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Original Research

Registry of implants for the reconstruction of pelvic floor in males and females: A feasibility case series

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HIGHLIGHTS

- A new web-based registry for the evaluation of implant assisted surgery for POP and SUI in males and females is presented.
- The presented case series show the feasibility of the registry with the need for indication based evaluation.
- The maximum score of cure was reached by 25–100% of patients depending on the indication.
- The preliminary results support the initiation of prospective registry according to IDEAL.

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ABSTRACT

Introduction: Most aspects of implant-assisted reconstruction of pelvic floor in males and females are under debate and the research is not standardized. Registries are supposed to shed light to the indications, surgical techniques and material properties and to establish a standardized evaluation.
Methods: A working group was formed to create an online platform for registration and outcome measurement of implant-assisted operations for pelvic organ prolapse (POP) and female and male stress urinary incontinence (SUI). 20 patients with modified mesh materials were evaluated over 23 months

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follow up in the registry to prove the feasibility of the registry. For validation a previously published modified "satisfaction, anatomy, continence, safety – S.(A.)C.S score" was used.
Results: A consensus was met on definitions and classifications of patient variables, surgical procedures and implants, as well as outcome parameters (efficacy, continence, satisfaction, complications). Different subgroup modules were formed in accordance with treated condition. The maximum score of cure was reached by 25–100% of patients depending on the indication.
Conclusion: A prospective registry in accordance with IDEAL-D framework is justified for the evaluation and regulation of implants for pelvic floor reconstruction.

Abbreviations

EDTA	Ethylenediaminetetraacetic acid
EuraHS	European Registry for Abdominal Wall Hernias
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GeSRU	German Society of Residents in Urology
ICS	International Continence Society
IDEAL	Idea, Development, Exploration, Assessment, Long-term
IUGA	International Urogynecological Association
PGI-I	Patient Global Improvement Inventory
POP	Pelvic organ prolapse
POP-Q	Pelvic organ prolapse quantification
PROM	Patient Related Outcome Measures
QoL	Quality of life
RCT	Randomized Controlled Trial
S.A.C.S.	Satisfaction Anatomy Continence Safety
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SUI	Stress urinary incontinence
TOT	Transobturator Tape
TVT	Tension-free Vaginal Tape

1. Introduction

To reduce the risk of recurrence, mesh-assisted repair of the pelvic floor has been introduced since the 1990's. First official approval of meshes by the Food and Drug Administration (FDA) dates back to 2003. To legalize the application of various prolapse and incontinence meshes the FDA approved a premarket equivalence notification 510(k). No clinical testing was demanded for the approval. In the last decade, the growing number of mesh operations and various presumed easy-to-use mesh kits from various manufacturers led to a widespread application of this outpatient surgical method [1,2]. Less attention was paid to possible new complications and only a few clinical trials were available prior to product approval and application [3,4].

Several FDA warnings from 2008 to 2016, reported on significant number of serious complications after the application of vaginal meshes or slings for POP and SUI repair. They proposed a higher risk-class for the approval of these medical products [2,5]. FDA reported mesh related complications including chronic pain, mesh infection, dyspareunia and long-term complications (mesh erosion and shrinkage), which were not analyzed in available studies. First, there was almost no reaction of the industry and surgeons to these warnings. Meanwhile, many manufacturers are confronted with a total of more than 100.000 law suits [6]. The consequence was a decrease of up to 40–60% implant-assisted operations mostly in the USA and this trend spills over into Europe and other continents [7]. Moreover, FDA released another announcement in 2016, demanding clinical trials prior to application of vaginal meshes for prolapse surgery. Otherwise, the products would be abandoned from market approval in the USA [5]. The scientific societies reacted and proposed a cautious application for alloplastic materials. Standardized classification of mesh related complications was proposed by International Continence Society (ICS) and International Urogynecological Association (IUGA) [3]. European Commission assigned the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) to clarify the safety of surgical meshes in urogynecology. The current release notifies the insufficient scientific data and proposes a better education and the conduction of long-term trials, guidelines and registries (http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scenihr_consultation_27_en.htm) (last access 25.07.2016).

An outstanding example for the evaluation and regulation of surgical products and techniques is the IDEAL system of surgical innovation, which proposes an adequate Good Clinical Practice (GCP) - similar process of evaluation and approval of surgical techniques and medical devices. The method was initially described 2009 by Peter McCulloch and includes 5 consecutive steps of innovation: preclinical stage (Stage 0), idea (Stage 1), development and exploration (Stage 2), assessment (Stage 3) and long-term follow up (Stage 4) (Fig. 1) [1]. An IDEAL-D(evice) framework on the evaluation of medical devices has been published recently [8].

Herewith, we present the first application of IDEAL-D framework for the evaluation of urogynecological implants. A case series with an early registry is introduced to prove the feasibility of IDEAL-D system. The registry includes all implants for male and female incontinence and female prolapse surgery.

2. Materials and methods

2.1. Expert panel

Based on the successful implementation of surgical hernia registries, German quality assurance system and registry for hernia surgery (Herniamed) and European registry for abdominal wall hernias (EuraHs), a working group was formed to create an online platform for registration and outcome measurement of operations with application of implants for POP and SUI repair. Development of the registry involved reaching agreement on clear definitions and classifications of patient variables, surgical procedures and implant materials used, as well as outcome parameters, the triple P-triangle of pelvic floor reconstructions (Fig. 2) [9]. The working group comprised of an interdisciplinary expert panel under auspices of the German Society of Residents in Urology (GeSRU) and the Study Group for Urogynecology and Plastic Pelvic Floor