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The (commercialised) experience of operating: Embodied preferences, ambiguous variations and explaining widespread patient harm

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Abstract

This article provides a detailed account of how surgeons perceived and used a device-procedure that caused widespread patient harm: transvaginal mesh for the treatment of pelvic floor disorders in women. Drawing from interviews with 27 surgeons in Canada, the UK, the United States and France and observations of major international medical conferences in North America and Europe between 2015 and 2018, we describe the commercially driven array of operative variations in the use of transvaginal mesh and show that surgeons' understanding of their hands-on, sensory experience with these variations is central to explaining patient harm. Surgeons often developed preferences for how to manage actual and anticipated dangers of transvaginal mesh procedures through embodied operative adjustments, but collectively the meaning of these preferences was fragmented, contested and deferred. We critically reflect on surgeons' understandings of their operative experience, including the view that such experience is not evidence. The harm in this case poses a challenge to some ways of thinking about uncertainty and errors in medical sociology, and calls for attention to a specific feature of surgical work: the extent and persistence of operative practices that elude classification as

right or wrong but are still most certainly better and worse.

KEYWORDS
commercialisation, embodiment, evidence-based medicine, medical uncertainty, patient safety, surgery, transvaginal mesh

INTRODUCTION

In recent decades, there have been a number of cases of extensive patient harm caused by surgical device-procedures. Most accounts of these cases have focussed on surgeons' failure to base practice on evidence and on inadequate regulatory systems that allowed for broad access to experimental and understudied devices. In this article, however, we consider surgeons' experience using such a device-procedure: transvaginally implanted permanent synthetic mesh for the treatment of pelvic floor disorders. We describe the commercially driven array of devices and techniques that surgeons using transvaginal mesh could choose from and establish that surgeons relied to a great degree on their experience operating to determine when and how vaginal mesh could be responsibly used. We then consider how the personal, embodied qualities of this experience were implicated in the harm that resulted by allowing for the persistence of clinically ambiguous variations in surgical practice.

We have previously shown how a moral-epistemological orientation towards repairing anatomy meant many surgeons were favourably disposed to transvaginal mesh procedures (Ducey et al., 2020). In a separate ethnographic study of one pelvic floor clinic, carried out in 2013, as the use of transvaginal mesh was beginning to be curtailed, we examined how pelvic floor surgeons develop and work with a set of rationales that allow them to justify undertaking elective surgery (Ducey & Nikoo, 2018). The analysis in this article, however, proceeds from surgeons' in-depth accounts of their experience operating with transvaginal mesh and considers this experience as a distinct element in understanding how these device-procedures came to be so widely used.

Starting in the early 2000s and continuing for at least 10 years, transvaginally placed permanent synthetic mesh was widely and globally adopted to treat urinary incontinence and prolapse, a descent of the pelvic organs that pushes down on the vagina, commonly resulting in a 'bulge' sensation and sometimes a protrusion of the vagina. Complications involved in the implantation of transvaginal mesh could be intraoperative, such as puncturing a blood vessel or entrapping a nerve, or emerge postoperatively, including mesh erosion (extrusion of the mesh into nearby organs such as the vagina, bladder or rectum) and pain, including pain associated with penetrative intercourse (dyspareunia) and chronic, less localised forms of pain. Because permanent mesh becomes incorporated into the body's tissues, it can also be quite difficult to remove. Not all these complications are equally serious, neither are they all unique to surgery that involves mesh nor to surgery that is carried out transvaginally. But the commercialisation of transvaginal mesh procedures expanded the number of ways and situations in which pelvic floor disorders seemed to be treatable with surgery. It allowed more widespread use than was previously accorded to 'traditional' prolapse and incontinence procedures, so that mesh became adopted into practice on a broad scale. Globally, the number of harmed patients is likely in the hundreds of thousands. In the United States, there are at least 100,000 plaintiffs involved in litigation against the makers of transvaginal mesh devices. The harms many women have reported are shattering, profoundly

affecting their quality of life (Uberoi et al., 2021), and the possibility of which they were not informed (Motamedi et al., 2022).

LITERATURE REVIEW: PRACTICE VARIATIONS, PATIENT HARM AND THE EXPERIENCE OF OPERATING

It is not surprising that surgeons working in the same specialty and treating the same sorts of disorders and patients can vary in their decisions about whether and how to operate (Apramian et al., 2016). The practice of operating is shaped by contingencies related to the case, the surgeon and external forces (Pope, 2002). Variable material tools and technologies and spaces may be used (Heath et al., 2018; Ott et al., 2020; Schubert, 2011) and surgery must be coordinated in interaction with others in the operating room (Hindmarsh & Pilnick, 2007) in distinct organisational and system contexts. Surgeons' practice preferences are shaped by the specific people with whom they train and work (Brattheim et al., 2011), and often organised into distinct repertoires, styles and identities (Grove et al., 2021, 2022; Schlich, 2015). Differing practices and styles are accepted in the culture of surgery. In his classic study of error and surgical culture, Bosk (1979) acknowledged variable operative practices as 'quasi-norms': practices some surgeons may prefer and even teach as superior, but which are not norms in the sense that practising otherwise would be considered an error.

Yet 'not all variations are created equal. At one end of the spectrum of variations live obvious errors that no surgeon would deliberately use and at the other live entirely inconsequential variations. The complexity exists between these two poles' (Apramian et al., 2016, p. 343). Practices between these poles are ambiguous—they are recognised neither as unquestionable mechanisms of good care nor as requiring sanction and control. As Mol furthermore observed, 'in health care most facts come as *comparative* facts. Few conditions or treatments are ever treated as simply *good* or *bad*—as if there were absolute standards. Rather they are *better* or *worse*...' (Mol, 2002, p. 180). Surgeons are not only aware of differences in practice but subject them to continual comparative assessment as part of their everyday work. Wilde and Hirst highlight that such differences in practice often seem to matter, and might therefore be considered 'contestable errors'—practices about which there may be concern but also 'legitimate room for debate' (2009, p. 51). The interpretation and negotiation of these differences is a special challenge to surgical trainees and surgical education (Apramian et al., 2015; Bosk, 1979), and arguably a determining feature of the culture of surgery as a profession.

On the whole, however, the implications of variations in practice that may be better or worse have not been fully considered in sociological research on surgery. Sometimes, this is because the recognition of better and worse practices seems to require researcher involvement in assessing surgeons' clinical judgement. This is fraught with epistemological and practical challenges (see e.g., Cassell, 1991). Bosk therefore fully considered errors, but minimised the significance of variable practices by dismissing quasi-norms as situations where 'some [surgeons] approach a problem in one fashion with very good results; others have equally good results with a competing approach' (pp. 62–63). When worse practices appear in ethnographic accounts of surgical work, they do so as unambiguous dangers or disruptions of accepted operative routines (Prentice, 2021; Schubert, 2007). And because much ethnographic work on surgery has been carried out in the context of learning, the analysis is often tilted towards how the profession is able to mitigate risk and patient harm rather than how it might allow ambiguous and possibly dangerous ways of practice to persist.

The full significance of better and worse practices likewise escapes attention in the rich sociological study of uncertainty in medical knowledge and practice (for an overview, see Mackintosh & Armstrong, 2020). Variations in practice may be more likely where there is uncertainty about

whether or how to operate, perhaps because available evidence is limited or surgical techniques are new or complex. Nevertheless, an emphasis on the complexity of medical practice, or the limits of what can be known and controlled by clinicians, can render bad outcomes as only occasional and unavoidable, or as part and parcel of the cutting-edge medical environs in which these studies are often carried out. In considering quasi-norms, for instance, Bosk was quick to emphasise 'great uncertainty surrounds much medical behaviour' and in the absence of conclusive evidence, 'a consensus fails to emerge' (p. 62). Close observers of medical practice have rightly critiqued simplified notions of mistakes and errors that do not take into account ambiguities and uncertainties (Jerak-Zuiderent, 2012; Lutfey & Freese, 2007). Yet 'it is intellectually important to not be in awe of, or in deference to...complexity' (Mol, 2002, p. 248), or to uncertainties and ambiguities.

The growing body of social science research on patient safety also, by necessity, tends to examine clinical situations in which there are clear breaches of proper practice and concomitant issues such as the barriers to reporting adverse events (Szymczak, 2016). In this literature, researchers also emphasise the complexity and uncertainty of many aspects of medicine and eschew reductive explanations of patient harm. Importantly, though, practices that are ambiguous in terms of their clinical meaning are also recognised as relevant to patient safety. Researchers have shown that whether some practices are deemed mistakes and errors varies, in part because practices are always local and differently situated amid institutional and socioeconomic forces (Aveling et al., 2016; Waring et al., 2016). Doctors, in particular, have considerable power to define situations and their preferred practices in ways that minimise risks and their responsibility (McDonald et al., 2005). Studies of work in operating rooms have shown how surgeons and anaesthetists normalise risks, making it possible 'some risks will be overlooked or underestimated, thereby allowing them to persist within the workplace, grow in significance or spread to other areas of patient care' (Waring et al., 2007, S1, p. 7). Such research allows for the possibility of a connection between patient harm and practices that are neither inconsequential nor unambiguously right or wrong.

Answering the question of when and why practices that might be worse are tolerated or allowed to persist requires consideration of the particular type of work and experience that is the act of operating. Surgical competence requires the gradual and painstaking acquisition of sensory and physical operative skills (Prentice, 2013) that are essential (if not sufficient) to sound clinical judgement. Because preferences about how to operate are derived to a significant degree from hands-on experience that can be passed along only via informal routes and direct exposure (Pope et al., 2003), they are often tacit in nature (Goodwin, 2009; Greenhalgh et al., 2008; Maslen, 2015)—difficult to make explicit or codify as rules, but also difficult to recognise as such. Knowledge acquired through operating poses particular challenges to being assessed, standardised and communicated (Ergina et al., 2009; Ott et al., 2020). Such embodied and tacit skills are nevertheless necessary for good medical care in many settings (Carmel, 2013; Gardner & Williams, 2015; Harris, 2016; Prentice, 2007; Underman, 2020) and have been arguably devalued, especially in relation to what is supposedly known through evidence produced by clinical trials (Kelly et al., 2019; Maslen, 2016; Nettleton et al., 2008).

In this article, we consider how the nature and experience of operating are involved in sustaining perilous ambiguity. Wilde and Hirst link the existence of contestable errors to the fact that surgeons' decisions about how to practice are always based to some degree on their experience using their bodies and senses in the act of operating, which can be highly personal and specific. For example, in a recent study in which 30 pelvic floor surgeons were videotaped performing what is regarded as a straightforward surgical repair for prolapse (not involving mesh), the authors documented so much variation in each step of the procedure that a 'combination of

these variable steps results in potentially hundreds of different types of...repair' (Fairclough et al., 2019, p. 1523).

In the case of transvaginal mesh, a market-driven proliferation of device-procedures expanded the field of possible practices and choices available to surgeons for when and how to operate. Surgeons found themselves working as field testers for products that were 'permanently beta': they came into market life and passed into market oblivion without leaving the testing stage (Neff & Stark, 2004; Ross et al., 2015). The case of transvaginal mesh therefore has implications not only for analysing the relationship between the experience and nature of operating and patient harm but also for considering the implications of the commercialisation of sensory and physical experience in medicine. The act of operating is subject to a 'politics of embodiment' (Spackman, 2020), that is, to tension and dispute over when and how physical and sensory experiences have meaning.

BACKGROUND

Procedures in pelvic floor surgery are organised into themes and variations. At the thematic level of the highest order is a division between procedures that enter the surgical space via the abdomen and those that enter via the vagina, though these approaches can be combined. As the placement of permanent materials to reinforce repairs became commonplace, an additional high-order distinction emerged between procedures that use reinforcement materials and those that only manipulate existing tissues, often through cutting and/or suturing them to suspend or support, known as 'native tissue repairs'. The two distinctions intersect—native tissue repairs and the placement of permanent materials can be approached vaginally or abdominally—producing another layer of options. In addition, at the same time transvaginal mesh was entering practice, abdominal procedures were increasingly performed laparoscopically, in which a camera and specialised tools, manipulated from outside the patient, are passed into the patient through three small abdominal punctures, creating another category of procedures.

Only the transvaginal placement of mesh, however, came to be seen as an approach that made surgical treatment feasible for a wider range of patients and clinicians. In the late 1990s, surgeons introduced a synthetic mesh strip known as the tension-free vaginal tape (TVT) for the treatment of stress urinary incontinence (SUI)—leakage of urine when 'stress' is placed on the abdomen, for instance, from coughing or jumping. The strip, or tape, was placed under the urethra (which carries urine from the bladder) via an incision in the vagina and two small punctures in the lower abdomen, functioning as a kind of 'backstop' to prevent leakage. The mesh was guided into place by feel rather than sight, using two long 'trocars', similar to knitting needles, and was left in a 'tension-free' position, eventually held in place by the incorporation of the mesh into the body's tissues.

When the definitive paper introducing the TVT appeared in 1996, the surgeon-authors had already sold the mesh and trocars to Johnson & Johnson (New Brunswick, NJ, USA) as a procedure-kit, and it was rapidly and widely adopted. In a 2004 print advertisement, Johnson & Johnson boasted that the TVT had been used in 500,000 patients worldwide. A number of competing kits were rapidly developed by manufacturers and surgeon-entrepreneurs. Emboldened by the possibility of procedures that were easier, less risky and more lasting, surgeons began to experiment with the transvaginal placement of larger pieces of mesh for the treatment of prolapse.

By 2005–2006, dozens of products for transvaginal mesh placement were being actively marketed. Data from England and the United States show that the overall rates of surgery for incontinence and prolapse increased in this period, as did the proportion of surgeries involving mesh. At the same time, increasing complications from these procedures were reported. In 2008, the device regulator in the United States, the FDA, issued its first public health notification on transvaginal mesh as a result of its receipt since 2005 of over 1000 adverse event reports from nine manufacturers. After this, the market for transvaginal mesh devices began a drawn-out collapse as regulators, manufacturers, insurers and health-care systems responded to extensive litigation, the public campaigns of harmed patients and widespread negative media attention.

Use of transvaginal mesh for prolapse was eventually prohibited in some countries (including the United States and Australia), and at this time, all of the major US-based companies have ceased manufacturing prolapse mesh kit-devices. Transvaginal mesh kit-devices for the treatment of SUI continue to have regulatory approval in most countries, although a smaller number of kit products are now available. Transvaginal mesh remains the dominant surgical approach to treating SUI where surgical trends have been studied, and some longer-term data suggests that the complication rates from the use of transvaginal mesh for SUI are low and consistent with those of non-mesh surgical procedures. Complication rates, however, have varied significantly according to the patients, surgeons, procedures, time period and geographic regions studied, as have general rates of incontinence surgery and rates of transvaginal mesh use. And not all complications have equal consequences. Kit-devices for incontinence procedures are the object of most lawsuits in the United States, and their use could and did result in devastating harm for some patients.

METHODS

This article draws from our qualitative research evidence from a study funded by the Canadian Institutes of Health Research, examining the moral economy of pelvic floor surgery, particularly interviews with 27 pelvic floor surgeons (median duration: 59 min) and ethnographic observations of 12 medical conferences hosted in Europe and North America for practitioners who treat pelvic floor disorders. The research was carried out between 2015 and 2018 and approved by the University of Calgary Conjoint Health Research Ethics Board. The data are not publicly available due to privacy and ethical restrictions. Even though the use of transvaginal mesh was declining by the time we started our research, it had been used by almost all pelvic floor surgeons in some form and was still in use by many surgeons internationally. It was a central topic in our data. By 2015–2016, the full negative effects of the widespread adoption of transvaginal mesh for patients and for the profession were indisputable, and surgeons were openly reckoning with their adoption of these procedures. Our interviews, which focussed on how surgeons' approaches to treating pelvic floor surgery had developed and changed, often included granular conversations about surgical approaches including the use of transvaginal mesh. In addition, we asked surgeons about challenges they encountered in their practice, which often elicited discussions about how their own practices differed from those of their colleagues, and the resulting professional and interpersonal dynamics.

The interviews with surgeons took place face-to-face (5) or on the phone (22). Of the surgeon interview respondents, 18 were practising in Canada, and the rest were practising in the UK, France and the United States. We interviewed participants at a range of career stages and with a range of experiences and views on the use of permanent synthetic mesh. All but one of the

surgeons maintained an international profile and were either leaders in their field or active participants in their profession. Many of the respondents had specialised training in pelvic floor surgery (beyond the level of residency in, typically, urology or gynaecology). At the conferences, detailed fieldnotes were created using standard ethnographic practices (notebook jottings, followed by the creation of extended narrative notes within a few hours). Most of the observations were carried out by AD; 16 of the interviews were carried out by AD alone and 11 with CD. All fieldnotes and interview transcripts were anonymised and participants who appeared regularly in the data were given consistent pseudonyms to use across the interviews and observations. In this article, we have referred to the participants using the initials of their pseudonyms. Fieldnotes and transcripts were coded according to the same project coding book, using qualitative analysis software. For this article, the primary codes analysed were those related to surgeons' use of, and views of using, permanent mesh; 'doing surgery'—a set of codes focussed on surgeons' accounts of the skill and senses involved in performing surgery; a code for how surgeons compared devices and procedures; and a code that captured surgeons' descriptions of the interpersonal dynamics of their work and profession.

The interdisciplinary and collaborative nature of the research team allowed for continual analytical and interpretive cross-checking. The interview and observation guides were developed by the team. Although the first author does not have medical training, MR was present as an attendee at many of the medical conferences, and the two met during them to discuss what was being observed (and the choice of what to observe), compare views of what was said and unsaid and for AD to check her understanding of relevant technical and clinical details. SR is a health services researcher with extensive experience leading clinical research in pelvic floor medicine, and she, CD and MR also observed and kept fieldnotes at selected conferences (two for CD; one each for MR and SR), as a way of sensitising everyone to the collection and use of ethnographic data. Themes in the interview and observation data were developed and discussed at regular team meetings, and the project coding book was developed through an iterative team process involving all the paper authors, including staged assessments of coding reliability between AD and CD. After this was completed, CD independently coded about half the project data. The argument here represents one piece of a broader story about the adoption of transvaginal mesh and the nature of contemporary surgical practice.

FINDINGS

Operative variations and navigating risk

The introduction of transvaginal mesh kit-procedures and devices introduced many, and different types of, choices into operative practice that surgeons regarded as potentially significant. Some of the surgeons we spoke to reported feeling, from their first encounters with transvaginal mesh, that the procedures entailed significant risks, some of them new. Surgeons we interviewed and observed were routinely engaged with questions of whether and how dangerous aspects of these procedures could be mitigated.

The perhaps starkest choice stemmed from the shift in sensory engagement required by transvaginal mesh. The trocars that were part of most kits were intended to allow for the placement of mesh without direct visualisation, to varying degrees. Instead, surgeons were expected to rely on their sense of feel and their existing knowledge of the anatomical space of the pelvic floor in the act of operating. Surgeons whose repertoire already included vaginal surgery were likely to have

prior experience operating by feel rather than sight, but not all surgeons were comfortable with procedures guided by feel or the extent to which this was required to place transvaginal mesh. BL, an early-career surgeon 3 years beyond the completion of her fellowship training, described the procedures as 'totally blind':

> Some of these mesh kits, you are putting trocars in so many different places in the pelvis, it is scary, there are so many vessels, nerves that you can't see when you are putting them in totally blind.
>
> (BL)

BL preferred the laparoscopic approach, the surgical style in which she was trained during her fellowship, which allowed her to 'visualise all the structures where you are putting the mesh, and where you are dissecting'. Another senior surgeon who favoured laparoscopy, CS, similarly argued 'anatomy is not necessarily very straightforward' and some anatomical features of the pelvic space not only cannot be seen in vaginal surgery, but cannot be felt:

> You don't see the vessel, you can't feel it. And you don't see the nerve, and you certainly can't feel it.
>
> (CS)

Here, CS was alluding to intraoperative complications that were reported to be comparatively more frequent in some studies of transvaginal mesh procedures—puncturing a blood vessel with the operative tools or placing the mesh too close to nerves—and dismissing any claims that blind procedures could be made safe.

But surgeons like BL and CS, who never placed mesh transvaginally, were in the minority of surgeons we interviewed as well as among surgeons internationally whose practice preferences were documented in surveys. For many surgeons, these risks appeared potentially manageable through adjustments in how they operated. The manufacturers of transvaginal mesh kits, who sent representatives to all the major medical meetings and to the offices of surgeons around the world and hired key surgeons to consult or co-develop products or support them in commercialising their approaches, capitalised on this perceived potential by developing iterations of their products that supported surgeons' adjustments and preferences.

OR, a mid-career surgeon who was experienced with vaginal surgery when the TVT was coming into use, decided she preferred a subsequent version of the original TVT procedure that allowed for a 'top-down' method of placing incontinence tapes, meaning the mesh was introduced through the abdominal punctures rather than the vaginal incision. OR's preferences illuminate the subtlety of some differences in operative technique and the kinds of variations that transvaginal mesh procedures opened up for consideration. Of the problems with the original TVT, a 'bottom-up' procedure, OR said:

> ...your hand is at the end of the handle which is like 30 centimeters away from where your needle tip is. So you don't have that same control because you're far away from the leverage ...a tiny little movement transfers into a wide movement at the other end, so it's not very precise... The handle is straight itself. It's a bit like a long ice pick right?
>
> (OR)

In OR's experience the top-down approach had an entirely different feel, allowing for precision and for directing the trocars away from the bladder and vessels that could be punctured:

> the needle is slightly curved, smaller caliber, looks like a knitting needle essentially. ...There's no force applied that far away and the non-dominant hand grabs the needle like a centimeter or two above the skin and that's the one that drives down and you can go in, you feel it going through the fascia, you feel the bone right there and you can inch your way for two centimeters until you're behind the pubic bone, just at the level of the pelvic floor, and from the vagina you can feel the needle and then guide it through slowly. You're going away from the vessels...away from the bladder.
>
> (OR)

By using a curved needle to inch behind the pubic bone starting from the abdominal punctures and feeling the needle from the other direction, OR thought she was able to mitigate some of the most common risks of the procedure. OR also makes clear the embodied, painstaking quality of operating and the subtle physical and sensory cues that can matter when operating (Prentice, 2013): the transfer of movements generated by the needle's shape, length and handle location; the ability to feel whether the needle was in fact travelling close to the pubic bone; and the position of her hands in order to guide the needle and feel its trajectory.

Among devices for incontinence, the market eventually evolved to include such major subcategories like the 'top-down' approaches just described; slings that were angled towards the inner thighs rather than the abdomen, known as the transobturator approach; and eventually, shorter 'mini' slings that could be placed using only the vaginal incision. Parallel variations emerged among kits for the repair of prolapse, but among prolapse kit-devices there was also greater variation in the size and shape of the mesh, since it was adapted to suspend organs and not only serve as a sling behind the urethra. Such kits established the parameters of distinct operative approaches, and surgeons often reported preferring some approaches and some kits to others. The transobturator approach, for instance, was developed because the surgical entry and exit points, trajectory of the trocars, and subsequent angle of the implanted mesh avoided the bladder and certain blood vessels, but it also brought the tape and trocars close to a bundle of nerves that pass through openings in the pelvic bone at the inner thighs. Eventually, studies showed nerve pain as an uncommon but more likely outcome of transobdurator tape approaches.

There were, however, multiple transobturator kits available, and surgeons did not see them as identical in relation to the possibility of nerve pain. GS, a mid-career surgeon, discussed at length his preference for the Monarc transobturator kit made by American Medical Systems (AMS) (Minnetonka, MN, USA) over a kit made by Boston Scientific (Marlborough, MA, USA), which he was expected to use when his provincial health authority brought it in under contract. Of the Boston Scientific device, he said:

> The trocar is shaped wrong. It's straight at the end instead of curved – and I'm curving it around the pubic bone, and so it damages the tissue too much...it makes you go high in the obturator foramen [the openings in the pelvic bone through which nerves run to the legs].
>
> (GS)

Another surgeon, AF, who had learnt to use the AMS transobturator tape in training, described his preference for it because of its 'outside-in' path, rather than the 'inside-out' path of

a device he was required to use when he went into practice in a health region that had contracted with Johnson & Johnson for devices:

> ...So with the outside-in tape...I knew that anatomically, I'm not close to the nerve. Because I know where I am going, I can see the entry point, I can turn it, and get outside to the inside, and that should not cause nerve damage. But when I first started to use the Johnson & Johnson product...I followed the curve of the trocar, [and thought] "geez, it's going too lateral! That must be closer to the nerve".
>
> (AF)

Surgeons could and did make adjustments within a given approach, or across approaches, or in the way they used a particular kit. AF eventually decided to stop using transvaginal mesh altogether, but in the period when he was using the Johsnon & Johnson transobturator device rather than his preferred device, AF reported, 'I tried to change the curve a little bit, or to manipulate the procedure to get away from the nerve'.

The transvaginal mesh approach therefore allowed for a great deal of variation in when and how surgeons operated, even though it might seem surgical 'kits' would simplify and standardise surgery. Surgeons explained their operative preferences in relation to their perceptions of the dangers of transvaginal mesh procedures. To a significant degree, they relied on their situated, personal experience with transvaginal mesh procedures to determine when and how they were acceptable to use. 'Procedural variation is not just a matter of reason, it is an embodied performance of problem-solving conditioned by an assemblage of spatial, temporal, material and social actors' (Ott et al., 2020, p. 149). At the same time, the meaning of these variations remained ambiguous and contested, as became evident when we talked to surgeons about whether their choices were relevant to others, and when we observed surgeons at medical meetings in various modes of sharing their experience and preferences.

The contested and ambiguous meaning of operative variations

Although surgeons established some definitive preferences in relation to how to operate with transvaginal mesh, the transformation of these preferences into collective meaning was often difficult. Surgeons, especially those actively engaged with their profession and/or those whose practice included research, conscientiously compared their experiences and preferences and sought to determine better and worse ways of practice (Mol, 2002). Surgeons' preferences around transvaginal mesh for prolapse seemed to have especially high stakes since such procedures involved larger amounts of mesh, more extensive dissection of tissues to place it and the passing of trocars or tools into and through more areas of the surgical space. So surgeons discussed, in various venues and settings, whether poor outcomes or adverse events were related to the mesh itself (which came in various shapes and might be manufactured in different ways), or the tools associated with kits, or techniques of operating, or the skills of those operating or the characteristics of the patient and their clinical situation.

Some surgeons came to regard some ways of using mesh as preferences that should have the status of universally shared principles (Apramian et al., 2015). At a didactic surgical workshop in 2016, a presenter showed a video of himself placing a 'second generation' mesh kit-device made by AMS. As the video played, the surgeon explained what he saw as the fundamentals of good mesh placement. One has to be 'absolutely diligent' in getting the mesh flat, he said, and ensure

the mesh is lying tension-free and always check for kinks and folds after placing the mesh. Laying the mesh flat and tension-free seemed to have the status of a widely shared norm by the time we carried out our fieldwork and interviews, but the extent to which special care with mesh placement protected patients from poor outcomes, or the extent to which poor mesh placement was responsible for poor outcomes, was not necessarily clear. GS, for instance, who was convinced of the value of incontinence tapes and was initially 'pretty excited' about kits for prolapse, tried one of the earliest prolapse kits in 'a few cases' after attending a training programme paid for by its manufacturer, AMS. He said, 'the results were abysmal' even though he placed the mesh perfectly:

> I would place it perfectly – at the end of the procedure it looked great, ok? ...and then at office follow-up, it was brutal – the mesh would be all balled up like a little chunk of chewing gum underneath the anterior vaginal wall.
>
> (GS)

Experiences and reports like these circulated among surgeons and device manufacturers and could often be channelled into a perceived need for new or different operative techniques or devices. The 'second generation' mesh-kit device by AMS was indeed designed to be anchored to the sacrospinous ligament to prevent the mesh from moving. And despite this type of abysmal result, GS said he 'didn't have any patients getting chronic pain or anything like that', so he decided to try another kit made by Johnson & Johnson, that 'had a more refined delivery system in my opinion'. But, he 'had the exact same result'.

Sometimes, when surgeons altered the way they used a kit, they recommended others do the same. The surgeon presenting on the second-generation AMS prolapse kit told those attending the training session not to place the anchoring devices 'as deep as recommended, because they can cause pain'. The presenter said that in the first two cases (or, women) in which he used the device, he did end up causing pain, but a colleague then told him 'to only place them at a depth of an inch'. He named the colleague, a well-known surgeon, illustrating not only how surgical styles but also surgical nuances can be affected by the specific people with whom surgeons interact and learn.

The possible role of varying approaches to dissection—how and where tissues were separated—came under particular scrutiny. When, in 2005, early in the uptake of mesh kits for prolapse, a group of Italian surgeons published a paper showing higher rates of erosion and dyspareunia than had been reported by the earliest adopters, they were faulted for not dissecting properly (Ducey et al., 2020). Surgeons who favoured mesh began to try to make tacit practices of dissection explicit, arguing dissection had to be at a 'deeper' level than surgeons might have been accustomed to from native tissue repairs. On many occasions, we observed surgeons trying to describe and show (with videos) the purportedly correct plane for dissection. At the didactic surgical workshop in 2016, the surgeon presenter said:

> On the initial dissection of the vagina it's important to have a deep incision, to "be brave," and never use a blunt (using a finger) dissection in someone who's had previous surgery because you can easily go into the wrong plane, only sharp (using a tool) dissection. If the mesh is placed in a superficial plane of dissection, it can increase the chances of pain.
>
> (Fieldnotes)

At an industry-sponsored session at an international meeting in 2017, however, a surgeon-presenter said he thought the reason for the high rates of dyspareunia in the much-discussed Italian study was not their dissection technique but the chemical coating on the particular mesh product they used. GS said he dissected properly when he used the first prolapse kits, but the results were still unacceptable. Another surgeon, CC, reported having used almost every mesh kit that came on the market. She discussed her experience with the same two early prolapse kits described by GS and said she 'still thinks' the Johnson & Johnson kit 'is an amazing product and I wish it hadn't gone off the market', but also that the delivery system with the AMS kit 'was actually safer'. Surgeons were aware of these differences, which raised questions about why their experiences could be so different, even among highly trained and highly engaged specialists.

Surgeons did not necessarily agree on what caused worse results and what needed to be changed in order to obtain better results. Surgeons contested whether the problems resulted from the kits themselves or who was putting them in. Surgeons contested both what were necessary surgical techniques and whether surgeons were in fact using those techniques. Surgeons contested what were relevant clinical and operative findings and outcomes. LS decided not to use transobturator tapes because, 'having examined hundreds of women who have had transobturator tapes done by skilled individuals, not-so-skilled individuals':

> ...when you do a vaginal exam [on patient who has had a transobturator tape implanted] there's two, like, guitar string ropes on the anterior wall [of the vagina].
>
> (LS)

'Yes', she said, 'the transobturator tape is working, and the patient doesn't have pain' but 'they just have a subtle change to the vaginal architecture that I don't think is normal'. This was an embodied perception to which LS thought most other surgeons were oblivious, because they were less experienced or less attuned to the outcome of vaginal shape and position.

Surgeons were aware of a lack of evidence to support many of the kinds of choices they were making, and often observed that the choices that mattered to them were not assessable using the standard tools of evidence-based medicine, such as clinical trials. As LS explained about her experience of being able to feel the transobturator tape during the vaginal exam (even though the patients themselves do not): 'how do you pick that up in a randomised controlled trial? You can't'. Surgical trials do not capture nuances such as whether there are any kinks or folds in the mesh when the surgeon is closing a patient up or the method and plane of dissection (Ergina et al., 2009).

We asked AF whether there had been any studies of the differences between the two transobturator device-kits he had used to confirm his perception that the inside-out Johnson & Johnson kit brought the mesh too close to the nerves of the inner thigh. He said:

> There are no studies to show any clinically significant difference in chronic pain. But there are studies that compare the two. But their primary outcome was not pain. It's very difficult to design a study with a primary outcome of an adverse event.
>
> (AF)

Surgeons like AF based their preferences on what they experienced in the act of operating. Yet AF was reluctant to suggest other surgeons should have altered the procedure as he did. A few years after he stopped using transobturator tapes, a study led by the Director of Medical Affairs at Johnson & Johnson was published showing their device could come as close as 1 mm to the nerves, not the 2 cm claimed in the company's instructional materials. The study made visible the procedure's anatomical path by placing the mesh in fresh cadavers and subsequently

dissecting them. Although AF had already decided, through the feel of the procedure, that the trocar 'must be closer to the nerve', he said only Johnson & Johnson knew the truth about the procedure: 'they knew, I did not know, but they knew and they didn't tell me'.

Surgeons thereby downplayed the value of decisions based on knowledge and experience that might be incomplete or idiosyncratic (Maslen, 2016). Another surgeon, AK, stopped using mesh kits for prolapse 'really quickly' because they 'didn't feel right' when she put them place, but said a colleague she worked with thought the same kits 'were the best thing on Earth'. AK said, 'it's hard to know why' and there was 'no indication that there was anything wrong with them [the kits]. So, my opinion, and my colleague's opinion, were just that'.

Evidence of a certain type seemed necessary to transform personal operative experience into a widely shared norm. GS described his efforts to voice his concerns about mesh kits for prolapse: 'we were seeing patients in consultation with terrible problems [from mesh procedures] from the same guys who were telling us in meetings that things were going very well'. GS said he then 'made some people quite angry' when he took a particular colleague 'to task' about his mesh procedure at a clinical meeting, in a 'big Q&A session'.

> ***GS:*** It was sort of enough cases to give me an inkling that allowed me to be outspoken at meetings, but not enough that I could compile a series and say, "Here's what's actually going on." You know what I mean?
>
> ***Q:*** Right, because you didn't publish any of it or--
>
> ***GS:*** No, no. All we had was smoke. But enough smoke for me to stand up in meetings and say, "What in Sam Hill! You know, I am seeing complications, my own and somebody else's."

Because he could not 'compile a series' as evidence, GS argued his experience was insufficient to produce collective certainty and change: 'all we had was smoke'.

Surgeons also pointed out the difficulty of disentangling preferences about how to operate from the specific circumstances and context of each surgeon's practice and each patient's situation. The presenter at the 2016 workshop gave but one example—dissection techniques will be affected by whether the patient has had previous surgery (due to scar tissue in the surgical area). OR was the only surgeon we interviewed who favoured the top-down approach to placing a TVT-type sling, and when asked whether there was any evidence to support her choice, she said:

> I don't think so...It's about patient comfort. In my hands, I don't feel comfortable, especially since I'm teaching residents
>
> (OR)

In this case, the feel of the procedure in her hands was crucial to her decision about how to operate, but so was the context of teaching residents, whom she wanted to teach in a way she thought most safe.

CS contended that transvaginal mesh was the preferred surgical approach for pelvic floor disorders only among surgeons who were insufficiently skilled with laparoscopy. CS also alluded to having to manage complications from transvaginally implanted mesh in patients treated by an unnamed colleague. And, when asked whether the harms reported in lawsuits were caused by 'something inherent to the kits' or were 'primarily a matter of who was putting them in', CS said, 'I think it was who was putting them in'. Yet CS resisted projecting herself into the situation

of her colleagues. When asked whether the patients in her practice get better care, she said, 'I don't know what kind of care they get at other places'. In these ways, surgeons were reluctant to position their experience as knowledge, even though experience led them to some certain and specific decisions about whether and how to use transvaginal mesh.

DISCUSSION

Transvaginal mesh procedures entailed an extensive array of practice options and choices. Many surgeons we interviewed and observed reported definite preferences for when and how to use transvaginal mesh, but their preferences often did not have the status of universal norms or principles. In this respect, their preferences resembled what Bosk called quasi-norms. In addition, these surgeons' stories confirm the ways surgery as a practice is complex and contingent (Pope, 2002), including how ways of operating are influenced by context: how a national health-care system organises the training and privileges to perform procedures; how a health region contract limits the devices available to surgeons; and whether surgery is performed in clinical settings that involve training.

However, in keeping with Mol's observations, these surgeons constantly compared practices. At the same time that many surgeons expressed doubt about the generalisability of their experience, they depicted practices different from their own as inferior. They talked as if their own surgical choices were better for patients—for instance, when surgeons spoke in terms of the need for 'absolute diligence' in placing the mesh flat. In so doing, they often cast themselves as superior practitioners, for instance, as those who were 'brave' enough to make the right dissection. Or they used dramatic language to describe approaches they did not favour: trocars became 'long ice picks' or transvaginal procedures were 'totally blind'. Furthermore, some surgeons reported that they felt, and not only in hindsight, that some procedures might be worse in the sense that they could entail new and unjustifiable risks. The term 'contestable errors' is therefore more apt than quasi-norms, because it highlights the existence of variations that are seen by relevant actors as consequential because they are not equally good but are also the subject of dispute.

Dispute might centre on the possible causes of better or worse results; or whether causes can be linked to effects by evidence; or what kinds of results are clinically important; or whether surgeons' accounts of how they operate match reality. These disputes, and the collective ambiguities involved in the use of transvaginal mesh, were rooted to a significant degree in the nature of operative work: the kind and array of variations operating allows for the centrality of surgeons' personal and embodied experience of procedures in their assessments and the elusiveness of this experience in relation to contemporary standards of evidence. Some surgeons seemed to regard as 'knowledge' only those forms of intelligence deemed publishable using the standards of EBM. GS challenged his colleagues' use of prolapse kits, after using two versions himself, but referred to his own experience and observations as merely 'smoke'. OR called her choice, as surgeons often do, the right one 'in my hands' (see also Ott et al., 2020), implying it was not a necessary choice in other hands. CS felt strongly that transvaginal implantation of mesh was an inferior practice rooted in some surgeons' insufficient repertoires, but rebuffed any suggestion that she might be able to explain cases of patient harm, on the grounds that she couldn't 'know' what others were doing in their practice. These are the ways differing practices are accepted, even if contested.

As a practice that involves tacit, physical and craft-based knowledge, the experience of operating can also be resistant to articulation and communication. Dissection, for instance, is an aspect of operative technique that is tacit to some degree and required explication in pelvic floor

surgery as practices began to include the placement of permanent mesh. Surgeons who used 'deep' dissection felt it should be a principle (Apramian et al., 2016)—dissecting otherwise was an error. In the previously mentioned study in which surgeons were videotaped performing native tissue repair for prolapse and interviewed afterwards (Fairclough et al., 2019), surgeons with experience using transvaginal mesh were more likely to use deep dissection. Yet the study authors found the terms surgeons used to describe their techniques were inconsistent among one another, and the researchers' perceptions of the techniques the surgeons used did not always match the surgeons' descriptions of what they did. It is not necessarily so that surgeons are doing the same thing when they describe their approach with the same terms, such as 'deep dissection' or 'tension-free', or that they are doing different things when they use different terms. It is difficult to know how the surgeons we studied actually operated and how that relates to their ways of describing the ways they operated. We do not know if GS did in fact 'perfectly' place the mesh that collapsed into a ball, and no doubt some of his colleagues wondered the same.

These difficulties around valuing what was known through operative practice and communicating the lessons of operative practice were exacerbated by the variety of practices the transvaginal surgical approach could entail. The commercially driven proliferation of device-procedures encouraged surgeons to view any problems as potentially solvable through operative adjustments, including the use of different kits. Surgeons who caused pain or had abysmal results with one kit made adjustments or went on to try another. We observed numerous industry-sponsored presentations by surgeons on why the latest kit was better than those that came before. Evidence in the form of clinical trial results and systematic reviews did emerge over time to compare some procedures and devices, but the number of variables and options involved in pelvic floor surgical procedures meant clinicians could usually and reasonably call into question whether the evidence was useful. Surgeons, therefore, seemed to be engaging in a losing battle as they tried to articulate and share what they had learnt from experience while practices around them were rapidly shifting and changing. Pelvic floor surgeons' experiences using transvaginal mesh were fragmented and dispersed across a range of practitioners and a range of products and procedures.

It is important not to be in deference to complexity (Mol, 2002) and ambiguity or uncertainty that may result, especially if it can allow for harm that is not occasional and not unavoidable. The part played by the nature of operating in the failure of this community of surgeons to mitigate patient harm should not be exaggerated. The place of transvaginal mesh procedures within the larger therapeutic field of pelvic floor surgery (Ducey et al., 2020) meant many surgeons wanted these procedures to work, and therefore may have placed excessive faith in what could be accomplished through changes to operative technique and devices. Many of the surgeons we interviewed saw their adjustments as making mesh kits safer, but it is also possible that their surgical adjustments provided a false sense of security.

It would also be incorrect to suggest that operative experience cannot be made explicit and meaningful (Pinch et al., 1997; Pope et al., 2003; Prentice, 2007). The surgeons we observed and interviewed attempted to communicate the value of their embodied knowledge (Nettleton et al., 2008) and reflect on its value (Shilling, 2017). At the medical meetings, surgeons tried to overcome the challenges created by a lack of physical co-presence in the operating room by showing pictures and videos or organising surgery demonstrations (on cadavers or by videocasting). Medical meetings were important spaces in which informal knowledge (Waring & Bishop, 2010) about transvaginal mesh, such as how 'deep' to place anchoring devices or what 'tension-free' placement meant, was shared. Some surgeons no doubt learnt on these occasions when and how to use mesh more safely.

Likewise, we should not assume it was impossible for this group of surgeons to identify better devices and techniques and collectively make better judgements about whether and when

to use mesh. We have shown that determining the source of problems with these procedures could be difficult, but some surgeons may have brushed aside danger through explorations of operative nuance. Uncertainty was not simply a natural and inevitable byproduct of innovation. To some degree, it was fostered and strategically used (Timmermans et al., 2018). Uncertainty and complexity sustained a profitable market (McGoey, 2012) for many years and buffered surgeons from critique and litigation. Resisting evidence can be a strategy for guarding professional autonomy and clinical discretion (Pope, 2003). So too, these surgeons' professional culture (Cassell, 1991) was in part to blame for any reluctance to 'speak up' and label some approaches as errant and some surgeons as irresponsible. GS said critiquing his colleagues' procedures at a large medical meeting was, 'like I sort of stood up and said "I must be a real lousy surgeon"'. To critique colleagues can be a serious emotional, social and professional gamble.

Finally, these surgeons' descriptions of the difficulty of extrapolating general lessons from their hands-on experience are impossible to separate from their ways of accounting for their, or their colleagues', use of these procedures (McDonald et al., 2006)—in gatherings such as professional meetings and in interviews with curious, potentially critical, researchers. Surgeons did, in some moments, seem to attempt to normalise the risks they were taking (Waring et al., 2007). When AF indicated he adjusted the inside-out transobturator tape procedure because he thought it came too close to the nerves, he declined to call that adjustment a result of knowledge. He defined knowledge in a way that made his use of the procedure justifiable: he did not truly 'know' the procedure came too close to the nerves, only the device manufacturer knew.

CONCLUSION

This article shows the extent and potential consequences of ambiguous differences in surgical practice. It suggests how the rootedness of this ambiguity in the act of operating allowed for some risks to be overlooked or underestimated, and for worse or dangerous practices to persist. Cases of widespread patient harm in particular call for attention to how and why the use of dangerous procedures or devices could come to be collectively tolerated, even if contested. It could be argued that many surgeons who used transvaginal mesh made what Bosk would call errors of judgement: they took up device-procedures in situations where the risk-benefit balance was questionable, even if many of their patients were successfully treated and most were not harmed. It is also certain some surgeons were 'not so skilled', as LS observed, and made what Bosk would call technical errors in their operative practice. Yet attributing the harm caused by transvaginal mesh to mistakes or errors is, on its face, insufficient. A device or procedure cannot come into such widespread use unless many surgeons have found ways to experience the use of that device or procedure as responsible.

The case of transvaginal mesh illustrates the politics of how and when embodied experience, in this case of operating, comes to have meaning (Spackman, 2020). There was considerable scope for operative experience in the use of transvaginal mesh to be contested, because of the variations and nuance the physical and personal work of operating entails (Ott et al., 2020). Furthermore, the commercialisation of transvaginal mesh procedures arguably made collective understanding more elusive and enabled ambiguous variations to be folded into everyday practice on a broad scale. The ensuing harm was therefore also extensive. The connection here between surgical practice and patient harm is not a matter of the outcomes of any given surgeon or surgical procedure, but is a matter of when and how the experience of operating is made sense of. The chances of harm from any transvaginal mesh operation will differ considerably according to a number

of factors, and to this day, there are circumstances in which many pelvic floor surgeons feel transvaginal mesh can be safely and responsibly used. This analysis does not assess clinicians' judgement, rather it reveals the perhaps underappreciated extent and persistence of variations in operative practice and shows how the rootedness of such variations in the embodied act of operating affects surgeons' perceptions of their own and others' practices and their response to harm.

AUTHOR CONTRIBUTIONS

Ariel Ducey: Conceptualization (Equal); Formal analysis (Equal); Funding acquisition (Lead); Methodology (Lead); Project administration (Equal); Writing – original draft (Lead); Writing – review & editing (Lead). **Claudia Donoso**: Conceptualization (Supporting); Data curation (Supporting); Formal analysis (Equal); Methodology (Supporting); Project administration (Equal); Writing – review & editing (Supporting). **Sue Ross**: Conceptualization (Equal); Formal analysis (Supporting); Funding acquisition (Supporting); Methodology (Supporting); Writing – review & editing (Equal). **Magali Robert**: Conceptualization (Equal); Formal analysis (Equal); Funding acquisition (Supporting); Methodology (Supporting); Writing – review & editing (Supporting).

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The data are not publicly available due to privacy or ethical restrictions.

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