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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

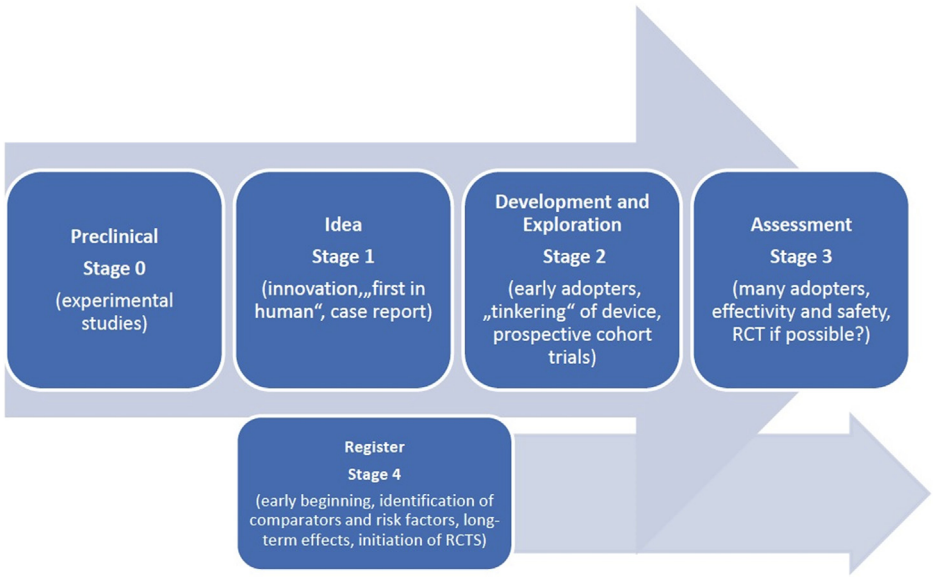

Fig. 1. IDEAL-D framework of the evaluation and regulation of medical devices [8].

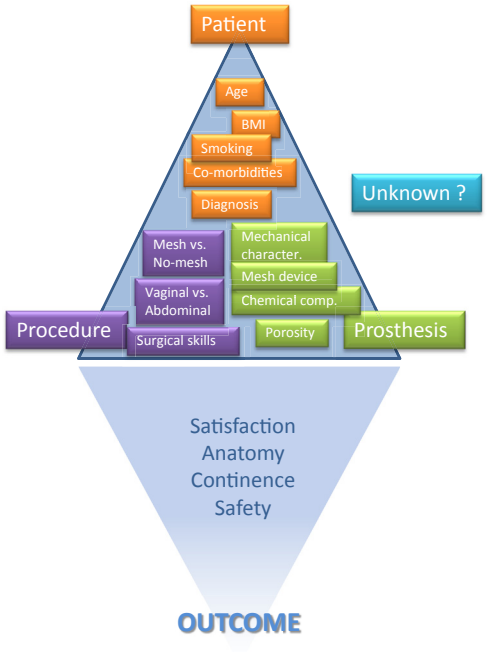

Fig. 2. The triple P-triangle of pelvic floor repair, adopted from EuraHS [9].

Reconstruction (AGUB) of the German Society for Gynecology and Obstetrics. Over several working group meetings, consensus was reached on ICS and IUGA - based definitions and parameters for the data to be recorded in the registry [10]. Existing classifications were used where possible. However, many variables have been described, defined and classified by the working group.

2.2. Registry

The scope of the registry will include all surgeries for SUI and POP repair with application of implants: vaginal and abdominal meshes, female and male slings, artificial sphincter, reconstructive surgery with alloplastic materials. Adult male and female patients older than 18 years should be included. The database will be used on a voluntary basis. A stratification of users will be offered. A Level 1 user will only have a small number of compulsory data fields to complete the registration of a case. These data will involve the variables needed for classification of incontinence and pelvic prolapse, the surgical technique and the materials used during the repair. Uploading a case should only take a few minutes. A Level 2 user will have the availability to complete a more comprehensive number of variables including detailed medical history, risk factors, detailed information on surgical technique and complications.

The surgeon uploading a case using his or her account will be the owner of the data. Various statistical analyses can be started from the web interface. The users will be able to extract their data in tables and in diagrams. Acknowledgement of the database as the source of the data has to be made every time it is used in public or in publications. However, the registry will not contain personal data like names or date of birth and will thus be completely anonymous. The link between the registration number and the patients' identity and the regular follow up 6 weeks, 6 months and annually after the initial surgery will be the responsibility of the user. To simplify the follow up, patients and referring physicians will be interviewed by telephone or mail. Additionally patients will be provided with implant identity cards. Pop-up windows with explanations of definitions, figures etc. are available on the platform. A registry logo is agreed upon and a website (http://winc030.informatik.uni-wuerzburg.de:8080/) with access to the database is provided (Fig. 3). The online platform for the registry was developed at the department of Artificial Intelligence and Applied Informatics, part of the Institute for Mathematics and Computer Science, at the University of Würzburg in Germany, under the supervision of Prof. Dr. Frank Puppe. The data were stored at the secured server area. A test-phase on the performance of the platform has been conducted by the working group members from October 2015 till March 2016. The work has been reported in line with the PROCESS criteria [11]. Additionally the study was registered at Research Registry, registration number researchregistry1149.

2.3. Ethics

All procedures performed in this study were in accordance with

Fig. 3. Logo of registry of urogynecological implants.

the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. An ethics committee vote is not necessary for this feasibility study, as a retrospective design was chosen to present the details of registry formation.

2.4. Patients

After obtaining corresponding informed consent, the first 20 patients (16 females and 4 males) with the application of a modified mesh-assisted SUI and POP repair have been evaluated as a consecutive case series and included in the registry. A retrospective study design was applied to evaluate the feasibility of the registry. Different mesh materials were used (TVT®, Seratim®, Ultrapro®, Vitamesh®) and were all modified by a new technique with preoperative surface coating with autologous plasma [12]. The technique has been evaluated previously in accordance with preclinical IDEAL stage 0 [13]. For the purpose of implant coating, 20–40 ml blood sample were obtained in the EDTA-tube (Ethylenediaminetetraacetic acid) from the respective patient by vein puncture before the induction of anesthesia and the clear supernatant (plasma) after centrifugation of the precipitation was removed with sterile syringe. Before the implantation the meshes were incubated for 30 min with 10–20 ml (depending on the size of the mesh) autologous plasma. The surgical technique was not altered by the application of this technology. The patients were examined pre- and postoperatively and interviewed before the operation and on telephone or per email after the operation.

2.5. Outcome evaluation

In reporting the goals of the surgery a previously published, practicable and timely S.A.C.S. score was adopted and used 24 months after the initial prolapse surgery, for the evaluation of male and female incontinence a modified S.C.S. (satisfaction–continence–safety) - score was used [14]:

– *Satisfaction*: to test patient's perception of success and the subjective measure of satisfaction, we used the validated version of Patient Global Improvement Inventory (PGI-I) scale. The surgery was defined as successful, if the patient felt “much better” or “very much better” after the surgery. Value = 1.

– *Anatomy*: to verify anatomical success of POP surgery, we used the POP–Q, which refers to an objective, site-specific system for describing, quantifying, and staging pelvic support in women. According to the POP-Q, we used very stringent criteria for the definition of complete success (the absence of any ≥2 stage prolapse). This parameter was only used for female POP evaluation. Value = 1.

– *Continence*: for the definition and grading of postoperative continence, we administered the validated ICIQ-SF2004 questionnaire, post-operative pad use and the Ingelman-Sundberg scale (score 0–3); for the score, we considered a complete success the absence of any degree of urine leakage and the use of no pad or only a protective pad. Value = 1.

– *Safety*: to analyze the safety of the procedure, we used the ICS/IUGA and Clavien–Dindo-classification of surgical complications (score 0–5) [7,15]. The absence of perioperative or delayed revision surgery due to a complication except for intraoperative bladder perforation (commonly not assumed as a severe complication) was defined as success. Value = 1.

Each component of the scoring system produced a binary nominal categorical variable (1 or 0). Perfect scoring systems, according to the S.(A.)C.S., were defined as the sum of satisfaction (plus anatomy) plus continence plus safety, with a total score of 4 for POP and a total score of 3 for SUI representing a ‘cure’. The degree of concordance among these scores was estimated using Cohen's kappa test of inter-rater agreement (with k-values ranging from 0 to 1).

3. Results

All pelvic floor reconstruction surgeries with application of implants like abdominal and transvaginal mesh or biological materials, male and female sling, and artificial sphincter were included and different modules were created. A set of well-described definitions, risk factors for recurrences and complications was listed. A comprehensive information on management strategies for complications can be provided by the user in Level 2. An online platform with statistical analysis was established, which can be used by individual surgeons, teams or for multicentre studies. The questionnaires were evaluated for the perioperative data of the first 20 patients. The first results showed the feasibility and the timely application of the registry. The data was entered by 3 different users, all Level 2 with minimum 2 follow ups after the initial implantation. All follow ups were done by telephone interview, a form of patient related outcome (PROM). The data on postoperative anatomy outcome was retrieved from referring physicians. The mean time for the data input (Level 2, extended) in the database was 18 min (range 12–26).

Between 04/2013 and 05/2014, 20 patients (16 females and 4 males) with the indication for SUI and POP repair with mesh graft were selected for surgery in a single institution. The mean age was 67 years (45–85) and the mean follow up was 23 months (17–29). 11 patients were treated for SUI (grades II-III, Stamey score) and 9 patients were treated for POP (POP-Q grades II–III, anterior and apical prolapse).

Three reoperations (15%) were needed due to complications (2 postoperative obstructions after TVT-procedure, 1 abdominal hernia 12 months postoperative after abdominal sacrocolpopexy). No other severe complications (mesh exposure, bladder or bowel injury, and fistula) were registered. Two reoperations (10%) were needed for persisting incontinence or prolapse (Table 1).

According to the S.(A.)C.S. scoring system, only 13 patients (65%, Table 1) reached the cumulative perfect score of 3 for SUI or 4 for POP at 24-month follow-up: high PGI-I score, no residual prolapse ≥2 according to the POP-Q staging system, no pad use (or no more than one protective pad), and no grade >2 complication nor delayed surgery related complications. However, significant differences between the procedures could be found with maximum 100% for anterior vaginal mesh vs. 25% for TOT male incontinence surgery. The highest agreement with S.(A.)C.S. score was reached for the satisfaction component of the score (Cohen's $\kappa = 0.88$).

Table 1
Classification of complications and S.(A.)C.S. score [14].

Procedure	TVT	TOT	Ant. Vag. mesh	Sacropexy	Total	IUGA/ICS-class.
Number of patients (gender)	7 (female)	4 (male)	1 (female)	8 (female)	20	
Complications, number (%)						
Clavien-Dindo Grade I						
Prolonged pain	0	1 (25%)	0	1 (12.5%)	2 (10%)	6Bd T2 S3/S4
Hematoma	1 (14%)	1 (25%)	0	0	2 (10%)	7A T2 S2-S4
Urge de Novo	3 (43%)	1 (25%)	0	0	3 (15%)	4B T2
Obstructive micturition (prolonged catheter)	1 (14%)	0	1 (100%)	0	2 (10%)	4B T2
UTI	2 (28%)	0	0	2 (25%)	4 (25%)	4B T2
Clavien-Dindo Grade II Wound infection	0	0	0	1 (12.5%)	1 (5%)	6Cb T2 S4
Clavien-Dindo Grade Grade III						
Obstructive micturition	2 (28%)	0	0	0	2 (10%)	4B T2
Hernia	0	0	0	1 (12.5%)	1 (5%)	6Bd T3 S5
Reopeartion for SUI/POP	0	1 (25%)	0	1 (12.5%)	1	
Clavien-Dindo Grade Grade IV-V	0	0	0	0	0	
S.(A.)C.S score						
Satisfaction	6 (86%)	1 (25%)	1 (100%)	6 (75%)		
Anatomy	na	na	1 (100%)	6 (75%)		
Continence	7 (100%)	1 (25%)	1 (100%)	8 (100%)		
Safety	5 (71%)	4 (100%)	1 (100%)	7 (87%)		
S.(A.)C.S score 4	5 (71%)	1 (25%)	1 (100%)	6 (75%)	13 (65%)	
S.(A.)C.S score 1–2	2 (14%)	3 (75%)	0	2 (25%)	7 (35%)	

na, not applicable

4. Discussion

A restart for the application and indication of alloplastic materials for pelvic floor reconstruction and standardized quality trials are needed urgently. We need to know the quality of our surgeries and educate the patients properly about possible complications. Mesh-related complications like erosion, exposure, infection, pelvic pain and mesh shrinkage should be considered and risk factors should be identified [3]. However, there is a number of late mesh-related complications, so that a long-term follow up is important for a proper evaluation of the procedure [16].

There are several reasons for the preliminary fail of the implants in urogynecology. Different modifications of a surgical technique, indications and follow up are not standardized. The main problem is the approval of medical products. The pharmacological studies are regulated by strict rules requiring phase I-III studies according to GCP. The medical products are less strictly regulated and can get approval without quality studies [1,6]. However, the difficulty is to evaluate medical devices with a clinical study. It is possible to look for a correlation between the medicament and a symptom in a pharmaceutical trial. In contrast, the result of a surgical procedure depends on many different factors. Thus, numerous subgroup and multivariate analyses with large patient cohorts would be necessary. Randomized clinical trials (RCT) remain the source of the best evidence for pharmaceuticals. In contrast, they are not always practicable for medical products. In a RCT, the randomized controlled variable is just one out of many. The long delay from surgery to the development of many complications such as recurrence and the impossibility to control all relevant parameters can hinder proof of the significant impact, in particular, when studying slight modifications of techniques or materials.

A functional solution with a simple approval of medical products without restrictions concerning the products efficacy and the safety of patients is obviously required. IDEAL-D is a simple and practicable system for the evaluation of medical devices. Surveillance by registries from small series would be an important part of IDEAL and would allow opportunities for using risk adjustment techniques to analyze large registry datasets to study small or long term effects in situations with multiple confounders, in which a randomized trial might be infeasible [8]. However, projects like IDEAL are still at their beginning and consensus on key outcomes (e.g. functional results, scope and severity of complications) as well as contextual factors (e.g. grading of patient risk factors, severity of comorbid pathology or general health, details of surgical technique and perioperative setting) will need consensus among specialist communities and specialities as well as journals in order to standardize reporting accordingly.

A registry allows the detection of poor and good results, if they appear more frequently than expected. Surgical hernia registries in general and national registries, like the Swedish TVT database and the Austrian TVT database have been previously successfully established and improved the quality of surgery after the implementation [17,18]. However, the Austrian registry was timely limited and Swedish registry is obligatory and under auspices of the government. The Austrian and Swedish models are not transferable to other bigger countries. Hereby, we confirm the feasibility of the presented registry with the possibility of timely and effective data entry. Further, we adopted a previously published simple score system to evaluate the surgical technique for POP and SUI repair. The 4-point S (satisfaction), A (anatomy), C (continence), S (safety) - score was presented by Mearini et al. to evaluate 233 women 24 months after open sacrocolpopexy [13]. The authors detected the sensitivity of 74.1%, the specificity of 90% and a total diagnostic capacity of 75.5% for the new score. According to the S.A.C.S. scoring system, only 160 patients (68.6%) reached the maximum score of cure in the above mentioned study. We applied the score for female POP implant surgery and modified it for female and male SUI implant surgery and used here a simplified S.C.S. score for evaluation, as the anatomy cannot be considered. In our collective, 13 patients (65%, Table 1) reached the cumulative perfect score of 3 or 4 at 24-month follow up, these results are similar to the data of Mearini et al. and were stable after 24 months. We found as well a strong agreement of the score and satisfaction. However, an internal validation was not applicable due to a heterogenic and small patient collective.

The main limitation of this study is the inclusion of male and female with different POP and SUI methods, which should be evaluated on each own. Further statistical analyses like logistic regression to analyze the possible risk factors for the outcome were not applicable due to small patient numbers. Another problem is the future interpretation of the results. Less than 70% of the whole group reached a perfect S.(A.)C.S. score, in the male SUI group only

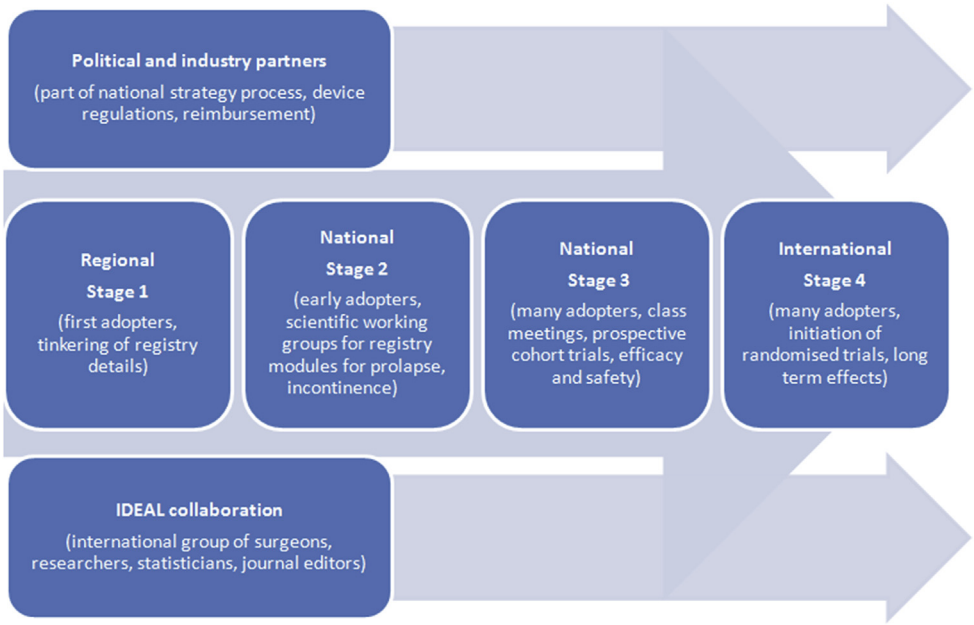

Fig. 4. Registry expansion process.

25%. Predetermined lowest score rates (cut-off) are necessary for the future to decide which procedure or implant does not meet the quality standards. Another limitation is the large time amount required for the data input. A timely solution with effective questionnaire are needed for high and consistent study number. However, first results show the feasibility and the value of the database. The aim of our study was to present a preliminary model on how to establish a long-term database for the evaluation of new implant techniques for POP and SUI repair in female and male. However, further proofs and internal and external validations on large collectives are necessary. A prospective registry-based evaluation of different indications and procedures, as described in this study, will shed light into the role of implants for the reconstruction of pelvic floor. The evaluation of the registry should be done by an independent committee under auspices of national and international scientific societies. The funding, obliged to register application of implants and regulation of the approval process should be provided by Medical Device Regulation authorities.

Given the fact, that IDEAL is an international collaboration, a fast international spread and improvement of the registry by publications and congress presentations can be expected. Recently a first outcome of the registry with a randomized trial protocol, exploring a new mesh improvement for pelvic organ prolapse surgery, has been published [19]. The participating scientific societies and industrial manufacturers will expand and update the registry towards a multi-country or multi-continent presence (Fig. 4). Our group is a member of “the national dialogue on implant register”, which is a part of a national strategy process “Innovations in medical technology” supported by the Federal Institute for Drugs and Medical Devices, the Federal Ministry of Economics and Technology, the Federal Ministry of Education and Research and the Federal Ministry of Health. The meshes will be classified as a class III high-risk product by the upcoming EU medical device regulation and the postmarket follow up data will be required prior to approval. An implementation of quality depending reimbursement is planned by the politics. A successful registry based on the experience and consent of participating gynecological and urological societies will pave the way for the mandatory registry system driven by politics and with the financial support of the participating industrial manufacturers.

Registries according to the IDEAL method of surgical innovation allow a standardized follow up of different techniques and implants and a better preoperative counseling of patients by surgeons, based on each individual's clinical situation.

Ethical approval

Not needed due to retrospective design.

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Author contribution

Dimitri Barski and Holger Gerullis: Project development, Data Collection, Manuscript writing, Register harmonising to IDEAL criteria, Statistical analyses.

Thorsten Ecke and Ralf Joukhadar: Project development, Manuscript editing, Register harmonising to ICS/IUGA guidelines.

Jennifer Kranz, Rana Tahbaz, Fabian Queissert, Laila Schneidewind, Sandra Mühlstädt, Markus Grabbert, Nadine Leistner, Alexander Pelzer, Uwe Klinge: Project development, Manuscript editing.

Laila Schneidewind: Statistical analyses.

Werner Bader and Gert Naumann: Project development, Manuscript editing, Register harmonising to ICS/IUGA guidelines.

Frank Puppe: Development of the website and online support

Mihaly Boros and Thomas Otto: Project development, Manuscript editing.

Conflicts of interest

No conflicts.

Guarantor

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