CHAPTER 8

IDEAL FRAMEWORK IN SURGICAL INNOVATION APPLIED ON LAPAROSCOPIC NICHE REPAIR

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ABSTRACT

BACKGROUND
Surgical innovation differs from drug development. The IDEAL collaboration (Idea, Development, Exploration, Assessment, and Long-term study) developed a framework of the innovational stages to provide guidance on research and improve the quality of surgical innovation. The IDEAL framework was applied on the laparoscopic niche repair, a novel technique which has recently been introduced.

METHODS
A systematic search of the available literature on laparoscopic niche repair was performed in PubMed, Embase, and the Wiley/Cochrane library. The articles have been classified according to the IDEAL framework and recommendations are given on additional required research before the technique can be safely implemented. The practical applicability of the IDEAL framework is also evaluated.

FINDINGS
According to the stages of IDEAL framework the introduction of laparoscopic niche repair matches Idea (1) and Development (2a) although most studies are retrospective and complications have not been registered structurally in a little over half of the articles. As feasibility and safety have been more or less established and surgery has been further developed we enter stage 2b (Exploration) and need prospective trials preferably comparing the effectiveness of laparoscopic niche repair to expectant management, the current standard care. Given the stage of implementation, we recommend to perform laparoscopic niche repair only in research setting in centres with special expertise.
BACKGROUND

Surgical innovation is a continuous process that aims to improve the quality of surgical health care by incorporation of technical progress. However, to minimise the risk of premature introduction of new surgical techniques a balance should be made between potential effectiveness and potential harm. If a technique is prematurely implemented, before safety and effectiveness are established, patients are exposed to possible harmful effects of faulty surgery, e.g. vaginal mesh surgery in pelvic organ prolapse, which may cause a negative image to surgery in general. In case of delayed implementation of an effective technique benefits will be withheld to the patients. Therefore in order to allow a safe introduction of new surgical techniques it should be managed in terms of timely evaluation, proper interpretation, and adequate action. In this way the innovation can be more efficient. In contrast with the strict regulation of drug development, the evaluation standards for introduction of surgical techniques are still under development.

To manage new surgical innovations an international steering group of surgeons, researchers, journal editors, research methodologists, and statisticians, described the IDEAL framework, a model for the implementation of surgery that defined stages of the innovation of a particular surgical technique. IDEAL comprises Idea (stage 1), Development (stage 2a), Exploration (stage 2b), Assessment (stage 3), and Long-term study (stage 4). These stages of surgical innovation are based on the underlying scientific evidence and therewith stress the eventual need to achieve a next level of clinical evidence to justify further implementation of the innovation. Table 1 shows the table of the stages of the IDEAL framework in the original publication of McCulloch P, Altman DG, Campbell WB et al. in 2009. In the method section the IDEAL framework is explained more into detail.

One of the surgical fields where the innovation has been under scrutiny is laparoscopic surgery. Laparoscopic surgery has been adopted by gynaecologists since the eighties of the previous century and is now firmly established in clinical practice as a minimally invasive technique. However in the early phase of its development, the scientific base was not sufficiently addressed. Moreover, during the early phase of the introduction of laparoscopic surgery, there was an undue high rate of complications that were related to the laparoscopic approach, such as entry complications causing bowel and vascular injury. This prompted the governmental health inspection in the Netherlands to issue a safety report in 2007 that defined quality criteria both for the surgeon and for the institution that hosted the surgery. Recommendations were given about training and education of the surgeon, issues related to surgical volume, and technical issues on instruments and equipment. Later randomised trials have confirmed a faster recovery after laparoscopic surgery as compared to open surgery.

One example of surgical innovation is the laparoscopic ‘niche’ repair. A niche is a defect at the site of a previous uterine cesarean section scar and is becoming an emerging problem. Only recently, its relation with gynaecological symptoms such as menstrual spotting has been demonstrated in prospective cohort studies. In addition we see
more caesarean scar pregnancies than in the past. A laparoscopic niche repair has been developed in order to restore the uterine anatomy and relief symptoms. The research objective of the current systematic literature review is to classify the laparoscopic niche repair according to the IDEAL framework of ‘innovation stages’ and to recommend the required research setting to facilitate safe but properly timed implementation of the technique. In doing so, we are also able to evaluate the practical applicability of the IDEAL framework.

**METHODS**

**STAGING THE LITERATURE**

The initial objective of the IDEAL framework has been to consider all published evidence supporting the different stages in table 1. In order to assemble the separate articles into one IDEAL stage, the articles must be appraised in a standardised way. Therefore we modified the original table 1 and made it suitable for scoring every individual paper as shown in table 2. As addition to this table we consulted a practical guide to the IDEAL framework written by Pennell et al.

The final IDEAL stage of each selected article was attributed based on the research objective, that is generally described at the end of the introduction section of the article. This first definition of the research objective was compared to the clinical outcomes, the design and number of patients in the study and was sometimes adjusted accordingly. E.g. Efficacy (IDEAL stage 2b) can only be assessed if clinical symptoms are prospectively followed up before and after surgery. E.g. the description of the surgical technique as an outcome specifically matches stage 1 Idea: ‘Proof of concept’. The outcome postoperative symptom relief is usually reported in a clinical trial and therefore matches a later stage of the IDEAL framework. The content of the selected articles was collected according to a standardised format using a case report form (CRF), containing the following items: design of the study, follow-up and outcome(s). Outcomes may be feasibility, technical description, complications, patient satisfaction, spotting, fertility, pain, pregnancy course, ultrasound and MRI outcomes.

To define the design of the study we distinguished case reports (≤ three cases), single arm studies (retro- and prospective), observational comparative studies, and randomised controlled trials. The item ‘number and types of surgeons’, which was in the original table of the IDEAL collaboration, was not used as this information is hardly to retrieve objectively from the literature.

After summarizing study characteristics and separate IDEAL-scores per article in table 2, the overall innovation stage of the laparoscopic niche repair is defined, being the result of the available literature. Every article included in this review was evaluated by two independent reviewers (C.N., H.B.). A third reviewer (J.H.) was consulted in case of any disagreement between the two reviewers. The IDEAL framework and criteria are shown in table 1. Below the different stages of innovation are further clarified.
<table>
<thead>
<tr>
<th></th>
<th>1 Idea</th>
<th>2a Development</th>
<th>2b Exploration</th>
<th>3 Assessment</th>
<th>4 Long-term study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose</td>
<td>Proof of concept</td>
<td>Development</td>
<td>Learning</td>
<td>Assessment</td>
<td>Surveillance</td>
</tr>
<tr>
<td>Number and types of patients</td>
<td>Single digit; highly selected</td>
<td>Few; selected</td>
<td>Many; may expand to mixed; broadening indication</td>
<td>Many; expanded indications (well defined)</td>
<td>All eligible</td>
</tr>
<tr>
<td>Number and types of surgeons</td>
<td>Very few; innovators</td>
<td>Few; Innovators and some early adopters</td>
<td>Many; innovators, early adopters, early majority</td>
<td>Many; early majority</td>
<td>All eligible</td>
</tr>
<tr>
<td>Output</td>
<td>Description</td>
<td>Description</td>
<td>Measurement; comparison</td>
<td>Comparison; complete information for non-RCT participants</td>
<td>Description; audit, regional variation; quality assurance; risk adjustment</td>
</tr>
<tr>
<td>Intervention</td>
<td>Evolving; procedure inception</td>
<td>Evolving; procedure development</td>
<td>Evolving; procedure refinement; community learning</td>
<td>Stable</td>
<td>Stable</td>
</tr>
<tr>
<td>Method</td>
<td>Structured case reports</td>
<td>Prospective development studies</td>
<td>Research database; explanatory or feasibility RCT (efficacy trial); disease based (diagnostic)</td>
<td>RCT with or without additions/modifications; alternative designs</td>
<td>Registry; routine database (e.g., SCOAP, STS, NSQIP); rare-case reports</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Proof of concept; technical achievement; disasters; dramatic successes</td>
<td>Mainly safety; technical and procedural success</td>
<td>Safety; clinical outcomes (specific and graded); short-term outcomes; patient-centred (reported) outcomes; feasibility outcomes</td>
<td>Clinical outcomes (specific and graded); middle-term and long-term outcomes; patient-centred (reported) outcomes; cost-effectiveness</td>
<td>Rare events; long-term outcomes; quality assurance</td>
</tr>
<tr>
<td>Ethical approval</td>
<td>Sometimes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

RCT = Randomised controlled trial. SCOAP = Surgical Clinical Outcomes Assessment Programme. STS = Society of Thoracic Surgeons. NSQIP = National Surgical Quality Improvement Programme.
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LITERATURE SEARCH

Computerized bibliographic databases that have been used for the literature search of this review were PubMed, Embase, and the Wiley/Cochrane library, until February 2017. Cross references of detected articles were included if present. Reports in all languages and of all dates were considered. A clinical librarian assisted in the search strategy and the following terms were included in the search: surgical procedures, operative (MeSH), laparoscopy (MeSH), caesarean section (MeSH), cicatrix (MeSH), scar, isthmocele, niche, diverticula, pouch and wound defect (Appendix 1).

In this systematic review, inclusion criteria were clinical peer reviewed studies publishing as full papers, assessing patients who had an indication for laparoscopic niche repair. Excluded were articles not based on patient treatment such as letters to the editor or literature reviews.

THE IDEAL FRAMEWORK

In stage 1 of innovation, referred to as ‘Idea’, a new treatment concept is proposed. The surgery has not yet or sporadically been reported in small numbers of selected patients. The article tries to give an answer to the question if the new surgical procedure can solve a specific clinical problem. In Stage 2a ‘Development’, surgery is being developed in a way that the new intervention is feasible and safe and described sufficiently to allow replication by others. This stage is characterised by small prospective case series to acquire experience with the procedure and frequent adjustments to the technique are implemented. In stage 2b named ‘Exploration’ the efficacy in different small patient populations is becoming clear and a wider use of the procedure justified learning of the professional community plays an important role through mentoring and evaluation of the learning-curve. In stage 3 (‘Assessment’) the effectiveness is compared to current standard treatment in order to evaluate if the new procedure has additional value. A randomized controlled trial may be the most optimal design to assess the effectiveness of the procedure.

<table>
<thead>
<tr>
<th>Items</th>
<th>1 Idea</th>
<th>2a Development</th>
<th>2b Exploration</th>
<th>3 Assessment</th>
<th>4. Long-term study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research objective</td>
<td>proof of concept</td>
<td>Feasibility, safety</td>
<td>Efficacy</td>
<td>Effectiveness</td>
<td>Quality assurance, surveillance</td>
</tr>
<tr>
<td>Design</td>
<td>Structured case report</td>
<td>Observational single arm development study</td>
<td>Prospective collaborative study</td>
<td>Randomised controlled trial</td>
<td>Registry in combination with RCT or observational study</td>
</tr>
<tr>
<td>Number of patients in every individual paper</td>
<td>≤3</td>
<td>4-20</td>
<td>&gt;20</td>
<td>&gt;50</td>
<td>&gt;100</td>
</tr>
</tbody>
</table>
In stage 4 Long-term studies are conducted, mostly prospective registries, to investigate for rare outcomes and for variations in results. In this stage large numbers of cases may be analysed, though depending on the frequency of specific procedures.

**SURGICAL PROCEDURE LAPAROSCOPIC NICHE REPAIR**

The niche repair is executed by gynaecologists experienced in advanced laparoscopic procedures. The laparoscopic localisation of the niche is generally guided by translucency of a 5 mm hysteroscope. First the bladder is dissected from the uterus and the niche can opened and excised. All fibrotic tissue in the uterine scar is to be excised in order to enable proper wound healing. The myometrium is sutured in one or two layers. The use of adhesion barrier may be considered in order to reduce reformation of adhesions. In case of retroflected uterus shortening of the round ligaments (Baldy anterior procedure) can be performed in order to position the uterus in a temporary anteverse position during the first weeks of wound healing to minimize counteracting forces on the wound. The effect on the niche is evaluated after surgery by hysteroscopy. A urinary Foley catheter is generally removed after approximately 12 hours.

**RESULTS**

**LITERATURE SEARCH**

The literature search in PubMed, Embase, and the Wiley/Cochrane library generated 2507 studies (see figure 1). After removal of duplicates 2123 studies remained. Of those 2123 articles, 2297 were excluded; 1615 for they contained a subject not related to the laparoscopic niche repair, two were a letter to the editor, two articles that included the same patients as a third publication (Donnez et al. (2008) and Marotta et al. 20, 21), 21 were video reports and 657 were abstracts. Finally, 15 records were assessed for eligibility. Based on full-text assessment, one article was excluded due to a conversion to a vaginal approach during surgery. Therefore 14 articles were included in this systematic review (Table 3). The included peer-reviewed articles were published between April 2005 and February 2017 and the course of disease of a total of 237 women were reported on.

**QUALITY OF INCLUDED ARTICLES**

No randomised trials have been published. All but three studies were retrospective. One study compared transvaginal repair of a cesarean scar defect with a laparoscopic repair in a retrospective way.22 Only three articles, staged with IDEAL-score 2a, reported ethical approval.22-25 Patients were consecutively included in three studies,22,26,27 in the other 11 studies the patients were selected. In- and exclusion criteria of patients were not reported on in most studies, except for three.22-24 All patients had a niche situated at the uterine cesarean scar and had complaints of postmenstrual spotting, abdominal pain or subfertility. Sometimes the perinatologist feared for fenestration of the scar in a subsequent pregnancy. None of the articles reported on the learning curve of the surgeon(s). Follow-up was
reported on by all studies and ranged from one month till 72 months. Most articles had no clear description of definitions and no standardized way of measuring outcomes such as abnormal uterine blood loss, pelvic pain and satisfaction. Taking all these items into account, the quality of the included articles seem to be poor.

Study characteristics of included articles
The characteristics of the studies included in this review are shown in table 3. In eight studies (57%) feasibility was the main outcome. In all studies the conclusion could be drawn that the laparoscopic niche repair was a feasible procedure. In 11 studies (79%), postmenstrual spotting was reported in a non-structured way as the main outcome. Patients who suffered from postmenstrual spotting were free of symptoms in all studies except for 14% of the patients in the study of Jeremy et al., 14% of the patients in the study of Zhang et al., 7.5% of the patients in the study of Li, Tang et al., 10.2% of the
patients in the study of Liu et al., and 9% of the patients of the study of Donnez et al. In some studies (n=5) no complications are mentioned anywhere in the article and in other studies (n=9) complications are not predefined in the method section but are reported on in the result section. Therefore the extent to which safety is addressed in all selected studies, is unknown. None of these eight studies found complications in their patients.

With regards to other outcomes, fertility, and pregnancy outcome was reported in seven studies (50%) and eight studies (57%) respectively. Successful pregnancies after surgery with subfertility before surgery were found in 6/7 patients of Li et al., 10/14 patients of Jeremy et al., 1/1 patients of Siedhoff et al., 14/22 patients of Tanimura et al., 1/1 patient of Masuda et al., and 8/18 patients of Donnez et al. The study of Liu et al. reported that some of their patients had fertility plans and 2/49 patients became pregnant. However, how many patients had fertility plans is not reported in the article. Regarding the pregnancy course of the pregnant women, all studies reported an uncomplicated pregnancy course and a delivery by cesarean section to avoid uterine rupture. Niche criteria by imaging (Ultrasound or MRI) were reported outcome, on ultrasound or MRI in eleven (79%) and five studies (36%) respectively. No sign of recurrence of the niche on ultrasound was found in 6/11 articles. La Rosa et al. did not reported on echoscopic outcomes after surgery. The study of Li et al. described an overall myometrial thickness of >3 mm on ultrasound, Api et al. found an myometrial thickness of 13.1 mm on ultrasound after surgery, and Tanimura et al., reported on a median myometrial thickness of 2.8 to 10.5 mm measured by ultrasound. Zhang et al. described a remarkably reduction of the cesarean scar defect in 86% of their patients. Resolution of the cesarean scar defect on MRI was found in the study of Siedhoff et al. One study reported a significantly increased myometrium thickness measured om MRI compared with values before the laparoscopic niche repair. The other three studies did not described on MRI findings after surgery. One study reported about the satisfaction of the patients after surgery, in which 13 of the 14 patients were satisfied with the results of the operation. None of the studies reported on quality of life before or after the surgery.

In general, the laparoscopic niche repair was carried out the same way in all studies. Two studies by Yalcinkaya et al. and Siedhoff et al. used the robotic-assisted laparoscopic approach to perform the surgery. Little differences in technical steps during the surgery with conventional laparoscopy are present. For example Donnez et al., Yalcinkaya et al., Jeremy et al., Li, Guo et al, Siedhoff et al., Ciebiera et al., and Klemm et al. did not use a combined hysteroscopy during repair, while others did. The combined use of a Baldi anterior (shortening of the round ligaments) was reported in one of the 14 studies. The use of adhesion barriers was used in one of 14 studies. It seems that the principles of the surgical intervention have not been changed over time nor the indication for surgery although it lacks solid registration incompletely.
IDEAL-STAGES OF INNOVATION

When using the IDEAL framework, seven studies matched the category of Idea (stage 1) \cite{26,31,35,37} and seven the category Development (Stage 2a) \cite{22,25,27,28,36,41,43}. There were no studies categorized in the stages 2b (Exploration), 3 (Assessment) and 4 (Long-term study), as shown in table 3.

<table>
<thead>
<tr>
<th>Article</th>
<th>Design</th>
<th>Follow-up</th>
<th>Research objective</th>
<th>Outcome(s)</th>
<th>IDEAL-score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Klemm, April 2005\textsuperscript{26}</td>
<td>Prospective case report (n=3)</td>
<td>Median: 30 months and range: 3-46 months</td>
<td>Feasibility, description of surgical technique</td>
<td>Feas, OT, compl, AUB, pain, PC, EMT, EVN</td>
<td>1</td>
</tr>
<tr>
<td>Yalcinkaya, May/June 2011\textsuperscript{34}</td>
<td>Prospective case report (n=2)</td>
<td>12 and 20 months</td>
<td>Description of surgical technique</td>
<td>Feas, OT, compl, AUB, fert, pain, PC, EMT</td>
<td>1</td>
</tr>
<tr>
<td>La Rosa, Jan/March 2013\textsuperscript{23}</td>
<td>Retrospective case report (n=1)</td>
<td>3 months</td>
<td>Description of surgical technique</td>
<td>AUB, compl, EVN, MVN</td>
<td>1</td>
</tr>
<tr>
<td>Jeremy, Oct 2013\textsuperscript{34}</td>
<td>Single arm retrospective (n=6)</td>
<td>10-36 months</td>
<td>Feasibility, clinical outcomes</td>
<td>Feas, compl, AUB, fert, sat, PC, pain, MMT</td>
<td>2a</td>
</tr>
<tr>
<td>Ciebiera, Dec 2013\textsuperscript{37}</td>
<td>Retrospective case report (n=1)</td>
<td>1 month</td>
<td>Description of surgical technique</td>
<td>Feas, OT, compl, EMT, EVN</td>
<td>1</td>
</tr>
<tr>
<td>Li, Guo, May 2014\textsuperscript{37}</td>
<td>Single arm retrospective (n=17)</td>
<td>3-16 months</td>
<td>Feasibility, description of surgical technique</td>
<td>Feas, OT, compl, AUB, fert, pain, PC, EMT, EVN</td>
<td>2a</td>
</tr>
<tr>
<td>Siedhoff, May 2015\textsuperscript{32}</td>
<td>Retrospective case report (n=1)</td>
<td>26 months</td>
<td>Feasibility, description of surgical technique</td>
<td>Feas, fert, PC, MVN</td>
<td>1</td>
</tr>
<tr>
<td>Api, June 2015\textsuperscript{31}</td>
<td>Retrospective case report (n=1)</td>
<td>3 months</td>
<td>Feasibility, description of surgical technique</td>
<td>Feas, AUB, EMT</td>
<td>1</td>
</tr>
<tr>
<td>Tanimura, Sept 2015\textsuperscript{23}</td>
<td>Single arm retrospective (n=18)</td>
<td>12 months</td>
<td>Feasibility, clinical outcomes</td>
<td>Feas, fert, PC, EVN, MMT</td>
<td>2a</td>
</tr>
<tr>
<td>Masuda, Dec 2015\textsuperscript{13}</td>
<td>Retrospective case report (n=1)</td>
<td>3 months</td>
<td>Description of surgical technique</td>
<td>Feas, AUB, PC, fert</td>
<td>1</td>
</tr>
<tr>
<td>Zhang, Jan 2016\textsuperscript{22}</td>
<td>Retrospective comparative study, comparing transvaginal repair and laparoscopic repair (n=59)</td>
<td>3 months</td>
<td>Clinical outcomes</td>
<td>OT, Compl, AUB, EVN</td>
<td>2a</td>
</tr>
<tr>
<td>Li, Tang, Feb 2016\textsuperscript{34}</td>
<td>Single arm retrospective (n=40)</td>
<td>6 months</td>
<td>Feasibility, clinical outcomes</td>
<td>Feas, OT, compl, AUB, EVN</td>
<td>2a</td>
</tr>
<tr>
<td>Liu, Dec 2016\textsuperscript{22}</td>
<td>Single arm retrospective (n=49)</td>
<td>6 months</td>
<td>Feasibility, clinical outcomes</td>
<td>Feas, OT, compl, AUB, fert, EVN</td>
<td>2a</td>
</tr>
<tr>
<td>Donnez, Jan 2017\textsuperscript{25}</td>
<td>Single arm prospective (n=38)</td>
<td>12-72 months</td>
<td>Clinical outcomes</td>
<td>AUB, PC, fert, EMT, MMT</td>
<td>2a</td>
</tr>
</tbody>
</table>
To classify the overall stage of innovation of the laparoscopic niche repair based on all available literature, the most advanced stage of innovation (stage 2a) should set the standard. Until now, 237 patients who underwent a laparoscopic niche repair were described in the available literature of the included papers. Based on the research objective, the majority of studies match stage 1 and 2a. This would justify a stage 2a in the IDEAL framework described as Development, although only in three of seven studies the data were collected prospectively which refers to the low quality of the selected studies. In general prospective data collection is recommended. As the stage of innovation clearly passed the proof of concept and the technique, feasibility, and safety now seem to be established in 14 studies. Future studies should focus on defining the selection of patients and efficacy in comparative trials (IDEAL stage 2b Exploration). According to the IDEAL framework this implies that surgeons in experienced centers may undertake collaborative observational studies or feasibility randomized controlled trials to compare efficacy of the laparoscopic niche repair with standard care, which is currently expectant management.\[19\]

**DISCUSSION**

**MAIN FINDINGS**

Based on the findings of this systematic search, the conclusion can be made that the laparoscopic niche repair, according to the IDEAL framework, is still in a preliminary stage of innovation. The 14 identified studies match IDEAL stage 1 (n=7) and 2a (n=7), Idea and Development respectively. The available studies, reporting on 237 women, do not fit in all studies within the IDEAL framework as only a little over half of the studies reported complications or adverse events not showing awareness of safety being an important issue. Moreover, the women undergoing laparoscopic niche repair are reported in the literature in predominantly retrospective reports. This low quality of the studies may be an obstacle for implementation of the technique and move on to the next stage of innovation (2b).

**STRENGTHS AND LIMITATIONS**

Within gynaecological surgery the use of the IDEAL framework has been limited so far. As far as we are aware of the guidelines of the IDEAL framework have only been followed once before concerning uterus transplantation executed by Brännström et al.\[44\] The laparoscopic niche repair seemed to be an ideal candidate for this exercise as it was in an early stage of development and therefore subject to possible improvement of implementation. Another strength of this review is the systematic search of studies, likely resulting in a complete overview by using a CRF to score the articles on IDEAL-stage of innovation. One of the limitations was the lack of prospectively collected data of the included clinical studies which makes it difficult to attribute an IDEAL stage to each article. The same accounts for the assessment of the research objective, which in some studies has to be based on interpretation and made results somewhat arbitrary.
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Of the 14 included studies 11 did not report on in- and exclusion criteria. Therefore it is not possible to determine profiles of patients that may benefit from the procedure. Selection bias may also be present since only 3 included studies have consecutively included their patients.

In this review the studies that include no more than three patients have been defined as studies of proof of concept. However, this number is arbitrary and the distinction between proof of concept and feasibility is vague.

INTERPRETATION

Others have also used the IDEAL framework to monitor the safe implementation of innovative surgery. In this study the innovation of radical surgery of esophageal cancer was registered and monitored with the help of the IDEAL framework within one institution through retrospectively evaluating a prospective collected database of 192 women. The IDEAL staging supported the adequate change of the surgical technique in case of adverse events.

In the current study we interpreted the IDEAL framework in a slightly different way and reviewed the available studies separately in a standardized manner to present an impression of the evidence base of laparoscopic niche repair. The IDEAL collaboration wants to facilitate safe introduction of new surgery using clinical evidence as instrument for staging the innovation process. There are many different types of surgery in all surgical subspecialties that have been currently implemented without proof.

In the first place the information is useful to professionals who consider adopting a new surgical procedure and want to meet the requirements, such as prospective registry or trial participation. The scientific societies can integrate the IDEAL framework into their guidelines. The stage of innovation can also contribute to defining the research agenda in a particular field enabling research funds and journal editors to accept grant proposals and manuscripts respectively. Moreover, given its necessity surgical innovation can be promoted under the condition that regulators are able to monitor safe implementation. In theory regulation may slow down the innovation process, which is an undesirable side effect. The current approach with the IDEAL framework however may shorten the innovation track by a more instant response on negative and positive research results. Regulation however should encourage treatment of patients in research setting in the introductory phase of a surgical technique and not discourage its use by means of reimbursement policy.

FUTURE PERSPECTIVES

The laparoscopic niche repair has the objective to improve gynaecological and reproductive outcomes in women with a large symptomatic niche. The conditions in terms of proof of concept and feasibility are met. The standardization of surgical steps are met as well, although small adjustments will always be possible. With regard to patient selection it seems obvious that only symptomatic patients should be offered surgical treatment.

It seems possible that infertility is related to the large niche because of fluid collection in the uterine cavity. After in future studies the relationship between niche and infertility has
been explored and unveiled (stage 2b), a prospective collaborative study or an RCT may be appropriate. Furthermore the learning curve of the surgeon(s) should also be a point of interest in the light of scientific assessment in future studies with IDEAL stage 2b.

To detect what studies, aiming at what IDEAL stage, are underway we collected abstracts reporting on laparoscopic niche repair of which the articles have not been published. Moreover we consulted the established trial registers to look for ongoing studies. There have not been found any RCT's on the laparoscopic treatment of the niche. However, there is one large prospective observational study being executed in the Netherlands by our group concerning laparoscopic repair of niches: ‘The effect of the laparoscopic reconstruction of a cesarean scar (Niche)’. The research objective is to study the efficacy of the procedure in treating menstrual as well as fertility problems.

CONCLUSION

With the use of the IDEAL framework the available studies were classified achieving an overall IDEAL stage to be 2a Development. In case histories and small series the concept has been proven. The feasibility of laparoscopic niche repair has been established as well as the safety. As the clinical outcomes, though poorly registered, have been substantially improved, the laparoscopic niche repair needs to be carried forward by more advanced study designs.

DISCLOSURE OF INTERESTS
None of the authors have any interests to disclose.

CONTRIBUTION TO AUTHORSHIP
H.B. and B.M. were initiators of the idea for this systematic review. C.N. and H.B. selected the articles and collected the data. The first draft was written by C.N. and H.B. All authors, C.N., A.V., B.W.M., W.H., J.H., and H.B., commented on and revised the draft. All authors approved the final version to be published.

DETAILS OF ETHICS APPROVAL
For this is a literature study no ethical approval was mandatory.

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REFERENCE LIST


