Conclusion

Contraception prevents unwanted pregnancies and provides better family planning and health care. Convenience, safety, efficacy, and cost as well as the quality of life are usually the concerns in choosing a contraceptive, and these very factors motivate the development of newer and better contraceptives. There is a pressing need to develop a non-hormonal, biocompatible, non-invasive, cost-effective, biodegradable, and convenient device to prevent pregnancy and infection without interfering with sexual relations. The success rate of a contraceptive depends not only upon the efficacy of the contraceptive method, but also upon the users' preference, reversibility, convenience, and compliance. Besides pregnancy, sexual relations can also result in infection. It is thus beneficial that the design of newer contraceptive devices should also consider the option of protecting women not only against pregnancy but also against transmission of sexually transmitted diseases (STDs). The new contraceptive devices could be free of hormones and toxic compounds and should allow women to insert by themselves in
conjunction with normal management of their menstrual cycle month after month, thus enhancing the quality of life. One of the recommendations made by the Committee on Contraceptive Research and Development in 1996 was to identify agents that are spermiostatic rather than spermicidal, modify mucus secretions from cervical epithelial cells to prevent sperm penetration and are anti-microbial and anti-viral. With current interest in the delivery of steroids as a contraception method and during post-menopause via non-biodegradable, hormonal intravaginal rings, it is innovative to create a biodegradable, non-hormonal and biocompatible intravaginal ring that acts locally and avoids a systemic route to deliver contraceptive agents. The new device could also carry anti-STD agents, since N9 spermicides are not available. Many women depend on them. Thus the development of BioRing is timely and has innovation and significance for women’s health care.

Studies presented lead to the conclusion that biodegradable hydrogels impregnated with L-ascorbic acid, ferrous gluconate and Ampholine could lead to the development of a non-hormonal and biocompatible intravaginal contraceptive device. However, further improvement of the hydrogel and comprehensive pre-clinical studies are necessary prior to use in women. The hydrogel also has a potential as a delivery system for anti-STD, and anti-HIV agents as well as drugs to treat pelvic diseases. Such devices will act locally and minimize adverse systemic effects. The hydrogel composition could be chosen to last for the period, up to one
month, as required by the user. Further, the gel could be used additionally as a spermicide inside a condom.

The contraceptive ring in development has taken into account many considerations and strives to deliver quality and effective protection from pregnancy, while not compromising comfort, ease, and peace of mind and body.

In view of the lack of toxicity and biocompatibility of the components used in the intravaginal device (ferrous gluconate, ascorbic acid, and polyamino-polycarboxylic acid), which have already been approved individually by the FDA, no additional safety data in humans is considered necessary. It will thus not be necessary to go through the IND or NDA process. The total month’s supply of iron in the ring is less than what is proven to be toxic in humans. Thus even if all the iron was somehow absorbed immediately from the ring, rather than over a 28-day period, the amount would still not be harmful. Moreover, the iron will be useful to these women of child-bearing age because they lose iron monthly through menstruation. Furthermore, the vitamin C in the ring will help the woman to absorb this beneficial iron.

The biodegradable, biocompatible, noninvasive hydrogel ring can also have uses independent of non-hormonal contraception. Filled with antimicrobicides, the ring could be used solely as protection against
STDs and/or HIV. In this capacity, the ring could be created for 1-day, 1-week, or month-to-month use.