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From anatomy to patient experience in pelvic floor surgery: Mindlines, evidence, responsibility, and transvaginal mesh

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ABSTRACT

Beginning in the late 1990s, surgeons around the world widely adopted the transvaginal placement of permanent synthetic mesh for the treatment of several common pelvic floor disorders in women. By 2012 it had become the subject of extensive litigation, including one of the biggest mass-tort cases in U.S. history, with litigants reporting debilitating and unexpected complications. Based on qualitative research that includes interviews with surgeons, observations of medical conferences, and analysis of archival materials, we argue the adoption of transvaginal mesh cannot be fully explained without recognizing the role of mindlines, or collective moral-epistemological ways of knowing and acting responsibly. The adoption of mesh was anchored in a mindline focused on repairing anatomy. The harms that resulted from transvaginal mesh necessitated a shift to a focus on patient experience. We analyze the role of evidence-based medicine (EBM) in the re-organization of these surgeons' mindlines, showing that mindlines are not reducible to evidence as defined by EBM and that evidence thus defined facilitated the adoption of transvaginal mesh.

1. Introduction

Beginning in the late 1990s, physicians whose clinical domain included surgical interventions in the female pelvic floor (typically gynecologists, urologists, and the growing number of specialized urogynecologists) rapidly adopted transvaginally-implanted permanent synthetic mesh as a means of treating several common pelvic floor disorders, especially stress urinary incontinence (SUI) and pelvic organ prolapse (POP). By 2012, the use of transvaginal mesh had become the subject of one of the biggest mass-tort cases in U.S. history, involving an estimated 100,000 plaintiffs in state and federal courts. Litigants reported debilitating complications including irreversible chronic pain. We propose the adoption of transvaginal mesh cannot be fully explained without recognizing its position within what has been called a "mindline," or a collective moral-epistemological way of knowing, feeling, and acting. Mindlines entail particular constructions of evidence and responsibility, and the harms that resulted from transvaginal mesh necessitated a shift in these constructions from a focus on anatomy to a focus on patient experience. In this paper, we examine the substance of these mindlines, their relationship to the standards and measures of evidence-based medicine (EBM), and the role of transvaginal mesh in their re-negotiation.

The findings are presented in five sections: 1) a description of the anatomy-centered rationale for the use of transvaginal mesh; 2) the development of evidence in this field in relation to EBM (objective and subjective outcomes); 3) how evidence was used by proponents of the anatomy mindline in the context of the rapid commercialization of transvaginal mesh and emergence of reports of harm; 4) the implications of an ascendant mindline centered on patient experience; and 5) a discussion of what this case shows about the relationship between evidence, responsibility, and mindlines. The analysis is a reminder that recourse to the evidence of EBM alone will not lead to the kind of critical reflexivity required to call into question surgical practices that make sense.

2. Background & literature review

Surgery for SUI, leakage of urine from "stress" such as coughing or jumping, was reconfigured in the late 1990s by the development of the tension-free vaginal tape (TVT). It entails pulling or pushing a strip of synthetic, polypropylene mesh into place under the urethra via an incision in the vagina and two small punctures in the lower abdomen,

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using two long trocars (not unlike knitting needles). Previously, the favored surgical treatment for incontinence entailed opening the abdomen. When the definitive paper introducing the TVT appeared in 1996, the mesh and trocars had already been sold to Johnson & Johnson as a procedure-kit, and it was rapidly and widely adopted. In a 2004 print advertisement, Johnson & Johnson boasted the TVT had been used in 500,000 patients worldwide.

In the case of prolapse, a descent of the pelvic organs that pushes down the vagina, sometimes causing a protrusion beyond the vaginal opening, prior to the widespread use of mesh most vaginal approaches were "native tissue repairs," in that surgeons depended, in varying ways, on a woman's existing tissues (such as ligaments) to create support for the pelvic organs, when the weakening of such tissues had likely led to prolapse in the first place. In seeking more durable methods of repair pelvic floor surgeons had therefore long experimented with reinforcement materials as overlays on the tissues. By the late 1990s, general surgeons already used synthetic mesh to reinforce inguinal hernia repairs, and gynecologists were starting to use mesh abdominally in selected cases of POP. The polypropylene used in the TVT seemed to be better tolerated than earlier materials and as it was incorporated into the body's tissue, it formed what one surgeon described as a kind of "rebar" in the pelvic floor. The transvaginal surgical approach using trocars was also considered simpler than emerging laparoscopic abdominal techniques, and could likewise claim the designation as minimally invasive.

Many surgeons and companies therefore began to develop techniques to transvaginally place larger mesh pieces, and by 2005–6, dozens of products for transvaginal mesh placement were being actively marketed, each as entailing an indispensable modification of the procedure or materials. Data (and the data is limited and fragmented) shows that in the U.S., from 2005 to 2010, rates of prolapse surgery involving mesh increased significantly and 74.9% of procedures used the vaginal route (Jonsson Funk et al., 2013). At the same time, increasing numbers of patients and doctors began to report debilitating complications of these procedures. In 2008, 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 surgical manufacturers, many of which were likely triggered by lawsuits (see Leiter et al., 2017).

Transvaginal mesh became one of several recent, highly-publicized scandals around implantable medical devices (on the case of hip implants, see Anderson et al., 2007), made more likely by insufficient regulatory systems, cleverly exploited by device manufacturers (Heneghan et al., 2017; Kent and Faulkner, 2002; White and Walters, 2018). In this paper, though, we focus on the fact that these procedures seemed, to many surgeons, to "make so much sense" (as one surgeon said of his first reaction to the TVT). Social scientists have shown sense-making in medicine to be collective and oriented toward specific contexts, in response to clinical and non-clinical considerations, using concepts like routines (Berg, 1992; Bloor, 1976), ontologies (Mol, 2002), or distributed protocols (Timmermans and Berg, 1997). They have also highlighted the normative aspects of sense-making: preferred practices or routines – and disputes about them – are bound up with the presentation and understanding of oneself or one's collective as moral and responsible. This is captured in conceptual work on communities of practice (Brattheim et al., 2011; Lave and Wenger, 1991); conventions (Biggart and Beamish, 2003); moral economies (Daston, 1995) in science; "indigenous morality" (Halpern, 2004; Bosk, 1979) or normative regimes (Pickersgill, 2012) in medicine; narratives of responsibility (Gordon and Paci, 1997; Kaufman, 1997; Waring, 2009); and historical and comparative research that highlights the moral dimensions of negotiations over evidence (Dodier, 1994; Dodier and Barbot, 2008; Schlich, 2007).

In the clinical and health services literatures, a similar approach has gained traction in the form of Gabbay and le May's concept of "mindlines" as "collectively reinforced, internalized tacit guides" that "have a much deeper and more pervasive function than merely guiding the diagnosis and management of patients: [mindlines] both embed and express professional norms and values. They embody the clinicians' conformity to the collective precepts and principles of their relevant communities of practice" (Gabbay and le May, 2010: 169). Notwithstanding its cognitivist connotation, Gabbay and le May use the term to systematically tie together what practitioners "know" with how they represent and feel about what they know and with the material technologies, embodied skills, and institutional resources and constraints that shape what they can do with what they know. The extensive citations of the original paper (Gabbay and le May, 2004) indicate the concept's face value in the medical and health services literatures and its potential as a conceptual bridge between the ways practitioners understand their choices and the ways social scientists do. We use the term in part because it was generated out of the analysis of medical practice in particular, though it bears particular resemblance to Daston's understanding of a moral economy. Unlike many analyses of moral economies, however, this case speaks to how and when that which makes sense is destabilized and transformed (see Dussauge et al., 2015).

We extend work on mindlines by emphasizing their ethical and political dimensions (see Wieringa and Greenhalgh, 2015). Mindlines structure understandings of how to be a moral and responsible actor (ethics), which are in turn embedded in broader contexts that shape and constrain how the medical community must conduct itself to be seen as responsible and deserving of authority and autonomy (politics). Of particular interest here is how the definitions and standards of evidence-based medicine (EBM) played into the negotiations over evidence and responsibility in pelvic floor surgery, and the field's changing "ecology of standards and measurements" (Moreira, 2018). While the meaning of "evidence" in EBM is neither fixed nor uncontested, as a particular "culture of evidence" (Tang and Schlich, 2017) it has privileged the randomized-controlled trial, and the development of research design methods and tools of quantitative measurement required for RCTs. EBM is a powerful "political operator" in recent medical history: an imperative in relation to which medical practitioners must position themselves (Dodier and Barbot, 2008).

Finally, because the use of transvaginal mesh resulted in extensive unnecessary harm, there is a link between this analysis and the social science of patient safety, which has shown the importance to safety of medical cultures, collective affects, and informal communication (Goodwin, 2018; Iedema, 2009; Martin et al., 2015) and the limitations of hinging patient safety on the implementation of standardized tools (Mitchell et al., 2017; Zuiderent-Jerak et al., 2009). Our focus is not on surgical cultures of managing errors, but the configurations of values and knowledge that shape what will or will not be considered an error.

3. Methods

This paper draws broadly and selectively from our qualitative research evidence. Between 2015 and 2018, we interviewed 27 pelvic floor surgeons (median duration: 59 min), observed 12 medical conferences hosted in Europe and North America for physicians and allied health care professionals who treat pelvic floor disorders, and compiled and analyzed documentary evidence such as print advertisements, commentaries and opinion pieces by clinicians, and clinical articles about when and how to treat pelvic floor disorders. The research was approved by the University of Calgary Conjoint Faculties Research Ethics Board and funded by an Ethics Catalyst Grant from the Canadian Institutes of Health Research (Funding Reference Number 139100)

The first three parts of the findings section are largely a socio-historical analysis of the clinical literature. However, as selected excerpts from the interviews and observed meetings in these sections show, it was in interviews and clinical meetings that surgeons most directly articulated positions that we locate within mindlines, and from which we learned to read for nuances and less-than-overt strategies of persuasion in the clinical literature. The final two parts of the findings section focus on the interviews and observations, as they better reveal

the emotional and ethical qualities of mindlines, and that they are not identical with what the evidence ostensibly reveals.

The interviews with surgeons took place face to face (5) or on the phone (22). Of the surgeon interview respondents, 18 were practicing in Canada, and the rest were practicing 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 maintain an international profile and were either leaders in the field or active participants in their profession. Many of the surgical respondents had specialized training (beyond the level of residency) in pelvic floor surgery. Interviews focused on their professional history and training, and always included often granular conversations about their preferred surgical approaches. At the conferences, we observed training workshops, scientific paper sessions, keynote lectures, panel debates and roundtables, industry-sponsored sessions, mini-lectures on the latest evidence, video sessions on surgical innovations, and we visited vendor booths in the exhibition halls. The transcripts and fieldnotes from this data are anonymized. In this paper, all surgeons are referred to using the initials of their pseudonyms. The data have been analyzed using qualitative analysis software (NVIVO) and a project coding book was developed through an iterative team process involving all the paper authors, and staged assessments of coding reliability between the PI (AD) and Project Manager (CD). In preparing this analysis, we re-read the relevant codes in our qualitative evidence database, and built the argument in team meetings and the exchange of memos.

4. Findings

4.1. The anatomy mindline and the appeal of transvaginal mesh

At an international medical meeting in 2016, about five years after the market for transvaginal mesh devices began its collapse in response to the FDA's second public health notification, a surgeon, speaking to a full auditorium about the proper clinical place for vaginal mesh surgery going forward, showed a video of himself doing a prolapse procedure that involved placing a lighter, smaller piece mesh a bit more loosely than in some of the earlier transvaginal mesh kit-procedures. Apparently because the procedure in the video did not look especially tidy, the surgeon remarked, capturing the shift this paper examines: "what we did not understand from the beginning [of using transvaginal mesh] … was the goal of mesh surgery was not to restore anatomy as we had thought – the joy of this surgery comes six weeks after surgery, not in the operating room."

In the lead-up to the widespread adoption of transvaginal mesh, the predominant view among pelvic floor surgeons was that their existing procedures largely failed. In a 2016 interview, one mid-career urogynecologist explained the moral-epistemological position that grew out of frustration with a common prolapse procedure, that involves folding and suturing the front (anterior) vaginal wall to create support:

> *EH: If you have a procedure that has such a high failure rate, like a native tissue anterior repair, then the question is, what don't we understand that is leading to this? Because clearly we keep doing this procedure that we know doesn't work. It's like the definition of insanity. … You can easily see why people wanted to put mesh in, because it's almost unethical to offer them [patients] a native tissue repair.*

These "failure rates" were perceived in anatomical terms as the recurrence of prolapse, and surgeons' clinical experience and perceptions of anatomy and physiology were sufficient for knowledge of this failure. In what would become a widely-cited paper, Nicita (1998) justified his use of a notably large piece of transvaginally-placed permanent synthetic mesh by stating, without apparent need of citation, "the majority of current procedures of prolapse surgery fail," because they do not address what he viewed as the underlying cause of prolapse, a separation of the levator ani muscle. Prolapse is categorized by the segment of the vagina that has collapsed (front/anterior wall, back/posterior wall, or top/apex). Nicita hypothesized his use of synthetic mesh would resolve and prevent recurrence of all types of prolapse "by returning the viscera to their correct anatomical seat." In a pivotal 1996 study in which an experimental group of twelve women with "severe, recurrent anterior wall" prolapse were treated with the transvaginal placement of a Marlex polypropylene mesh, Julian (1996) argued the failure of these patients' previous surgeries was due to what he called "underlying connective tissue weakness." Julian reported 100% success in the group treated with mesh, as indicated by the absence of descent of the anterior segment at two-years follow-up.

Surgeons experimenting with transvaginal mesh isolated fixing anatomy as a distinct criteria for responsible practice, but in so doing implicitly or explicitly differentiated it from, and downplayed, patients' experience of their anatomy. For example, Julian did cite support for his claim of a 20–40% rate of anterior prolapse recurrence after native tissue repair, notably a report by Morley and DeLancey (1988) on their experience with sacrospinous ligament fixation (SSF), in which the top of the vagina is suspended to ligaments using sutures. Morley and DeLancey found at follow-up of one year or more that 45 of 71 (63%) patients had "excellent support in all respects," which it seems Julian read conversely as a high failure rate. Julian did not mention that Morley and DeLancey also reported 90% of patients studied were asymptomatic at follow-up, including many with lesser levels of post-surgical anatomical support, concluding "these success rates are surprisingly good considering the inherent weakness of the tissue" (pg. 879).

In another important early paper, Flood et al. (1998) reported on their use of a transvaginally-implanted strip-like piece of Marlex mesh beginning in 1977, to reduce the rate of recurrence of "anterior wall defects," which "may be as high as 37%." They cited a study, led by Paraiso (1996), which showed 42% of patients experienced a "support defect in at least one segment" of the vagina after SSF native tissue surgery. Significantly, though, it was recognized that the typical support defect – at the anterior (front) vaginal wall – was often asymptomatic. In their paper, Paraiso and coauthors therefore articulated the idea of responsibility that could justify changing surgical approaches to prevent an often asymptomatic anatomical consequence of the existing approach:

> "Perhaps the concern we have with regard to pelvic floor defects is 'much ado about nothing.' Most patients with anterior wall defects do not have symptoms and few require subsequent surgery. On the other hand, one of our goals is to correct all anatomic defects, restore anatomy, and prevent recurrent vaginal support defects" (1430).

Since native tissue repairs could not "correct all anatomic defects" and reliably prevent all recurrence, they were unsatisfactory, even if the subsequent defects were not experienced by patients. The potential loose coupling between anatomic "defects" and experience was acknowledged but set aside by Paraiso and coauthors. And in his classic paper, Julian did not state whether the four patients in his control group whose native-tissue surgery failed because he observed a degree of prolapse post-operatively were symptomatic or subjectively better or worse after surgery.

Some of these surgeon-researchers likely regarded the state of the anatomy as directly correlated with, even identical to, the state of patients' well-being. They also saw their turn to transvaginal mesh as patient-centered, because it was likely a more durable fix than native tissue repair and, some felt, less invasive. In the surgical milieu, minimally invasive surgery was increasingly expected (Frampton and Kneebone, 2017; Tang and Schlich, 2017). But statements like that of Paraiso and coauthors suggest some awareness of the potential trouble in downplaying patients' perceptions of symptoms in the interests of repairing anatomy. This awareness may explain the enormous weight given to a single statistic, from a study led by Olsen (1997), that among

all patients in a major U.S. nonprofit health plan who underwent surgical treatment for prolapse and incontinence in 1995, 29.2% were repeat procedures. This not only supported the perception of a high rate of surgical failure, but also that in many cases of recurrence patients were sufficiently impacted to opt for reoperation. However, Olsen and coauthors reported no information about when and how these patients were initially surgically treated, the disorders they were treated for, and why re-operation was elected. A later, prospective study by some of the same researchers (Clark et al., 2003) found a lower reoperation rate of 13% in a community-based population, but the Olsen statistic confirmed what many surgeons viewed as self-evident. While mesh was adopted by surgeons on the basis that it durably restored anatomy, women's perceptions of mesh repairs were not measured.

4.2. The development of objective and subjective measures

In the late 1990s, there was a flurry of activity to improve the evidence base for pelvic floor surgery, in keeping with the expectations of the EBM movement and as this subspecialty began to take shape, with its own fellowships, professional societies, and clinical meetings. As a result, efforts to specify and measure disorders as well as surgical outcomes, both objective and subjective, gained momentum. The specification and measurement of subjective outcomes, however, remained marginal until the crisis around mesh took shape.

In the case of prolapse especially, the lack of a standard anatomical measure was recognized as a significant hurdle to creating consistent, comparable clinical studies and a sign of inadequate collective conventions (Cambrosio et al., 2006). The POP-Q Assessment tool was introduced in 1996 as an "objective, site-specific system for describing, quantitating, and staging pelvic support in women" (Bump et al., 1996). Previous classifications were regarded as too vague. The POP-Q system considered two major anatomical signs – the location of the "leading edge" (front, back, or top of the vagina) of the prolapse and a fixed point on vaginal wall – in relation to the "hymenal ring" (remnants of the hymen typically located just inside the vaginal opening). Basically, if the leading edge of the vaginal wall was more than 3 cm above the hymenal ring, the prolapse was stage 0. Stage I prolapse was descent up to 1 cm above the level of the hymenal ring. Stage II included prolapse within 1 cm above or below the hymen, and stages III and IV were degrees of descent greater than this – situations in which there is a visible protrusion out of the vaginal opening.

These anatomical stages, however, required clinical interpretation. In 2001, a consensus panel of the U.S. National Institutes of Health used the POP-Q tool to establish what would be defined as prolapse and its successful surgical treatment (Weber et al., 2001): prolapse would be "descent of Stage I or greater," and an "optimal anatomic outcome (cure)" after intervention would be stage 0. A "satisfactory anatomic outcome" after intervention was defined as stage I, and an "unsatisfactory anatomic outcome" as stage II or greater, "or no change or worsening from the pre-treatment stage." The authors acknowledged that the clinical definitions of prolapse and success after intervention should ideally include symptoms and noted they did not intend to signal what was "normal" and "abnormal." So too, the creators of POP-Q system had called for more research on the characterization of "functional deficits" caused by pelvic organ prolapse (Bump et al., 1996). But, until "data correlating symptoms to physical findings" became available, the authors of the 2001 consensus statement argued, "only the complete absence of prolapse should be considered 'normal.'" (180–1).

Some researchers had been working for some time on the definition and measurement of symptoms and patient experience. As early as 1982, Norton, a nurse in London (UK), published a structured questionnaire to "ascertain the degree and extent of restrictions which were imposed on the individual by incontinence." Norton's scale included questions about the effects of incontinence on "physical health, mental well-being, domestic chores, social life, relationships with family, relationship with husband or boyfriend, work, dress and whether fear of odour or embarrassment restrict activities" Norton (1982: 10). Five years later (Wyman et al., 1987), Norton's questionnaire was elaborated into the Incontinence Impact Questionnaire (IIQ), consisting of three broad categories of effects: activities of daily living, social interactions, and self-perception. And in a 1994 paper, the scale was separated into two measures: a "Urogenital Distress Inventory" (UDI) measuring symptoms and the extent to which women found them bothersome; and an expanded IIQ (Shumaker et al., 1994). In the 1990s, a number of such inventories for urinary disorders were developed.

At the early stages, the main purpose of these measures seemed to be to elevate patient experience to the status of "objectively demonstrable" and establish the significant distress that could be caused by such disorders to marshal support for their study and treatment. The role of these measures in assessing when and how to treat patients, and to gauge treatment success, was given less weight. By the mid-1990s, however, this had begun to change. Shumaker et al. argued, "as new treatments are made available … it becomes increasingly important to develop measures that both adequately characterize the impact of the condition on the health-related quality of life of individuals, and are sufficiently sensitive to detect the effects of treatment" (1994: 297–8). And in a paper presented at the 1994 annual meetings of the International Continence Society (ICS), the authors of another scale of subjective outcomes, the Kings' Heath Questionnaire, critically observed, in relation to the introduction of laparoscopic techniques, "there have been no published studies documenting the improvement in quality of life of women undergoing … incontinence surgery" (Cardozo et al., 1994). Measures to assess quality of life in relation to prolapse emerged later: the same year as the NIH consensus conference on the POP-Q, researchers published an expansion of the incontinence scales to include prolapse, as the Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Disorder Impact Questionnaire (PFIQ). The authors stated forcefully, "quality of life is critical when evaluating a new therapy or comparing treatments for these disorders" (Barber et al., 2001: 1393).

The potential import of these measures for clinical research and practice were several. The studies pointed to multiple dimensions of patient "experience": patient reports of symptom severity, whether symptoms were bothersome ("distress"), whether the symptoms affected their ability and/or desire to undertake activities ("impact"), whether the symptoms affected women's perception of their health in specific or general ways, or whether their symptoms affected their perception of their quality of life or well-being. Some researchers also argued sexual intimacy was an important and notoriously poorly-documented dimension of patient experience that, when studied, had been often reduced (rather anatomically) to a matter of vaginal capacity for intercourse (Rogers et al., 2001). Researchers also began to consider the potential distinct importance of patients' goals for surgery (Elkadry et al., 2003; Hullfish et al., 2002). The many dimensions of "experience" introduced new complexities into the design of clinical research studies. And since levels of patient satisfaction after pelvic floor surgery tend to be high and similar for many procedures, larger sample sizes would be needed in clinical studies to detect differences between procedures. In addition, these studies showed that individual women might experience pelvic floor disorders differently and that their experience of their disorder did not neatly correspond to anatomical defects objectively established upon physical examination.

Therefore, the anatomically-oriented outlook that justified the placement of permanent synthetic mesh in the pelvic floor was able to more readily find support in measures and definitions that fit with the terms of EBM. The growing scientific literature around subjective outcomes complicated research design for clinical trials, but the POP-Q simplified it. In the early aughts, very little research in pelvic floor surgery met the standards of EBM. The first Cochrane review of surgical management of POP in women (Maher et al., 2004) concluded there was not enough evidence to draw conclusions, and of the 14 studies considered sufficiently rigorous (as RCTs) to be considered, all reported

"objective evaluation of the specific pelvic defect that was repaired" but the impact of surgery on symptoms, quality of life, cost and patient satisfaction were "poorly reported" (pg. 11). In a major 2008 meta-analysis, the authors stated, "it is increasingly recognized that in prolapse surgery, subjective failure is a more appropriate outcome measure of efficacy than objective failure," but could not draw conclusions about subjective failure rates from the existing research, and noted "subjective prolapse outcomes are difficult to quantify" (Jia et al., 2008: 1358). In 2012, leading professional groups published standardized terminology for reporting outcomes that gave equal place to subjective and objective outcomes (Toozs-Hobson et al., 2012).

In addition, the findings around subjective outcomes often cast doubt on the extent to which many surgical innovations added benefit (Barber et al., 2009). So, a broader feature of surgical culture – the inclination toward surgical action and innovation – no doubt worked against the recognition and use of the literature on subjective outcomes. And it is important to note the anatomically-oriented outlook rationalized the use of mesh both when placed transvaginally and when placed abdominally. As abdominal surgery came to be carried out laparoscopically and eventually robotically, however, a major justification for vaginal surgery – as less invasive – began to lose currency. A more extended analysis would consider how the expectation for "minimally invasive" surgery and the distribution and acquisition of laparoscopic skills also played into the development and reception of transvaginal mesh (Whitfield, 2018; Zetka, 2003), which were significant factors. We propose, however, that the necessary condition for the widespread adoption of transvaginal mesh was the existence of a moral-epistemological mindline around fixing anatomy, which continued to be mobilized in the context of the market-driven explosion of "kits" using transvaginally-placed synthetic mesh.

4.3. Negotiating evidence and mindlines in the context of the commercialization of transvaginal mesh

The implications for practice of subjective and objective outcome measures, and indeed the relevance of EBM to the trajectory of surgical practice in this community, cannot be separated from the ways in which evidence was filtered through mindlines, in the context of the commercialization of transvaginal mesh. It is by no means certain that the shift to practice oriented toward patients' experience would have been an inevitable outcome of an improving evidence base (Lynch et al., 2020). Even as the dangers of the widespread adoption of transvaginal mesh became apparent, surgeons who prioritized repairing anatomy and used transvaginal mesh to do so found support in EBM as a culture of evidence, while also disregarding or discursively disguising increasing evidence that patients' perceptions of outcomes did not simply correlate with anatomical outcomes.

In the late 1990s, in the wake of the enthusiastic response to the TVT and studies like those of Julian and Nicita, more surgeons and manufacturers began to combine the concept of vaginally placed slings and mesh overlays to create new procedures for prolapse. Petros (a co-developer of the TVT) reported on procedures carried out as early as 1992–93 in which he placed a mesh "posterior sling" to elevate the top of the vagina (Petros, 2001). Since 1999, a French group had been using a piece of hernia mesh made by Ethicon, a subsidiary of Johnson & Johnson, and re-branded for use in the pelvic floor as Gynemesh with the addition of two arms, to treat front (anterior) wall prolapse, as reported at the 2001 annual meetings of the International Urogynecological Association (IUGA) (de Tayrac et al., 2001). At the same meetings, Goh and Dwyer, working in Australia, presented a paper and a teaching video on the transvaginal placement of polypropylene "prostheses" for prolapse (Goh and Dwyer, 2001a, 2001b). Dwyer, also President of IUGA from 2002 to 2004, presented again at the IUGA meetings in 2003, with co-author O'Reilly (2003), on their use beginning in 1999 of polypropylene mesh patches with arms that could be fashioned for repair of the front or back segments of the vagina, manufactured by Atrium. By 2002, another group of surgeons from France were developing a procedure to be known as Prolift (when trademarked by Ethicon), a "total prosthetic implant"—a piece of mesh which, for women with prior hysterectomy, could be wrapped over the top of the vagina and along both front and back walls, with three sets of arms anchoring the mesh (two sets extending into the upper thighs, and one toward the back of the pelvis) (Fatton et al., 2007). For women with a uterus, the mesh was cut to allow placement of the front and back sections separately. Notably in many of these studies mesh was used not only for recurrent prolapse, but as a primary (first) surgery. American Medical Systems (AMS) brought the first two commercial transvaginal mesh kits for prolapse repair to market, brand-named Apogee and Perigee, and approved by the U.S. FDA for marketing in May 2004, prior to their use in humans. Initial reports of their use were made at international meetings in 2005. Ethicon brought Prolift to market in March 2005, three years before its FDA approval, and in late summer of the same year, Prolift's creators made their first international presentations on the branded procedure (Cosson et al., 2005; Lucente et al., 2005). Many other kits shortly followed these to market.

Surgeons using, and sometimes developing and financially invested in, transvaginal mesh continued to present their efforts through the mindline of correcting anatomical defects. In the first published paper on the results of Prolift, in 2007, Fatton and colleagues reported (Fatton et al., 2007), at just 3-months follow-up, an anatomic failure rate of only 4.7%. The research group included any post-operative prolapse that was symptomatic in their count of failure, but they gave no indication as to how post-operative symptoms were measured, and other functional outcomes were not systematically assessed. To justify their technique, they cited biomechanical research suggesting "classical pelvic reconstructive surgery" (i.e., without mesh) can restore "only 50% of pre-operative strength of native tissues." They also cited the 29.2% recurrence rate from Olsen (1997) and the 13% rate of re-operation for prolapse from Clark (2003) without commenting on the limitations of either study. They further used the Clark study, which showed that when there is recurrence after native tissue repair it occurs 60% of the time at the anatomic site originally treated and 40% of the time at a different anatomic site, to suggest the only way to truly prevent recurrence would be to do a "total" repair.

The possible implications of patient experience for the assessment of transvaginal mesh techniques were downplayed. Fatton et al. cited a 2004 study by Whiteside (Whiteside et al., 2004) and coauthors for its finding that of 176 women who had one-year follow-up evaluations after non-mesh vaginal repair for prolapse and incontinence, 58% had recurrent prolapse of POP-Q Stage II or greater. The French team did not note, however, that Whiteside et al. also assessed the extent to which women were bothered by their prolapse before and after surgery and concluded, "we add to the growing evidence that prolapse symptoms are not described adequately by the anatomic arrangement of the lower genital tract organs" (pg. 1537). POP-Q Stage II was increasingly regarded as problematic in relation to this, as Whiteside et al. noted. One of the first studies attempting to correlate symptoms and signs in a general population of women (Swift et al., 2003) found women "with the leading edge of the prolapse beyond the hymenal wall" were much more likely to report symptoms. The POP-Q Stage II anatomical range (plus or minus 1 cm from the hymen) therefore included women with highly differing likelihoods of experiencing symptoms and considering them bothersome, and the Whiteside et al. data also showed that prolapse descending beyond the hymen occurred in 11% of women with Stage II recurrence and in 17% of women with recurrence overall.

Since leading international surgeons began using transvaginal synthetic mesh to treat prolapse in the late 1990s and formally reporting on their results in major medical meetings in 2001–2003, many pelvic floor surgeons were aware of the growing use of transvaginal mesh well before the commercialization of transvaginal mesh kits took off in 2004–5. And while the quality of evidence around the use of mesh was poor by the standards of EBM, some new kinds of problems with the

procedures were apparent from early studies and reports such as the increased chance of mesh migration into surrounding organs when implanted simultaneous with hysterectomy and the dangers of certain mesh material, such as polyester materials or multifilament polypropylene with smaller pore sizes.

Furthermore, aspects of the surgical approach that might not be as readily isolated and mitigated were arguably also apparent early on – such as those that might be related to surgeon skill and/or variations in surgical techniques. In 2002 a group of Italian surgeons presented at ICS about high rates of dyspareunia (pain with intercourse) resulting from transvaginal implantation of prolene grafts. In the subsequent paper, the authors concluded "the use of prolene mesh should be discontinued" – even though their reported anatomic success rate was 94% (as stage 0 on the POP-Q system) (Milani et al., 2005). But in a letter about the Milani study, Dwyer and O'Reilly (2005) suggested it was the particular surgical technique of dissection and mesh placement used by the Italians that resulted in higher rates of dyspareunia than found in "other recent studies," including their own 2004 paper on Atrium mesh showing a post-operative decrease in dyspareunia (Dwyer and O'Reilly, 2004). On balance, they were optimistic about transvaginal mesh, despite their reported 9% rate of post-operative mesh erosion (migration of mesh).

Dwyer and O'Reilly took a position prominent among leaders in the profession, writing, "it is too early … to determine the final place of synthetic mesh in the treatment of pelvic organ prolapse" because "we need to await randomized controlled trials assessing long term functional outcome" (2005). In July 2005, participants in IUGA's specially-convened roundtable on the use of grafts concluded similarly: "outcome measures should include anatomic as well as functional parameters over a reasonable observation time period" (Davila et al., 2006: S54). Such statements acknowledge patient experience, as "functional parameters," while also deferring its importance, in a call for further research. In a June 2005 editorial (Shull and Karram, 2005) in IUGA's journal, Shull and Karram pointed out, "our understanding of functional complaints of the pelvic organs as they relate to anatomic findings is poor" and critically raised the prevailing mindline, writing, "simply reducing a bulge [anatomical appearance of prolapse] to worsen or create a functional complaint is generally unacceptable. Although anatomic outcomes are important, we must continually remind ourselves that they are only a part of our ultimate surgical goal."

Reportedly, "widespread concern surfaced" regarding the use of transvaginal mesh for the treatment of prolapse at the October 2006 American Urogynecologic Society (AUGS) meetings (Isom-Batz and Zimmern, 2007). AUGS President Ingrid Nygaard (2007) described it as "a spirited discussion." Post-surgical "functional complaints" were increasingly recognized to include devastating harm. In 2007, a group of surgeons at the UCLA (Deng et al., 2007) reported that between 2001 and 2005, 26 patients were referred to them for the treatment of major complications after the placement of transvaginal mesh slings for incontinence: severe urethral, pelvic and genital pain, urinary retention, recurrent urinary tract infections, and *do novo* (new onset) urgency (feeling of needing to urinate) and related incontinence. During examination, the authors found most of these patients had mesh in the urethra or bladder. They noted 154 reports of major complications from the TVT made to the FDA's database of adverse events (MAUDE) between 1999 and 2005, including eight deaths from operative injuries, concluding the "paucity of major complications" reported in the literature may give surgeons "a false sense of security."

Nygaard suggested any controversy around mesh tapes for incontinence, as opposed to mesh for prolapse, was old news: "I can think of no other surgery in our field … grounded in so much data." However, not all criticisms of mesh hinged upon the availability of evidence showing long-term anatomic and functional outcomes, nor did they necessarily dispute the effectiveness of transvaginal mesh procedures. Nor did all criticisms of mesh claim the complication rates from the procedures were necessarily higher than for native tissue repairs – though they might be, when these procedures were adopted by surgeons with less skill and experience, and/or adopted in situations that might not have previously been addressed with surgery. Rather, a distinct criticism of mesh was that it could result in complications that were, to a greater degree than native tissue repair, out of proportion to the experience of the conditions they were used to treat. Isom-Batz and Zimmern argued in 2007, "even if the rates of these devastating complications are fairly low, they are life-changing for the patient, sometimes irreversible and often sources of litigation."

Many in the profession therefore continued to view the evidence through the lens of the desirability of repairing anatomy, even as the full extent of the transvaginal mesh crisis came into view. And the standards of EBM were useful in this effort, in that the anatomy mindline could more easily find support in the expected types of measures (i.e., in objective anatomical failure rates using a collective standard) and the general insufficiency of EBM-type evidence could be used to defer a reckoning with increasing numbers of harmed patients and forestall serious consideration of subjective outcomes. The use of EBM in this way helped surgeons who favored mesh to position it as a responsible surgical approach.

4.4. From anatomy to patient experience

Even as late as 2015, when we observed one of the final industry-sponsored educational sessions on a transvaginal mesh product to be held at a major medical meeting (for the time being), one of the surgeon presenters pitched the approach in terms of anatomical results. His way of doing so was sometimes subtle (at least to non-surgeons), as when he began by claiming the transvaginal mesh product "re-hammocks," whereas abdominal mesh procedures "pull up," the anatomy – implying the former re-creates the natural, normal anatomical arrangements, "mimicking the ligaments," while the latter distorts it. He was taking up the longstanding intra-professional debate about whether abdominal or vaginal surgical approaches offer the best anatomical result (and in relation to what types of prolapse), but using anatomy as the primary consideration nonetheless. In the question and answer period, he also accused his colleagues who had abandoned transvaginal mesh of shirking their responsibility: "it's a sacred trust: to do the best surgery for your patient and not let the lawyers decide what is best for the patients."

At the same time, the presenter acknowledged a shift when he said the first goal of surgery is to "meet patients' needs" while the second is to "restore anatomy." And he argued this latest transvaginal mesh product was superior to those before because it restored anatomy, but did not attempt to restore "their anatomy of 18 years of age." The presenter also made clear in response to a question that he only used the product to treat symptomatic prolapse, though another session presenter commented she "sometimes wishes" she could use this particular mesh product "prophylactically." In the question and answer period, one surgeon in attendance remarked that where he works (a major U.S. city) patients would no longer consider transvaginal mesh procedures, but "I agree the anatomical results with vaginal surgery are superb."

While observing medical meetings from 2015 to 2018, we often saw paper discussants or members of the audience at scientific sessions raise questions such as, "why didn't you include or report on subjective outcomes in this research?" Or, "how would your study results differ if you considered patient goals as distinct from patient-reported outcomes?" Similarly, we observed panels at the meetings where patients were invited to speak or that were explicitly focused on the issue of patient expectations. The mesh crisis and public and media scrutiny of pelvic floor surgeons without question triggered a new level of reflexivity for many, and forced them to articulate and assess mindlines that would otherwise be taken for granted.

For some, the importance of patient symptoms in surgical practice has become part of new surgical mantra. As EH, who started post-

residency specialist fellowship training in 2009, said in an interview:

EH: If you're asymptomatic and you have prolapse, you know, it's very hard to give you a cohesive argument to have an operation … that was probably the mainstay of my training: you can't fix somebody who's asymptomatic.

We asked a senior, internationally recognized surgeon whether her criteria for when she will perform surgery had changed over the course of her career:

MM: Yeah, I'm probably less fixed on what prolapse looks like than I am on what the patient tells me she feels.

A shift to a mindline anchored in patient experience entails profound changes in how the need for surgery and outcomes are assessed. It arguably even implies many surgeons will have to learn to see a difference between anatomy and function, where previously they assumed anatomy was a surrogate for function by, for instance, designing anatomical categories (such as POP-Q Stage II) in fact experienced in varied and disparate ways. As part of an interview discussion about another senior surgeon's personal history of surgical approaches – and that while her repertoire included native tissue repairs, the TVT, and the laparoscopic placement of mesh, she had never used transvaginal mesh to repair prolapse – we asked what she thought about the argument that prior to the use of mesh, existing native tissue repairs had unacceptably high rates of failure:

JD: I think what those people are saying is they would operate for three or four hours [doing native tissue repair], and the patient would come back at 6 weeks or 6 months and the anterior wall was at the hymen again. But the patient might have been fine, and the re-operation rate for those women is actually very low. So I wouldn't consider that such a terrible failure.

JD's comment suggests the existence of an effort-to-result ratio: that for some surgeons, if after spending three or 4 hours operating, and presumably creating a good anatomical result, patients would return sooner rather than later with some degree of prolapse, the surgery was a failure. For JD, however, if the re-operation rate is very low in these cases, the surgery is not a failure. MM also articulated a critique of what some surgeons might mean by "failure," in relation to time:

MM: So if you look at how people report their outcomes, they report them in terms of cure, improved, and failure, but they don't differentiate between failure and recurrence of a disease process. So if you see a patient and you've done an operation six months ago and she still has the symptoms and the physical findings that she had when she came to you, your operation's failed. But is that true if they come back to you ten years later?

Now that the mindline around anatomy has been opened for closer scrutiny, new attention has been paid to the "disease process" itself and the "natural history" of prolapse – when and how a quite common anatomical change in women becomes a medical problem.

4.5. Mindlines, evidence and practice

The fate of transvaginal mesh did not rest upon the knowledge generated through standardized outcome measures, but the consequences of the widespread use of transvaginal mesh at the very least hastened a shift from a mindline that found justification in "objective" outcomes to a mindline with justification in "subjective" outcomes, and it became more difficult to downplay the patient's experience and desires in assessing treatment options—or, at least, to do so and be viewed as trustworthy in this community. But these measures, these standardized ways of knowing generated by the call for evidence-based medicine, do not determine mindlines or practice. Even now that the evidence in pelvic floor surgery is in some respects improved, and patient experience is more likely to be given primacy in medical practice, it would be inaccurate to see mindlines as identical with what the evidence reveals.

A late-career, internationally recognized surgeon involved in developing an early transvaginal mesh procedure and who was still using transvaginal mesh at the time of this interview in 2017, described the introduction of standardized measures in his practice:

DS: I've always been very close to our patients and I've seen most of the time most of our complications and reinterventions, so I was very concerned by the failures and complications from the beginning …. there were no official questionnaires, now there are. So you are able to ask questions, but it was difficult to assess some of the symptoms. Rectal symptoms are not so easy to assess and something that was very taboo even twenty years ago. Even now it's not very easy to talk about that with patients. Sexual symptoms are not very easy to talk with the patients. …. Now we have official questionnaires that are reproducible which was not the case before, so it's much better now for sure. Not perfect, but much better …

This surgeon says questionnaires are helpful because they are reproducible, things are now more "scientific" and "much better." But here there is also resistance to the idea that these scientific, formalized methods of considering patient experience allows him to know things about his patients he did not know before. DS also indicates despite the use of formal measurements, patients still do not want to talk about, and therefore may not disclose on questionnaires, certain aspects of life with a pelvic floor disorder.

JD, who had advocated for greater attention to patients' goals, responded when asked in any interview whether she developed an instrument to measure them:

JD: When we tried we didn't get that far. One of the problems is that you would think goals are kind of standard … but health goals move around a lot … plus people don't have goals of avoidance … You usually have a goal of action, not of avoidance. So we never solved that one. Not yet.

Nevertheless, JD said she always discussed goals with patients, which affected her reasoning about whether to do surgery and what type. These two surgeons had different positions on the use of transvaginally-placed mesh to treat prolapse but both indicated they consider their patients' anatomy and experience in their thinking about when and how to operate. Their decisions about whether and when to use transvaginal mesh had not been determined by standardized metrics, nor even required them (as in Greenhalgh et al., 2008).

And the state of the evidence in pelvic floor surgery continues to be messy by the standards of EBM (Globerman and Robert, 2015; Heneghan et al., 2017). This is in part because of inherent complexities of producing such evidence in surgery (Ergina et al., 2009). But even if or as improved evidence in the vein of EBM emerges, it will face the longstanding tradition in surgery of resistance to the usefulness of RCTs (e.g., Jones, 2000; Pope, 2003), rooted in the fact that the relevance of any evidence to clinical practice requires interpretation and collective judgment. If many surgeons now believe "you can't fix someone who's asymptomatic," there is still considerable work to be done to apply this in practice because, as one doctor said, "symptoms are funny … they present in funny ways." The issues raised by MM do not have objective answers: At what point in time does a recurrent prolapse shift from being a "surgical failure" to a "recurrence of a disease process"? Is it a surgical failure if the recurrent prolapse occurs at a different site than that addressed by the first operation? In these circumstances, it is collective conventions that assure consistent practice that is understood as responsible (Ducey and Nikoo, 2018).

5. Conclusion

Examining the recent history of pelvic floor surgery with the concept of mindlines adds an important layer of explanation for the adoption of transvaginal mesh. Rather than foregrounding that these

devices were taken up without adequate evidence of their safety and effectiveness, it highlights how much was known, confirming that knowledge includes a wider array information than typically considered legitimate in EBM (Greenhalgh et al., 2014; Martin et al., 2015), and that knowledge is tied up with understandings of responsibility and historically specific contexts – such as changes in technology and EBM. This analysis suggests that too great a focus on the need for better evidence, as usually defined, can disguise mindlines behind technical guidelines. EBM continues to generate an expectation that controversies in medicine are largely technical or scientific, and can thus be resolved by recourse to evidence, in particular through objectification and measurement.

In this case, EBM was also useful for deflecting debate and criticism. The story we have told here is not news to many pelvic floor surgeons, as indicated in some of their own published reflections (Cundiff, 2017; Swift, 2011) and talks we have seen them give, but surgeons often use the story of the evidence ("first it was bad, now it is better" or "we should have been more cautious until we had good evidence") to suggest there was no way they knew or could have known earlier, through different means, about the dangers of turning to permanent mesh in the quest to repair anatomy. Such a story permits a simplification of what shapes their practice, and a "denial of the way that careful deployment of science can support commercial over patient interests" (Sismondo, 2015:47). In this case, the careful deployment of EBM at times took the form of a strategic ignorance, useful for deflecting blame and for the development of a profitable market (McGoey, 2012).

Nevertheless, an analytical concept such as mindlines is necessary because the use of transvaginal mesh made so much sense to so many surgeons. The mindline around repairing anatomy organized ways of feeling and reasoning so that the use of transvaginal mesh could be not only presented, but also regarded, as responsible. For many, there was a period of time in which it seemed "almost unethical" to offer native tissue repair. Transvaginal mesh promised a "total" and permanent anatomic repair, achievable with less operating time, lesser scarring, and using a surgical approach (through the vagina) that distinguishes pelvic floor surgeons from all other surgeons. The shift to a mindline oriented around patient experience has implications for surgeons' sense of satisfaction and worth, in part because the responsibilities and practices entailed by mindlines are intertwined with surgeons' embodied, and painstakingly acquired, skills (Prentice, 2013). Finding joy six weeks after surgery, rather than in the operating room, is not only a matter of re-setting what one knows, but also how one feels.

CRediT authorship contribution statement

Ariel Ducey: Writing - original draft, Conceptualization, Methodology, Formal analysis, Writing - review & editing. **Claudia Donoso:** Conceptualization, Methodology, Formal analysis, Writing - review & editing. **Sue Ross:** Conceptualization, Methodology, Formal analysis, Writing - review & editing. **Magali Robert:** Conceptualization, Methodology, Formal analysis, Writing - review & editing.

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