The scientific justification for the use of pelvic floor meshes has been based on studies with small numbers of patients and a short follow-up. After the initial rapid rise in popularity of various pelvic floor meshes, frequent reports began to appear about complications, some of which were serious. In the United States, their risk class assignment was thereupon adjusted (pelvic floor meshes from class II to class III and pelvic floor mesh kits from class I to class II).? Gynaecologists, especially those in the US, initially assumed without sufficient proof that the use of meshes in abdominal wall surgery was directly comparable to pelvic floor surgery. The fact that vaginal use of meshes cannot be compared to their abdominal use, e.g. to treat inguinal hernias, argues for initiating new studies into vaginal applications. The large-scale introduction of these interventions after just one favourable publication in 2004 has various causes, including the high recurrence rate after conservative treatment. In view of the limited evidence and the insufficient evaluation structure, however, it is not surprising that the risks of transvaginal surgery using pelvic floor meshes were underestimated. Subsequently, it took too long before these risks were recognised and addressed, compromising the health of some of the patients.

Registration of pelvic floor meshes has been made compulsory in the Netherlands, initially by the Dutch Society of Obstetricians and Gynaecologists (NVOG) and later on also by the government. A thorough registration procedure requires sufficient funding. One suggestion has been to include the cost of registration in the medical expenses to be covered by patients or their insurers. Registration procedures will yield more long-term data on pelvic floor mesh surgery.

The low numbers of pelvic floor meshes that are being implanted indicate that few of the gynaecological surgeons are able to meet the requirements made of them. This means that centralisation is inevitable.

Another major problem is that of the public opinion, which is generally opposed to pelvic floor meshes. Negative publicity and the high costs of legal proceedings, especially in the US, are hampering the further development of transvaginal pelvic floor mesh surgery. Sound research is lacking and will not be initiated as long as profit expectations for manufacturers of pelvic floor meshes remain too low.

A 2016 systematic review study in the Cochrane Library allows the conclusion that transvaginal pelvic floor surgery using non-absorbable meshes is effective for a selected group of women, especially for those with a recurrent prolapse, but does carry risks. It is important that women are fully informed of the advantages and disadvantages of a permanent transvaginal pelvic floor mesh, so that they can decide, in consultation with a pelvic floor specialist, whether to undergo this intervention or not. The limited follow-up duration of the studies carried out so far remains a major issue. Setting up well-designed, preferably randomised studies requires large numbers of patients and sufficient funding.

Since many of the transvaginal pelvic floor meshes that were the subjects of studies in the past have been taken off the market, few meshes are now available. A recent survey showed that four different pelvic floor meshes were available in the Netherlands (table 3), while one of the manufacturers refused to provide information on their product due to ongoing claim procedures, especially in the US.

After the introduction of transvaginal pelvic floor meshes, various serious complications have emerged. One reason why these incidents could happen was the lack of satisfactory registration requirements, insufficient surveillance of production, and inadequate reporting of adverse effects and long-term efficacy. By now, some measures have been taken to prevent further problems, but unfortunately only after practice had shown that the cure was sometimes worse than the disease.
References


42. Davila GW, Baessler K, Cosson M, Cardoza L. Selection of patients in whom vaginal graft use may be appropriate: Consensus of the 2nd IUGA Grafts Roundtable: optimizing safety and appropriateness of graft use in transvaginal pelvic reconstructive surgery. Int Urogynecol J. 2012;23 Suppl 1:7-14.

45. Website ‘Meetbaar beter’. Via: http://www.meetbaarheter.com

*The literature refers to the Dutch text.