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Review article

New frameless and framed intrauterine devices and systems — An overview☆

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Abstract

There is a need for new, improved birth control methods which are easier to use, with less side effects and which avoid daily action, such as the pill. Perfect use requires consistent daily use or use at every act of intercourse. Long-acting methods eliminate the need for specific action at the time of coitus, or for daily action.

Developing a new contraceptive is a major challenge. It is generally estimated that it takes 10–15 years to develop a new method and bring it to the market, at a cost of US$200–300 million, and the industry is reluctant to take the risk of such long-term investment. However, both risk and investment can be reduced by taking small steps. Slight improvements of existing contraceptives could result in a giant step forward.

The development of frameless intrauterine systems (IUS) is an attempt to improve the performance and acceptability of intrauterine contraception. Both the frameless GyneFix® IUD and the frameless FibroPlant levonorgestrel (LNG)-IUS possess features which may solve the main problems encountered with conventional IUDs (e.g., expulsion, abnormal or excessive bleeding and pain). The performance of frameless devices, however, is dependent on correct anchoring of the device, which requires technical skill. Becoming a proficient GyneFix® or FibroPlant provider is easily acquired if the provider follows the procedural instruction strictly. For the less technically skilled provider, the Femilis™ LNG-IUS, using the new, simplified insertion technique, could be an excellent contraceptive option.

It is usually not necessary to provide pain relief for insertion of an IUD/IUS, particularly in parous women. IUD providers should, however, realize that no woman likes to suffer from the insertion of an IUD. Severe discomfort may create a negative attitude towards the method. If the woman is anxious and fears pain (as most nulliparous women do), probably the most convenient, safe and effective method is to use local (intracervical) anesthesia using a dental syringe which can be applied with minimal risk in the office. In some women, the use of misoprostol 400 μg, 3 h prior to fitting of the IUD/IUS, may be useful to dilate the cervical canal. The popularity of the IUD could be much improved if attention is given to this aspect of IUD insertion.

Keywords: Frameless; T-shaped; Intrauterine devices; Intrauterine systems; Copper; Levonorgestrel

1. Introduction

There are several long-acting contraceptive methods that are safe and minimize the risk of unintended pregnancy. These are copper intrauterine devices (IUDs), progestin-only intrauterine systems (IUSs), progestin-only injectable contraceptives, progestin-only subdermal implants and estrogen-progestin combined vaginal rings. Intrauterine methods are safe contraceptives. With nearly 160 million users, the IUD is the second most popular contraceptive method worldwide after sterilization. Much of the popularity of the IUD stems from its efficacy, combined with its long duration of action. Intrauterine contraception is also the most cost-effective reversible method of contraception today [1]. New generation, miniature copper and hormone-releasing intrauterine methods are available for trouble-free contraception for women of virtually all ages, including young women who do not have children yet; for contraception and treatment of excessive menstrual bleeding; and for other frequently occurring gynecological problems.

The development of frameless copper IUDs started in 1985. The first frameless copper IUD was approved in the European Union in 1995 and is currently marketed in Europe

☆ Competing interest: Dirk Wildemeersch is a Belgian gynecologist and Medical Director of Contrel Research, a company which was established to manage clinical research and to develop and study innovative drug delivery technologies. Contrel is the manufacturer and patent holder of the GyneFix®, FibroPlant and Femilis™ intrauterine systems.

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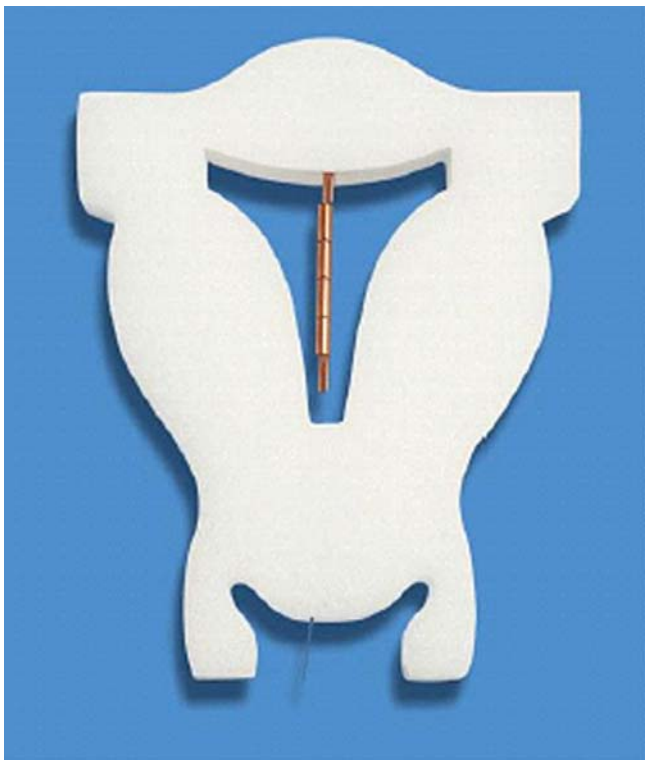

Fig. 1. GyneFix® 330 IUS.

and China. The frameless levonorgestrel (LNG)-releasing IUS, under development since 1997, and the framed, T-shaped LNG-IUS, developed since 2002, are currently in the last stage of clinical testing. The first LNG-IUS (Femilis™, see below) was recently approved for marketing in Mexico.

The purpose of this paper was to provide an overview of the clinical aspects of these devices and systems in randomized and nonrandomized comparative clinical trials.

2. Frameless IUDs and IUSs

2.1. Background to the development of frameless IUDs and IUSs

Uterine cavities differ considerably in size and shape in all women, and the uterus is subject to changes in size and volume during the menstrual cycle [2,3]. These changes are most pronounced at the time of menses. It is therefore unreasonable to expect one standard-sized IUD/IUS to fit uterine cavities with different sizes and volumes. Clinical experience has shown that incompatibility between the IUD/IUS and the uterine cavity can lead to partial or total expulsion of the IUD/IUS, pain, unintended pregnancy (due to partial expulsion) and abnormal and heavy uterine bleeding leading to removal of the device. The Lippes Loop, developed in the 1960s, had a high discontinuation rate because of side effects caused by its large surface area and size. Another major development was the smaller TCu200 and later the TCu380A which benefited from the discovery of copper as a potent antifertility agent [4]. As a consequence, the size of the plastic frame could be much reduced. It seemed logical that the T-shaped design would cause less distortion of the endometrial cavity. Although incompatibility problems and the effect of the TCu380A IUD on menstrual bleeding are significantly reduced compared to the Lippes Loop, bleeding, pain and expulsion problems still occur and there is, therefore, room for improvement [5]. For these reasons, the frameless copper-releasing GyneFix® IUDs and the frameless FibroPlant LNG-IUS were developed.

3. GyneFix® 330 and GyneFix® 200 copper contraceptives

3.1. Description

The GyneFix® 330 IUD (Fig. 1) consists of six copper sleeves (standard version) or four copper sleeves (small version or GyneFix® 200; Fig. 2), each 5 mm long and 2.2 mm in diameter, threaded on a length of polypropylene suture material. The sleeves are prevented from sliding off the material by the upper and lower sleeves, being crimped onto the thread. The proximal end of the thread is provided with a knot which, at insertion, is placed in the fundal myometrium with an inserter for anchoring the device. The total, effective surface of copper, including the inner and outer surfaces, is 330 mm^2 for the standard version and 200 m^2 for the small version. This implant device has no plastic body, making it a completely flexible unit.

It should be noted that the GyneFix® IUD is different from conventional copper IUDs, which have a copper wire

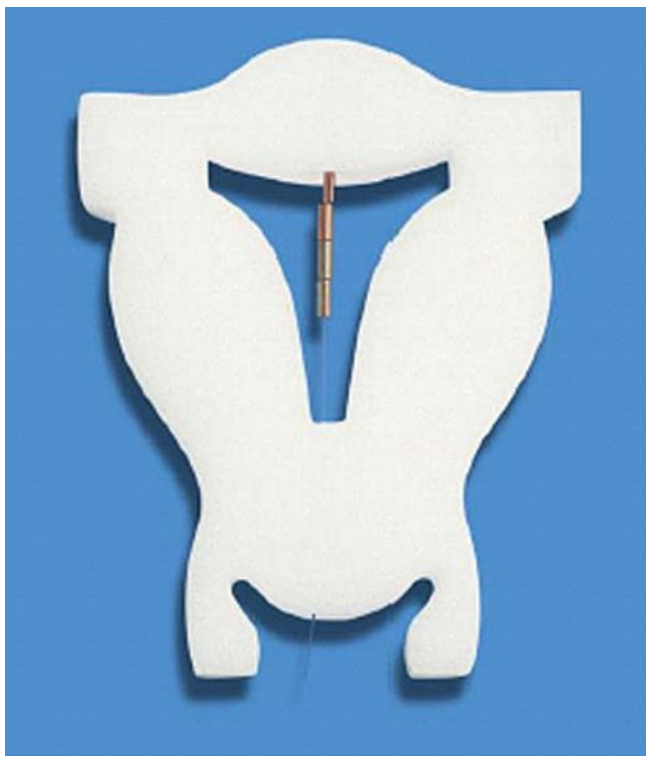

Fig. 2. GyneFix® 200 IUS.