

Ethics in Surgical Innovations from the Patient Perspective

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Summary

Objective: Surgical innovation (SI) can place patients at risk. We sought to explore what clinical information is readily available to patients who have been offered innovative surgical procedures, using two examples drawn from our recent experience: one a surgical technique, and the other a prosthetic material. We wanted to determine from our review the extent to which information available on the Internet might augment the medical literature and help satisfy the ethical requirements for patients to be adequately informed before they proceed with innovative surgery.

Methods: A scoping review of the medical literature was performed to look for studies addressing the review aims; targeted searches on Google, YouTube, and patient websites were carried out to find readily available patient information on two chosen innovative surgical procedures. We conducted a content analysis of the selected references to determine the availability, relevance, and the utility of the published information to a layperson.

Results: Medical database searches identified 614 records, 91 were screened and only six were relevant. The Internet searches returned thousands of results; however, we limited our screening to the first five pages of results for those sources. From both types of searches, 348 references were excluded because they did not meet the inclusion criteria and 51 were included in the analysis. The findings are presented in four themes: safety and feasibility of the technique, availability and accessibility to a layperson, relevance and utility to a layperson, and commercial information.

Conclusion: The review has shown that lay people seeking to find out more about the two innovations would get very little useful information from Google, YouTube, or patient websites. Practitioners offering SI should provide sufficient information to allow their patients to make an autonomous decision about whether to proceed. For major SI, we encourage innovators to develop a plain language statement that would be made available on the Internet to the mutual advantage of both innovators and patients.

Keywords

Ethics, surgical innovation, patient information, social media, internet

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Introduction

Surgical innovation (SI) is widely accepted as a “good” - something to be encouraged and facilitated in the public interest. But it involves a degree of experimentation and can put patients at risk. “Innovation” includes a spectrum extending from the original Idea (I), through Development (D), Exploration (E), Assessment (A) and Long-term (L) study, whose stages have been labeled with the acronym “IDEAL” by a collaboration of experts [1]. With IDEAL, lay people can appreciate the stages whereby new surgical procedures or devices are introduced into practice, and if a new procedure is offered, they can make an informed choice about undergoing that procedure. In addition, patients or patient advocacy groups can contribute to the discussions and recommendations of the IDEAL framework by sharing their perspectives, values, and experience [2]. While the later stages of SI are usually the subject of formal research, the early stages often occur without it, and we suggest that the ethical principles that apply to research involving human participants should apply equally to the early stages of SI.

The Australian National Statement on ethical conduct in human research defines the following ethical values and principles: research merit and integrity, justice, beneficence, and respect [3]. Using IDEAL, Rogers and her colleagues have aligned these principles to the SI spectrum, identifying four important areas for consideration [4, 5]: a) minimizing harm, b) autonomy and consent, c) justice issues, and d) managing conflicts of interest (See Table 1).

The principles indicate that care and planning are crucial in SI, including the gathering of information about the reasonably predictable risks and anticipated benefits of the proposal.

At present, any information statements are largely bespoke efforts but making information available on the internet presents opportunities to consolidate the efforts of many and facilitate their dissemination in a form accessible to the public.

Objectives

The purpose of the review was to explore what clinical information is readily available to patients who have been offered innovative surgical procedures and to determine the availability, relevance, and utility to a layperson, of information readily accessible on internet.

The authors have chosen two examples of innovative procedures representing the two main types of interventions being applied for by contemporary would-be innovators: innovative procedures and innovative devices. They were chosen because they were the subject of recent applications for oversight approval at the authors’ institution, and thus were probably still at the “D” and/or “E” stages of the IDEAL spectrum. The chosen innovations are:

- 1) Transoral Endoscopic Thyroidectomy (TET) - an innovative surgical technique that accesses the thyroid gland from the mouth through the soft tissues of the neck, enabling it to be removed without leaving any disfiguring skin-scar on the neck.
- 2) Inguinal Hernia Repair with Mesh (IHRM) - a conventional surgical operation, but with a novel prosthetic material [Parietex™ProGrip™ mesh] designed to be self-fixing in the surgical wound, and thus should not be needing to be sutured in place. This has the potential benefits of speeding the surgery and decreasing the risk of nerve, spermatic cord or vascular injuries.

Table 1 Key ethical principles and applicability to surgical innovations. Source: Adapted from Rogers W, Hutchison K, McNair A [4].

Ethical principles	Applicability to surgical innovations
Minimizing harm	Primarily concerned with harm to patients. In pre-IDEAL studies, harms to animals may also be relevant. Reputational and psychological harms to health professionals can follow unsuccessful innovation.
Autonomy and consent	Primarily concerned with ensuring rigorous processes of patient consent. This includes informing patients of the innovative nature of the procedure and providing transparency about the limits of existing knowledge and associated risk of unexpected complications.
Justice issues	Concerned with fair distribution of the risks and benefits of surgical innovation. Selection of patients for risky procedures must not target those who are vulnerable. Access to successful innovations should be fair.
Managing conflicts of interest	Concerned with impact of conflicts of interest on judgment. These may lead to prioritizing surgeons' and device manufacturers' interests over those of patients and also give rise to injustices. Conflicts of interest arise when surgical innovation leads to financial and other rewards.

Methods

Search Strategies

We undertook a narrative review of the literature and conducted analysis following the methods outlined by Pare *et al.*, [6] and Ferrari [7] to understand what information is available to the layperson about the selected surgical innovations and how it is presented.

We wanted to review reported outcomes of TET and IHRM. We also wanted to investigate reports of any patient decision aids or other patient decision-making processes related to these two innovations. We performed targeted searches on the electronic databases Medline, EMBASE, and Scopus to search for studies describing TET and new devices for IHRM. We used subject headings and keywords for the following concepts: *innovative procedures, innovative devices, transoral endoscopic thyroidectomy, inguinal hernia repair, mesh, patient decision aids*. We limited the search to English language articles published between January 2016 and September 2019. We hand searched reference lists and citing articles of relevant studies for additional papers. A second search of the Internet was conducted to obtain information on the two innovations that patients would most likely be able to access and understand. Internet searches included Google, You Tube, and patient social media sites: PatientsLikeMe [8] and Surgery squad [9].

Screening and Quality Assessment

The references derived from the databases and Internet searches were screened independently by both authors (YK and TE) according to the selection criteria. When it was not possible to determine whether a reference was relevant, it was included at this stage.

Internet searches on both TET and IHRM identified thousands of results. We limited our screening to the first five pages of results for those sources. References were excluded if they did not meet the inclusion criteria (See Table 2). Selected references for inclusion in the analysis were discussed and agreed upon by both authors.

Table 2 Inclusion and exclusion criteria used to identify patient information on Internet related to Transoral Endoscopic Thyroidectomy (TET) and Inguinal Hernia Repair with Mesh (IHRM).

Inclusion criteria	Exclusion criteria
Available publications about TET and IHRM	Patient materials not related to TET or IHRM
Relevant patient materials described in lay language	Very technical publications
Accessibility of information to patients	Information not accessible to patients
Published in the English language	Publication not in English language

Data Analysis

We conducted a content analysis of the selected references in accordance with our objective to determine the availability, relevance, and utility of the published information to a layperson. We chose a narrative review format to report the results, as we aimed to identify and synthesize a broad range of literature available to patients as well as health professionals in the chosen clinical innovation areas and demonstrate the gaps in the knowledge, rather than seeking generalization of the outcomes [6]. The process of screening and the analysis of search results are depicted in the flow diagram displayed in Figure 1.

Results

The medical databases searches yielded 614 records, 91 were screened and only six were relevant. They were all focused on the safety and feasibility of the technique or the device. Altogether from both types of searches 327 references were excluded due to not meeting the inclusion criteria, and 51 were included in the analysis.

The findings of our analysis are presented in four themes: safety and feasibility of the technique, availability and accessibility to a layperson, relevance and utility to a layperson, and commercial information.

Safety and Feasibility of the Technique

Of the 40 screened titles and abstracts from the database searches related to TET, only two papers had a patient focus. The article by Bakkar *et al.*, [10] concluded that patients who agree to undertake a novel surgical procedure should be properly counseled especially about unconventional procedure-related complications. A systematic review by Camenzuli *et al.*, [11], including 785 patient cases, determined that the TET procedure is a safe and feasible technique and demonstrated acceptable complication rates and good outcomes.

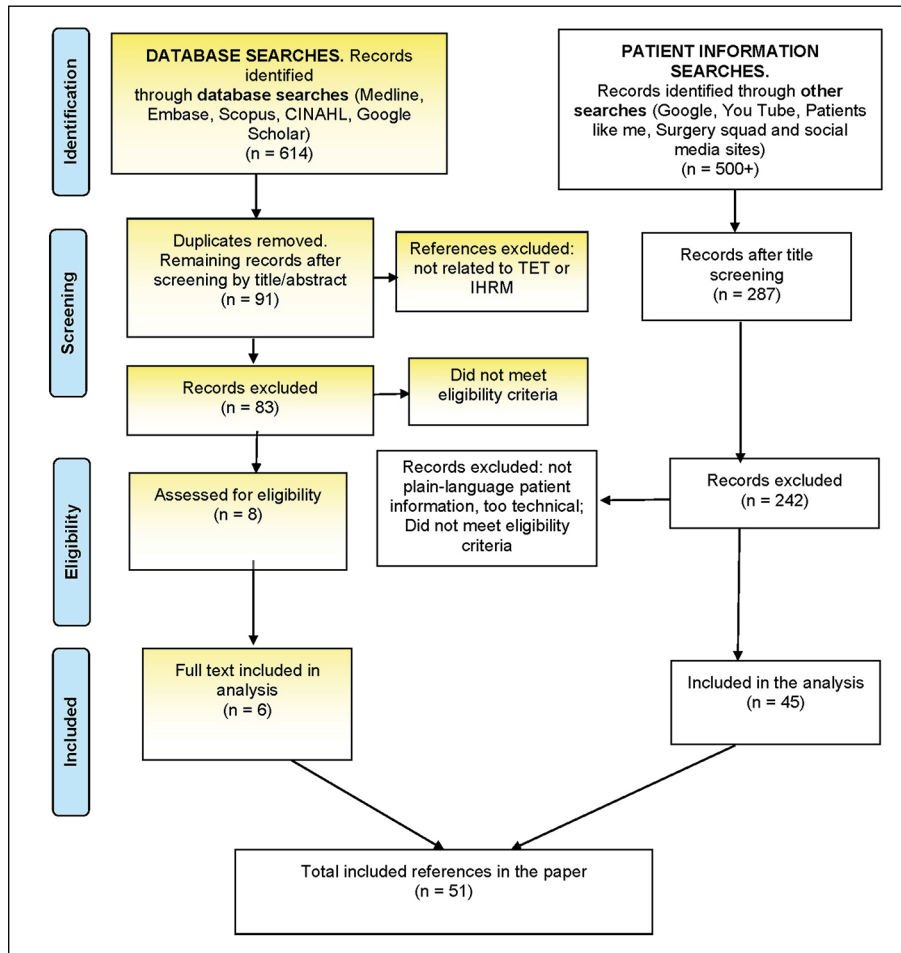


Fig. 1 Flow diagram of database and other sources searches.

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. *PLoS Med* 6(6): e1000097. doi:10.1371/journal.pmed1000097. For more information, visit www.prisma-statement.org.

The Google search on TET led to a cluster of scientific articles and a video that concluded the technique was new, and under either evaluation or assessment (at “E” or “A” in IDEAL) [12-14]. It rapidly became clear that TET is a cluster of procedures and thus confusion could easily arise as to precisely which technique is being proposed, and what IDEAL stage the technique is at.

The following six different techniques we found could be grouped as “laparoscopic - or endoscopic thyroidectomy”

- TransOral Endoscopic Thyroid surgery Vestibular Approach (TOETVA),
- TransOral Endoscopic Thyroidectomy (TOET),

- TransOral Robotic Thyroidectomy (TORT),
- TransOral Robotic Surgery (TORS),
- TransOral and Submental Technique (TOaST), and
- Total Endoscopic Thyroidectomy via Areola approach (ETA), in contrast to “Conventional Open Thyroidectomy (COT)”.

Database searches for IHRM identified 30 titles, only one of which passed screening. It was an observational study on laparoscopic ventral hernia repair using self-fixating mesh performed on 41 patients, which reported a decrease in the operative time, no complications, and a positive quality-of-life evaluation one month after the procedure [15].

The Google search for IHRM identified some scientific papers [16-18] that were beyond the comprehension of a layperson. There was also evidence of a litigious interest in the area of mesh repair [19]. Parietex™Pro-Grip™ mesh was identified as an innovative product in the process of assessment (at “A” in IDEAL) [20]. A website called “Mesh Injured Australia” [21] cited a Cochrane review whose conclusion was: “*Hernia repairs with and without mesh both proved effective in the treatment of hernias, although mesh repairs demonstrated fewer hernia relapses, a shorter operation time and faster return to normal activities. Non-mesh repairs are still widely used, often due to the low cost and limited availability of the mesh product itself*” [22].

Availability and Accessibility

Google searches on TET and IHRM identified several specialized articles that were very technical. However, we found three patient discussion forums which were easily accessible to people who have undergone an inguinal hernia surgery [23-25] and the British Thyroid Association has a dedicated patient information page with leaflets on various thyroid-related conditions and links to professional organizations [26].

The Advances in Surgery channel [27] has video resources related to TET [28] and IHRM [29] but this site is very technical, and would probably be of limited value in informing laypersons on risks and benefits.

Google searches for patient forums for TET led to two chat threads published in support group forums [30,31] and two informative consumer-oriented resources [32, 33]. From the YouTube searches we identified patient information on thyroidectomy in general, but not endoscopic thyroidectomy [34].

There were no patient-specific decision aids for TET or IHRM from the targeted database searches on patient education. We identified a Cochrane systematic review that analyzed a range of patient decision aids which can be applicable for the two selected examples. It concluded that patients exposed to decision aids would feel more knowledgeable, better informed, and clearer about their values and they would have more accurate risk perceptions [35].

Relevance and Utility to a Layperson

A study by Tamhankar *et al.*, [36] found that a big proportion of patients undertaking common surgical procedures used the internet to inform themselves, and about one-third of them specifically searched for information about their operation. The information provided on the Internet can confuse and trouble patients.

Decision support resources that might be useful to a layperson considering both TET and IHRM were identified in the “Decision Aids Library Inventory” produced by the Ottawa Hospital [37]. Plain-language information on IHRM and patient resources were also available on the websites of organizations such as UCI (University of California Irvine) Health, American College of Surgeons, and US Food and Drug Administration [38-40].

For IHRM we found some informative videos on YouTube [41, 42] and two informative resources about inguinal hernia repair with or without mesh [43,44]. We also found a promotional/educational video, clearly sponsored by the manufacturer Coviden™ [45] but nonetheless informative for a layperson.

The PatientsLikeMe website provides information about conventional thyroidectomy [46] and inguinal hernia repair [47]. One private patient Facebook support group “Hernia Mesh Australia” [48] offered membership to Australian men and women who have had hernias repaired and are suffering resultant pain. The Surgery Squad platform [9] provides surgery games and some patient education, but when accessed, none of the 34 available posts were related to thyroidectomy or hernia repair and as well changed to “Commercial Information”.

Commercial and Litigation Information

Internet searches for IHRM led to two pages of the mesh manufacturer’s website [49, 50] that were inaccessible to a layperson. A Google search on “should I have mesh hernia surgery?” led to a significant number of sites reflecting a widespread concern about its use [51, 52]. We found evidence of litigation [53] and a BBC documentary [54] on “Parietex-

Mesh that appears to have been posted by BioHernia, an organization promoting and offering hernia repair using established techniques which do not use mesh. We felt that the evidence of controversy would lead a reasonable enquirer to ask patients whether they should have their hernia repaired with mesh. Health Issues Centre, a consumer advocacy organization offered participation in a survey, “to identify other patterns of malfunction in medical devices and implants” [55].

Discussion

Ethical Considerations and Implications for Practice

In its early stages, SI has little or no evidence-base, and (as in Phase 1 clinical trials) it is important that expected outcomes are likely to outweigh the known (or reasonably predictable) risks, that the outcomes will be assessed and recorded adequately, that the patient’s proper informed consent has been obtained, and that the voluntary nature of their participation is confirmed.

SI has some special aspects which play into these ethical considerations, -quantum of change, diffusion of innovation, and advocacy issues.

Quantum of Change

Much SI is minor and represent little more than an incremental change. These are very common in surgical practice, and there is yet no clear understanding of what constitutes a treatment “variation” as opposed to an “innovation” of enough magnitude to warrant a deliberate plan and formal oversight [56]. The more major the proposed SI is, the more important becomes full adherence to the principles.

Diffusion of Innovation

“Diffusion” is “a social process through which cultural knowledge, practices, and materials spread in social systems” [57]. In 1962, Everett Rogers [58] applied it to innovative farming techniques and concluded that “*in a social system, a decision to adopt an innovation depends heavily on decisions made by other members of the system*”. He argued people were influenced more by their peers than by the evidence. He identified those involved as “*innovators*”, “*early adopters*”, “*the early majority*”, “*the late majority*”, and “*laggards*”, and dispersed them in his now well-known bell-curve (See Figure 2) according to their propensity to either adopt or resist change. Rogers’ work achieved wide acceptance and is taught and

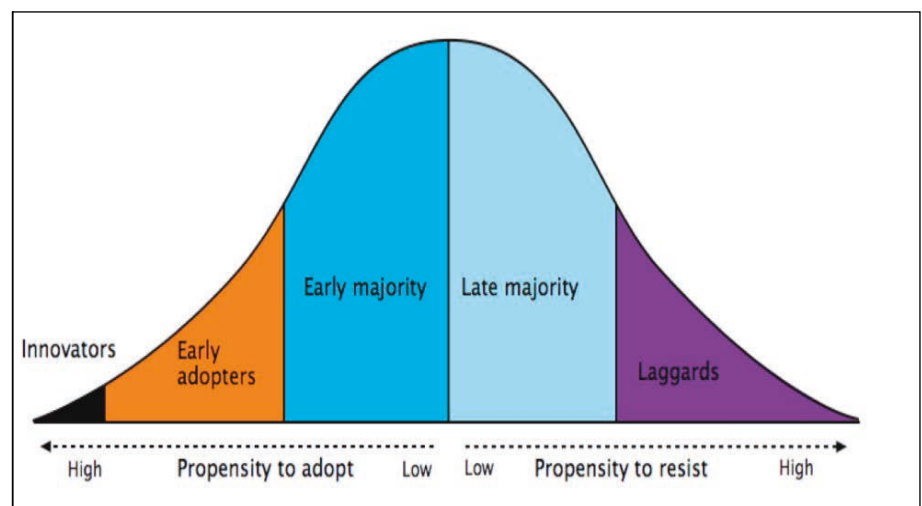


Fig. 2 Different adopter categories.

Source: <http://sphweb.bumc.bu.edu/otlt/MPH-Modules/SB/BehavioralChangeTheories/BehavioralChangeTheories4.html>

practiced in contemporary marketing [59]. It is often applied to SI, making it important that both innovators and their patients appreciate that peer pressure and marketing may be influencing the SI.

Advocacy Issues

Most SI take place without sponsorship by independent third parties. Practitioners offering the SI may also be its sponsors, but more often they are advocates of the procedure and stand to benefit professionally from its success. If the innovator is the inventor of the SI (and thus might have Intellectual Property claims), is providing any support (whether financial or support in kind), or stands to benefit from its success, there are potential conflicts of interest. Ethically, these must be declared and managed appropriately.

Implications for Practice

Each of the three elements discussed above can affect the informed consent process adversely, and in SI the consent process warrants particularly close attention. Patients must understand what is going to be done differently, what are the likely benefits and potential risks, and need to be assured of the voluntary nature of their participation.

Innovators have the option of giving their patients procedure-specific handouts as part of the informed consent process. When decision aids are offered to patients, it improves their knowledge and helps achieve shared treatment decisions [60]. Procedure-specific handouts are emphasized in the “Guide to good practice for surgical innovation, new techniques, and technologies” published by The Royal College of Surgeons of England [61]. The guide offers a framework and a decision tree for surgeons, their teams, and hospital clinical managers, on what to consider when developing a new surgical technique or innovation and the ethical, regulatory, patient consent, and cost requirements. SI is an area where patient-directed information would be extremely useful.

However, as Alsaffar *et al.*, noted, a pamphlet alone might not be enough and should be supplemented by additional patient

education using emerging technologies [62]. This might be challenging for many would-be innovators. According to Hoffman *et al.*, “*emerging evidence suggests potential benefits to delivering patient decision aids on the Internet. However, additional research is needed to identify best practices and quality metrics for Internet-based development, evaluation, and dissemination, particularly in the areas of interactivity, multimedia components, socially generated information, and implementation strategies*” [63].

Conclusions

This review has confirmed that lay people seeking to find out about the two selected examples of SI currently in their early stages would get very little useful information from Google, YouTube or social media sites. However, due to the focus on just two clinical examples in our narrative review, the results are not generalizable to other surgical innovations.

Lay people would be able to connect with patients who have issues with various aspects of their care and with individuals in recovery from surgery which appears to have gone well enough. They would also encounter a plethora of promotional material and various other options which may not be at all relevant to their situation.

It is an ethical requirement of practitioners offering SI to provide sufficient information to allow their patients to make an autonomous decision to proceed. We believe a good description of the procedure, including the potential risks and benefits, the experience of the clinical team, and any available alternatives, can be very beneficial for the patient and for the successful introduction of the innovation.

There is clearly a place for the use of electronic media to disseminate patient decision aids and make them more accessible, but this is still in its infancy [63]. At present, persistence would be required to find reputable information, including decision aids, but even that seems unlikely to be able to directly inform patients regarding the risks and benefits of the innovation.

For major or significant innovations, we encourage practitioners to develop a plain-language statement and make it available on the Internet to the mutual advantage of both innovator and patient.

Our sample was limited, but for these two specific SIs the Internet was not helpful. But we did encounter the Ottawa Hospital site [37] which provides an example of a useful resource. We advocate the development of sites which focus on innovative treatments, enabling practitioners trying to develop decision aids for SI to collaborate and promulgate patient-directed information.

Strengths and Limitations

The authors are members of an institution with an established interest in the ethics of surgical innovation. Both are members of an Institutional Human Research Ethics Committee, and of a hospital committee which assesses and provides approval for innovative surgical procedures.

Due to time restrictions, the authors selected two recently proposed innovations representing the two broad categories of SI and performed a descriptive analysis of the findings, rather than using an online health information scale to evaluate the SIs.

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