rate during the first few months of insertion. In the present study, PLGA films having proper degradation period were prepared by extrusion method which could prevent initial bulk release of copper ions from a copper intra uterine device, leading to increased efficacy and acceptability. Based on our experiments, we proved that PLGA film with thickness 0.1±0.02 mm coated over the copper Intra uterine device is safe and effective in controlling copper ion release in the required level of contraception. The biodegradable polymer coated copper T (Coated CuT) has been characterized and intracutaneous irritation studies showed that coated CuT is a non irritant and non sensitizer. The results of acute systemic toxicity study suggested that coated CuT did not induce any toxic symptoms till the end of the experimental period and there was neither development of gross abnormalities nor pathological lesions observed in any of the tissues during the histopathological evaluation. Hence, the novel device meets the requirements of the standard practices recommended for evaluating the biological activity for implantable devices. A randomized multicenter clinical evaluation of the device is in progress on 100 subjects in India.

Biography

Abi Santhosh Aprem has completed his PhD from Mahatma Gandhi University, Kottayam, Kerala, India. He is currently the Deputy Vice President of Corporate R&D Centre of HLL Lifecare Ltd. He has published more than 26 papers in peer reviewed journals.

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