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Original Article
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'What research was carried out on this vaginal mesh?' Health-related concerns in women following mesh-augmented prolapse surgery: a thematic analysis

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Objective To understand health-related issues in women following mesh-augmented prolapse surgery.

Design Inductive thematic analysis of free-text comments from participants in a cross-sectional study of laparoscopic mesh sacrohysteropexy.

Setting Tertiary urogynaecology centres, United Kingdom.

Population Women who underwent laparoscopic mesh sacrohysteropexy by surgeons based at two tertiary urogynaecology centres between 2010 and 2018.

Methods A total of 1766 potential participants were contacted by post and invited to complete paper, online or telephone questionnaires containing a free-text comments section. Of 1121 participants (response proportion 63.5%), 752 (67.1%) provided such comments. These were analysed with a six-stage inductive thematic analysis, using NVivo 11® software.

Main outcome measures Themes developed from free-text comments.

Results Following familiarisation, 29 codes and 189 sub-codes were identified. These defined six themes: pelvic floor symptoms, health status, treatment success, mesh, pain and care received. The majority of comments centred on the first of these six themes. There were concerns about mesh use and a desire for more information. A range of pain symptoms were mentioned, often associated with pelvic floor symptoms, prolapse surgery or mesh.

Conclusions Despite the mesh controversy, pelvic floor symptoms and their impact on quality of life remain the principle concern of women following mesh-augmented prolapse surgery. There is a need for quality, accessible and evidence-based information sources for those women with concerns, and for those considering such surgery in the future, particularly regarding mesh safety and postoperative recovery. The relationships between pain, prolapse, mesh and pelvic floor surgery require further study.

Keywords Laparoscopy, pain, pelvic organ prolapse, qualitative, surgical mesh.

Tweetable abstract Following mesh-augmented prolapse surgery, pelvic floor symptoms remain women's main focus; pain deserves further research.

Linked article This article is commented on by M Bracher, p. 140 in this issue. To view this mini commentary visit https://doi.org/10.1111/1471-0528.16394.

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Introduction

Mesh-augmented pelvic floor surgery has been subject to significant scrutiny and media attention over the last decade. Introduction of tension-free vaginal tape in 1996 appeared to mark a revolution, succeeded by a proliferation of mesh-augmented devices.[1] However, some mesh uses, specifically vaginal placement for prolapse, result in high rates of mesh-associated complications.[2] This has led to a temporary suspension of vaginal mesh in the UK, and loss of approval elsewhere.[3] At present, the future for women with pelvic floor dysfunction and the role of mesh-augmented surgery remain uncertain.

Mesh augmentation was developed to address shortcomings with native tissue repair, including high rates of recurrent prolapse and morbidity associated with colposuspension.[4,5] They also provide patients with choice. Although vaginal hysterectomy for prolapse is common, the rate of subsequent reoperation for vault prolapse is at least 8% and most women would prefer uterine conservation.[6–8] Laparoscopic mesh sacrohysteropexy offers higher apical suspension, stronger fixation and allows uterine preservation, with promising short-term and mid-term data.[9,10] A meta-analysis has shown perioperative and anatomical advantages compared with various vaginal approaches.[11]

Multiple reports into mesh have been undertaken to address some of the controversies.[12–15] Many noted systemic delays in recognising mesh complications and called for greater emphasis on the patient voice within healthcare systems. Baroness Cumberlege's review, commissioned in 2018, will make recommendations on improving UK healthcare systems' ability to respond to safety concerns about clinical interventions.[3] It aims to 'listen to those who have suffered harm', adding 'their voices, their experiences and views will be at the heart of our Review.' Yet, there remains little academic literature looking at the patient perspective following mesh-augmented pelvic floor surgery.

Qualitative research methodologies such as thematic analysis have previously been used to study women's perspectives of other health issues subject to controversy, such as termination care, postpartum pelvic floor health, and decision-making for pelvic floor disorders.[16–18] It allows rigorous and systematic exploration of narrative-type data, unrestrained by the pre-determined outcomes used in quantitative methodologies. Adopting this interpretivist approach provides meaningful insights, rather than a focus on simply the frequent or common emerging themes.[19]

The aim of the present study was to understand health-related issues in women who have had mesh-augmented prolapse surgery, in light of the current controversies around mesh use.

Methods

Design

This study analysed comments provided by women participating in a multicentre questionnaire study of laparoscopic mesh sacrohysteropexy. Participants underwent surgery by one of five surgeons, based at two tertiary urogynaecology centres in the UK between 2010 and 2018. The questionnaire offered the opportunity for participants to provide any comments they felt relevant in a free-text response component, asking:

> 'Are there any comments or further information you would like to provide to the research team about the operation, your recovery and/or current symptoms with regards to general health and prolapse?'

The free-text approach to obtaining data was used because it provides the opportunity for patients to describe their experiences in a way that would not be possible through closed questions. The full questionnaire is contained within the Supplementary material (Appendix S1). Questionnaire items were assessed for face validity among the study team and piloted at one site before commencing the study. Study outcomes were based on qualitative methodologies. A core outcome set for pelvic floor disorders is subject to ongoing development and therefore not applicable to this manuscript. The closed-question quantitative data regarding mesh complications are presented in a separate manuscript currently awaiting peer review publication.

Selection of study participants

Potential participants were identified from the operating databases of five consultant surgeons based at University College London Hospitals and Oxford University Hospitals. Inclusion criteria were women who had undergone laparoscopic mesh sacrohysteropexy at an enrolled centre and aged 18 years or over. Participants had to have an ability to complete questionnaires, and good written and spoken English. Women who had undergone previous or subsequent mesh rectopexy or placement of vaginal mesh for the treatment of prolapse were excluded from participation.

Data collection

Potential participants were sent postal questionnaires and were able to respond by post in a prepaid envelope, online via a secure database (REDCAP®), or request a telephone questionnaire. Telephone interviews for the questionnaire were carried out according to a pre-determined telephone script following verbal consent. After 8 weeks, non-responders were sent a repeat questionnaire. Responses by post and via telephone were digitised, and all responses were transferred to NVIVO® 11 software.

Thematic analysis

The thematic analysis was undertaken based on the methodology proposed by Braun and Clarke.[20] This method was chosen because of its flexibility, as well as dynamic potential. Themes were developed and adapted according to observations within the data, attempting to find a meaning for the comments in what is referred to as an interpretivist approach. Using the analysis in this way develops a 'patient voice', bearing witness to and exploring women's health issues and concerns through analysis of their comments. This allows observation of the lived experience of an individual's own body, a term described by medical anthropologists as embodiment.[21]

Steps of the analysis are shown in Figure 1. Familiarisation with the data and transcription were undertaken independently by MI and CL. MI is a doctoral student with a clinical background in women's health and CL is a medical student undertaking a BSc in women's health. These authors then separately developed a broad set of codes to summarise the comments. Codes and the more detailed sub-codes can be loosely defined as a word or short phrase that assigns a summative, salient and essence-capturing attribute for a portion of data.[22] An inductive approach was used, where the findings within the data drove the development of subsequent codes and sub-codes, with no preconceived intentions with respect to subsequent themes, and allowing for detailed coding. The final codes and sub-codes that were agreed upon between the authors were those that were felt to best provide narrative and meaning to the comments that women had left, these were then applied to the data using NVivo®. The codes were subsequently independently mapped and collated into what are termed themes, which represent patterns of responses or provide meaning to trends within the coded data, allowing for a summary of the comments.[20] These were reviewed, consolidated and assessed against the available codes, before being clearly defined into a set of core themes. From this re-coding, it was possible to analyse the data and the significance of the comments in a more focused way, observing links between the various themes. Interpretation and development of the report were then undertaken as described by Braun and Clarke.[20]

There was no patient and public involvement in the development of this study. Funding for consumables was received from the Elizabeth Garrett Anderson Charity and British Society for Gynaecological Endoscopy. Our study protocol was approved by the UK's Health Research Authority (HRA) and received a favourable research ethics committee (REC) opinion from the London – City & East Research Ethics Committee on 11 May 2018 (REC reference 18/LO/0637).

Results

We identified 1766 potential participants and following two rounds of postal contact, 1121 women responded (response proportion 63.5%), of whom 752 (67.1%) gave a free-text response (Figure 2). The median length of time from surgery to response was 46 months (range 2–141 months). The mean age of participants at the time of surgery was 58 years (range 24–86 years).

In total, 29 separate codes were developed, further defined by 189 sub-codes. The subsequent charting stage led to the creation of six core themes to encompass all codes. Codes, sub-codes and themes are illustrated in Figure 3, with the coding hierarchy listed in the Supplementary material (Appendix S2).

Our six core themes are outlined below, along with illustrative examples that helped to shape the analysis. Further illustrative quotes are contained within the Supplementary material (Appendix S3).

Pelvic floor symptoms, health status and treatment success

Women provided many comments consistent with the current understanding of the impact of pelvic floor dysfunction on quality of life and the improvements seen in

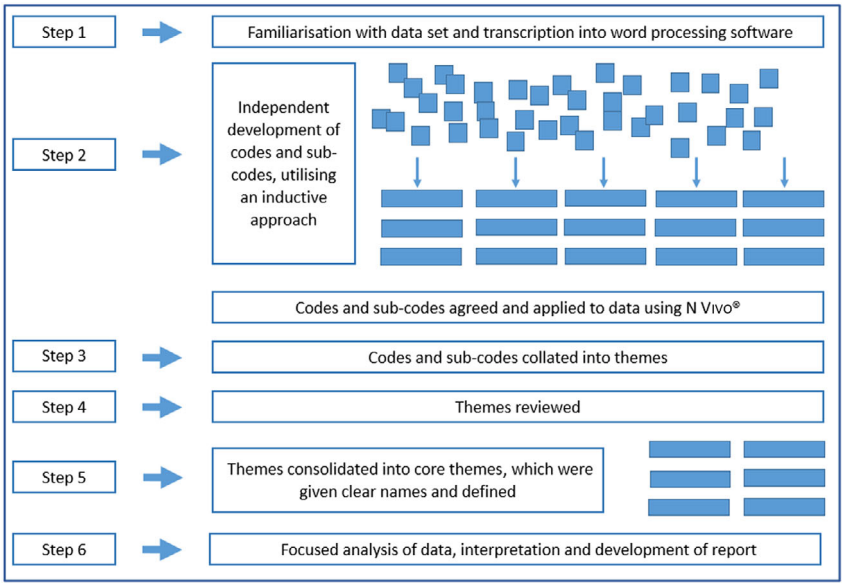

Figure 1. Process of inductive thematic analysis for this study.

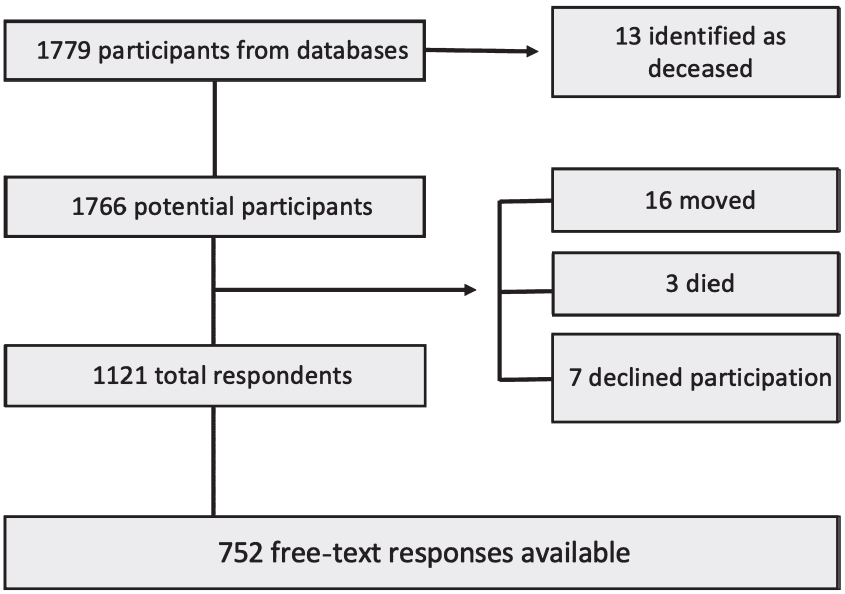

Figure 2. Study flow diagram.

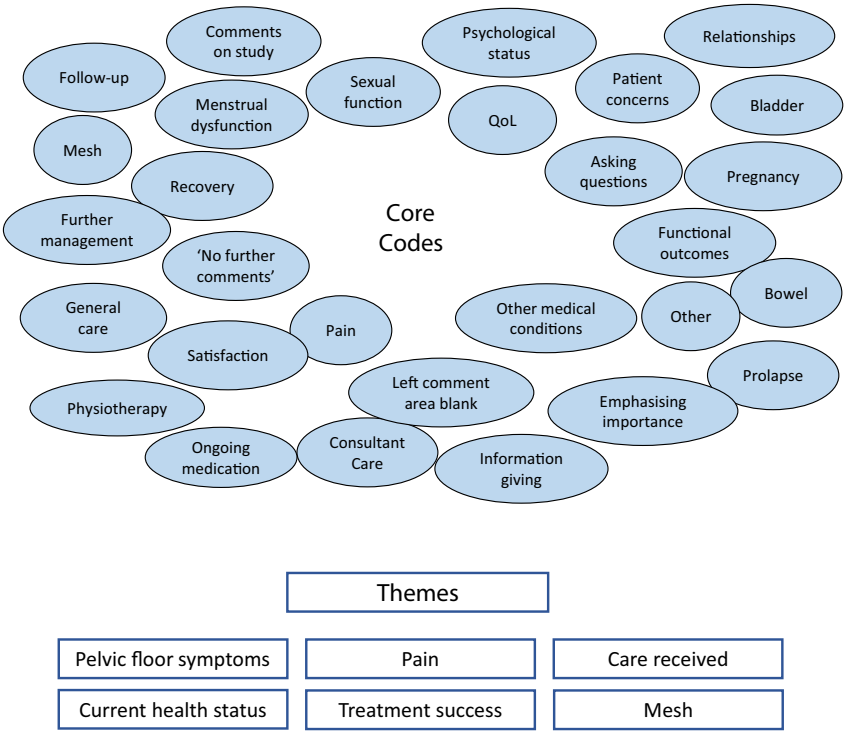

Figure 3. Codes and themes.

quality of life following successful surgical treatment. From the analysis of these comments, three overlapping themes emerged. These were pelvic floor symptoms (263 total codes, 14.0% of the total 1877 codes), health status (461 total codes, 24.6% of the 1877 total codes) and treatment success (562 total codes, 29.9% of the 1877 codes). Many participants correlated symptom resolution with benefits in psychological wellbeing, overall health status and general health-related quality of life (69 women, 9.2% of respondents). Other women chose to discuss the presence of

current symptoms or changes in symptoms seen following surgery, commenting how they had responded to, coped with and felt about these ongoing issues. Figure 4 outlines the frequency of all codes as shown in more detail within the Supplementary material (Appendix S2), with the predominance of codes within these themes clearly illustrated.

Some women remarked that their surgery had been successful in resolving their prolapse symptoms (37 women, 4.9% of respondents).

> I have had absolutely no health problems following the operation. It was a total success. I had the surgery because of a prolapse that could not continue to be managed with a ring pessary. The surgery transformed my quality of life
>
> Study ID 163. Aged 72, 77 months since surgery.

Yet they often recognised that surgery was not a cure all and discussed changes in health status and quality of life following the treatment.

> 'This surgery has enabled me to take up exercising again, and has very much improved my day to day life. While not 100% better, the improvement is dramatic and I am glad I did not need a hysterectomy'
>
> Study ID 1131. Aged 39, 22 months since surgery.

Interestingly, many women appeared satisfied with their treatment, despite ongoing pelvic floor dysfunction (55 women, 7.3% of respondents).

> 'I've been very pleased with the outcome of my surgery. I do still have some urine leakage and take 2 mg tolterodine tartrate twice a day, but it's easily managed'
>
> Study ID 517. Aged 66, 62 months since surgery.

Those with apparently significant ongoing symptoms voiced regret at the choice of surgical intervention (20 women, 2.7% of respondents), with cross-reference to preoperative counselling and information giving.

> 'I am still suffering since my laparoscopic sacrohysteropexy. I wish I had a hysterectomy'
>
> Study ID 309. Aged 45, 93 months since surgery.

Mesh

This core theme incorporated the variety of opinions expressed by respondents regarding the use of surgical mesh, and was particularly focused on participants' concerns about the safety of mesh usage (123 total codes, 6.6% of the total 1877 codes).

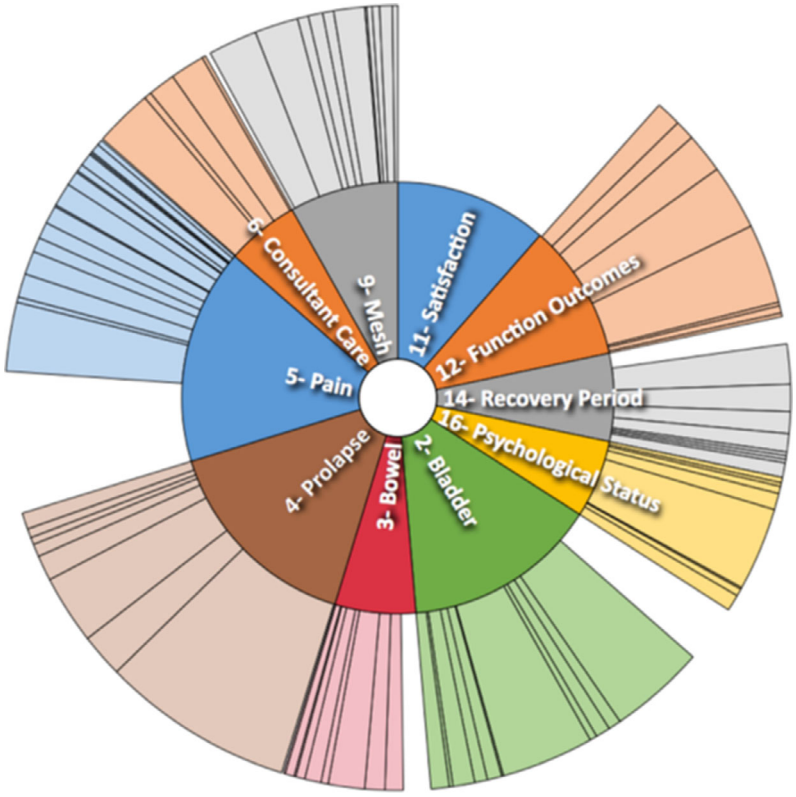

Figure 4. Frequency of codes.

A handful of women expressed concern at the fact that they had undergone a mesh-augmented procedure (18 women, 2.4% of respondents). Women considered themselves fortunate that they had not experienced mesh-associated complications, but expressed anxieties about future risks (31 women, 4.1% of respondents).

'I haven't had any problems after surgery but I am worried I might have problems in the future, as I have heard it has gone wrong for a lot of women'

Study ID 904. Aged 66, 38 months since surgery.

Negative comments regarding mesh tended to be broadly directed at those who developed and regulated mesh, rather than clinicians.

'What research was carried out on this vaginal mesh?'

Study ID 910. Aged 76, 37 months since surgery.

A number of women voiced a lack of available information and uncertainty about whom to contact and where to seek help should a complication arise (11 women, 1.5% of respondents).

'It would really help to know what the procedure would be, should I begin to experience these painful side effects in the future'

Study ID 891. Aged 59, 36 months since surgery.

Pain

The theme of pain was defined by any reference to acute or chronic pain, covering a variety of anatomical locations (227 total codes, 12.0% of the total 1877 codes).

Most comments about pain referred to the impact on quality of life (27 women, 3.6% of respondents) and psychological wellbeing (8 women, 1.1% of respondents). It appeared to have a greater influence over quality of life compared with pelvic floor symptoms, with more subcodes linking it to other themes. In contrast to the tendency to downplay the impact of ongoing pelvic floor symptoms, the presence or prospect of pain appeared to impact the patient perception of surgical success. In spite of these issues, many women concluded that their pain was manageable (22 women, 2.9% of respondents).

'Lower back pain and heaviness in the vaginal area. I don't undertake any heavy lifting now'

Study ID 829. Aged 63, 42 months since surgery.

Although some participants directly queried an association between the presence of mesh and pain (25 women, 3.3% of respondents), it often appeared linked to concerns about how the mesh had been placed (6 women, 0.8% of respondents) or the recurrence of prolapse (4 women, 0.5% of respondents).

'I am in pain every day since the operation. I feel that this is because of the mesh but visits to a doctor and consultant have not confirmed, but not diagnosed anything else'

Study ID 1253. Aged 54, 42 months since surgery.

Care

Care incorporated comments made about participant's perception of the care received from healthcare professionals, as well as references to aspects such as information giving and postoperative recovery (346 total codes, 18.4% of the total 1877 codes).

There were widespread and recurrent positive comments regarding clinicians and the multidisciplinary team involved in care (59 women, 7.8% of respondents). This was frequently associated with affirmation of the care pathway and counselling process.

'Pre-op, operation and post-care was excellent and made such a difference to my quality of life'

Study ID 645. Aged 71, 54 months since surgery.

Recovery time was often noted to be longer and more painful than patients' recollection of what they had been advised preoperatively, often taking many months (18 women, 2.4% of respondents).

'I experienced a great deal of pain immediately after my op and my recovery took much longer than suggested so I think expectations should be adjusted when advising women of possible'

Study ID 1688. Aged 59, 26 months since surgery.

Some participants stated that they would have liked more information about alternatives and the potential adverse events associated with mesh (17 women, 2.3% of respondents). Women appeared to use the study as an opportunity to highlight their concerns about its use, following the media coverage.

'. . . with all the talk in the press of painful and negative results of sacrohysteropexies, I worry sometimes. Will this apply to me one day? Will my body reject the mesh one day? Are the little 'niggles' I have – probably due to ageing – related instead to the mesh inside me?'

Study ID 67. Aged 68, 93 months since surgery.

Discussion

Main findings

This data set provides a unique insight into the health-related issues experienced by women following mesh-augmented prolapse surgery, particularly in light of media coverage and controversies surrounding the use of mesh.[2]

From six core themes, three important conclusions can be drawn. First, despite ongoing media coverage and public conversation surrounding mesh, the principle focus for women is their pelvic floor symptoms and associated quality of life. As the sub-codes and codes were developed from the data, it was clear that our respondents often linked what would then emerge as the themes pelvic floor symptoms, health status and treatment success, corroborating the established relationship between prolapse and quality of life in the literature.[23,24] Women appear to determine the success of surgery based on an improvement in pelvic floor symptoms and enhanced ability to function in daily life, rather than by the side effects of surgery or ongoing symptoms. This illustrates the considered and nuanced interpretation by women of their own personal treatment success, and an understanding that surgery may not be a panacea for the complex spectrum of pelvic floor disorders, a finding noted in similar studies.[25]

Second, we uncovered women's concerns about the use of mesh following their pelvic floor surgery. This often exists in the absence of complications attributable to mesh and in women who report a successful surgical outcome. Participants voiced concerns about the development and regulation of mesh-augmented surgery, an issue highlighted in the medical literature.[26] Anxiety about future mesh-associated complications was common. Women also commented on the need for quality preoperative and postoperative information sources, a subject recognised in previous qualitative studies of prolapse.[25,27]

Finally, there was regular reference to pain, associated with other pelvic floor symptoms as well as attributed to the surgery and use of mesh. Chronic pain clearly has huge implications for sufferers, and has been associated with many forms of gynaecological surgery.[28] Although most women clarified that their pain was manageable, the frequent reference to pain symptoms in women who have had prolapse surgery raises questions as to the relationship between pelvic floor symptoms, reconstructive surgery and pain.

Strengths

The use of an inductive approach to thematic analysis has allowed for a wide-ranging documentation and examination of comments. Although open to interpretation, this methodology allows for a more detailed understanding of key issues, not afforded with closed questions. It delivers an open, patient-reported data set, rather than pre-defined and categorised responses found with more quantitative methodologies.

Our data come from one of the largest available studies of women who have undergone mesh-augmented prolapse surgery and are therefore more likely representative of this cohort of women. This sits in contrast to data likely to be presented in the Cumberlege report and in national reviews, where those with mesh-associated complications have been actively solicited, providing an unrepresentative study sample.[3,13] We have provided a balanced commentary of women's experiences of this form of surgery, studied in a rigorous and systematic process.

Limitations

Questionnaire studies have inherent methodological limitations such as response and recall bias. Despite attempts to provide as balanced analysis of comments as possible, qualitative researchers bring with them their own subconscious bias in how they interpret data and draw conclusions from this. The methodology used addresses this through the independent development of sub-codes and codes that are then agreed upon before the development and review of themes. This allows researchers to ensure consistency between sub-code, codes and themes.

Interpretation and the future

Our interpretation of the data set provides several key elements for women's health researchers and the medical community to consider. The number of responders and free-text responses in our study illustrates that women value research participation. The patient voice should be placed in the centre of medical research, and routinely integrated into the wider healthcare infrastructure, a concept promoted by health organisations internationally.[29–31]

From our analysis we would advocate three courses of action. First, the mesh controversy should not distract clinicians caring for women with pelvic floor dysfunction from the fact that pelvic floor symptoms remain the patient's predominant health concerns as illustrated by our first three themes. Second, recognition that controversies surrounding mesh have created a public health issue in the form of widespread concern. We would posit that this needs two issues to be addressed. One is the provision of evidence-based and high-quality information resources for reassurance of the many women who we found to be actively concerned about having had mesh-augmented surgery. This means quality research into mesh-associated complications and rapid translation into patient-friendly resources. The other is that women affected by potential mesh complications need accessible and high-quality care. This requires coordinated and regulated centres of excellence delivering evidence-based care with appropriate governance and care pathways. Our final recommendation would be the need for further study of the relationship between pelvic floor dysfunction, pelvic floor surgery and pain. Any such relationship has not been adequately explored in the literature to date.

Other pertinent issues raised cover aspects such as information giving and surgical regret. This highlights the need for routine and comprehensive education and counselling, and reaffirms the latest National Institute for Health and Care

Excellence guidance that emphasises conservative management and a framework for shared decision-making.[32] Finally, the appreciation of the care provided and the value of the patient–clinician relationship both remain highly regarded.

Conclusion

This is the first systematic and comprehensive study of comments from women who have undergone mesh-augmented prolapse surgery. It is clear that pelvic floor symptoms remain the main priority for women regardless of other treatment controversies. Clinicians working in pelvic floor medicine should remain alert to the main conditions for which women seek care. There is a need for high-quality research and information sources looking at mesh-associated complications as well as exploring further links of pain and pelvic floor symptoms and treatments. With widespread calls for the voices of women to be put at the centre of regulatory and clinical decision-making, this study shows that a truly representative patient voice gives valuable hitherto unheard insights, far beyond messages captured by the mainstream and medical media headlines.

Disclosures of interests

MI, CL, RC, SJ and NP have no conflicts of interest. AK has received honoraria from Olympus. AC has received honoraria from Olympus and provides consultancy to Fannin. AV has received honoraria from Olympus and BARD medical. Completed disclosure of interests forms are available to view online as supporting information.

Contribution of authorship

Study concept and design: MI, AV, RC, AK, AC, SJ and NP. Acquisition of data: MI and CL. Analysis and interpretation of data: MI, CL and AV. Drafting of the manuscript: MI, CL, RC and AV. Critical revision of the manuscript for important intellectual content: MI, AV, RC, CL, AK, AC, SJ and NP. Statistical analysis: N/A. Obtaining funding: MI and AV. Administrative, technical, or material support: MI and CL. Supervision: AV.

Details of ethics approval

Our study protocol was registered with the UK's Health Research Authority (HRA) and received a favourable research ethics committee (REC) opinion from the London – City & East Research Ethics Committee on 11 May 2018 (REC reference 18/LO/0637), and favourable HRA approval on the same date.

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Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Appendix S1. Questionnaire sent to potential participants.
Appendix S2. Codes and sub-codes, with frequency of coding.
Appendix S3. Quotes illustrating themes. ■

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