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OXFORD INFORMED VIDEO CONSENT TOOL (OXIVCT): A PILOT STUDY OF INFORMED VIDEO CONSENT IN SPINAL SURGERY AND ITS IMPACTS ON PREOPERATIVE PATIENT SATISFACTION.

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3 **OXFORD INFORMED VIDEO CONSENT TOOL (OXIVCT): A PILOT STUDY OF**
4 **INFORMED VIDEO CONSENT IN SPINAL SURGERY AND ITS IMPACTS ON**
5 **PREOPERATIVE PATIENT SATISFACTION.**
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ABSTRACT

Objectives: A ‘three-legged stool’ approach to consent, advocated by British Association of Spinal Surgeons (BASS) calls for updates in consenting practice. This study investigates the utility and acceptability of a personalised video consent tool to enhance patient satisfaction in the preoperative consent giving process.

Design: Pilot study using questionnaires to assess video consent and its impacts on preoperative patient satisfaction.

Setting: A single centre, pilot study of individuals undergoing surgery at a regional spinal centre in the UK.

Outcome measure: As part of preoperative planning, a self-administered questionnaire regarding patient satisfaction with the use of a video consent tool as an adjunct to traditional consenting methods was completed.

Participants: 20 participants with a mean age of 56 years ($SD = 16.26$). who watched their personalised consent video at least once prior to consenting for surgery.

Results: Median number of video views were 2-3 times. 85% of patients watched the video with next of kin and family members. 80% of participants reported that the video consent tool helped to their address preoperative concerns. All participants stated they would use the video consent service again. All would recommend the service to others requiring surgery. Implementing the video consent tool did not endure any significant time or costs.

Conclusions: Introduction of a video consent tool was a positive adjunct to traditional consenting methods. Patient – clinician consent dialogue can now be documented. A randomised controlled study to further evaluate the effects of video consent on patients’ retention of information, pre and postoperative anxiety, PROMS and length of stay is in process.

Key Words: Video consent, Informed consent, Patient satisfaction, Spinal surgery.

ARTICLE SUMMARY

What this pilot study adds to the literature:

1. First report of a personalised consent tool in preoperative care (currently deficient in the published literature)
2. First report of a multimedia consent adjunct used outside of the clinical environment, allowing patients to review their consent dialogue at a time and place convenient to them.
3. First report of a personalised consent adjunct promoting shared decision making and promoting patient empowerment.
4. First report of a correlation between frequency of interaction with multimedia consent adjuncts and patient satisfaction levels.
5. First report of multimedia to document the patient – clinician consent conversation

Strengths and limitations of this study

The strengths of the study have been outlined above. Although this pilot has achieved its overall aim, it is important to acknowledge the limitations. As a small non-randomised study, further work is needed to provide robust conclusions. While the quantitative data collected yielded statistical data, the introduction of qualitative data collection methods could provide further insights into patient satisfaction and experience.

INTRODUCTION

Informed consent is a legal and ethical principle which is required prior to any intervention that may violate autonomy. The *Montgomery v Lanarkshire* judgement (1) initiated a change in how healthcare professionals obtain informed consent. *Montgomery* (1) confirms the shift from an already eroding paternalistic approach to consent set by *Bolam v Friem Hospital Management Committee*,(2), to the adoption and acknowledgment of a person-centred approach seen in *Sidaway v Bethlem Royal Hospital* (3), *De Freitas v O'Brien* (4) and *Bolitho v City & Hackney HA* (5). Others concur that *Montgomery* marked a decisive shift in the legal test of duty of care, from the perspective of the clinician to that of the patient (6).

In acknowledgement of the recent changes in consenting practice, the British Association of Spinal Surgeons (BASS) recently published consent guidelines (7). BASS advocates a ‘three-legged stool’ model to informed spinal consent. The three pillars of this model are: 1) provide

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3 patient information, 2) engage in and document patient centred dialogue and 3) provide
4 procedure specific information. However, there is currently a gap in consenting practice
5 relating to documenting the preoperative consent conversations. Preparing to undergo surgery
6 is a stressful event for both patients and their families, often important information discussed
7 within the consent consultation is forgotten (8). By providing patients access to a tool that
8 captures their consent conversation, it is proposed that the video will provide them with an
9 opportunity to reflect and revisit the previously discussed dialog, prior to consenting to
10 treatment. The addition of this step to the preoperative consenting process may safeguard
11 patients from medical coercion and promote autonomy to make an informed decision about
12 their care, while reducing potential litigation claims.
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22 Enhancements in digital technology are driving changes in information practices, which has
23 influenced how informed consent may be delivered (9), examples include the use of iPads to
24 deliver consent information (10) to the use of a smartphone app's to assist informed consenting
25 practice (11). The acceptance of multimedia technology in preoperative consenting has been
26 demonstrated across a variety of surgical disciplines, foot & ankle surgery (12), spinal surgery
27 (13), vascular surgery (14), ophthalmic surgery (15), gastrointestinal surgery (16) and
28 urological surgery (17). Notably, such preoperative multimedia consent technologies are often
29 generic and not patient specific. There is currently a lack of research regarding the use of
30 personalised multimedia consenting adjuncts within surgery.
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40 In order to improve service delivery and comply with the updated guidelines, we piloted a
41 video consent tool as an adjunct to traditional consenting methods for patients attending a
42 spinal Preoperative Outpatient Assessment Clinic (POAC). To our knowledge the use of an
43 informed video consent tool has not been used before in spinal surgery. The aims of the study
44 were to evaluate acceptability of a novel consent tool as an adjunct to traditional verbal and
45 written consent in patients attending a spinal POAC, while providing documentary evidence of
46 the patient – clinician consent conversation, which now forms part of the medical notes,
47 improve patient experience and enhance patient satisfaction within the preoperative consent
48 process and generate an evidence base for future research.
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56 **METHODS**

57 **Procedure**

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3 We conducted a single centre, non-randomised, non-comparative pilot study in patients
4 undergoing a spinal procedure at a spinal centre in the UK. A flowchart of the study procedure
5 is outlined on Figure 1. All participants who agreed to take part were consented by fellowship
6 trained Consultant Spinal Surgeons using verbal and written consenting methods in addition to
7 a precis of the consent consultation being recorded. Participants were all informed that their
8 participation was voluntary and they were free to withdraw at any time. The precis was
9 conducted in a structured way and consisted of the following, a discussion around the patients
10 reasoning for choosing surgery, followed by an overview of the surgical procedure, its intended
11 benefits and associated risks ending with an opportunity for the patients' to check their
12 understanding by asking questions.
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22 A password protected email and a hospital trust approved web transfer service was used to
23 send the personalised consent videos to study participants. Participants reviewed their
24 personalised consent consultations at home with their family or friends. Participants had the
25 option to forward their personal consent videos to family members outside of the UK. All,
26 participants were invited to contact the spinal team, to seek clarity or ask further questions
27 regarding the video content (two participants utilised this service). The recorded consent was
28 stored securely within the patient's electronic health records, accessible only to the research
29 team. Participants were asked to contact the spinal team once they had reviewed the consent
30 conversation, acknowledging the risks and benefits of the proposed treatment. Prospective data
31 from patients was obtained in the form a self-administered questionnaire regarding patient
32 satisfaction with the use of a video consent tool as an adjunct to traditional consenting methods.
33 Participants were invited to complete the measure following the consent consultation and after
34 reviewing their personalised consent video.
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46 **Participants**

47 Participants were recruited over a four month period (September to December 2017).
48 Twenty two people were approached to take part, two declined, twenty volunteered. (n=20).
49 Participants did not receive a honorarium for taking part in the study. Study inclusion criteria
50 were: all participants must be over the age of 18 years of age and have capacity to make
51 informed decisions. Participants were also required to have an active email address with
52 access to the internet. Participants were excluded from the study if they lacked capacity to
53 make informed decisions or if they had any visual or hearing impairments which may inhibit
54 their ability to review their consent video.
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Assessments

Electronic Self-Administered Questionnaires (SAQ) were distributed via email to patients who agreed to partake in the study. Participant demographics, which included gender, age, number of times the video consent tool was viewed as well as who they watched it with was collected. In addition to this, quantitative data was collected via the validated CSQ-8 tool (18) . The tool consists of eight questions, each constructed with a four point Likert scale reply.

Data was collected at one point, post consent consultation. The minimum achievable satisfaction score is 8, indicating poor satisfaction, a maximum score of 32 would indicate high levels of satisfaction (19, 20). The CSQ-8 tool has been extensively tested for reliability and validity (19-21), to date it has been translated into more than 30 languages since its first launch in the early 1980's (22).

Data analysis

The data collection period finished once 20 completed SAQ's were received. Normality of data was assessed using a Kolmogorov-Smirnov test. Descriptive, bivariate and inferential statistics were calculated and reported using two-tailed methods with the assistance a statistical program from IBM, SPSS 24 for Microsoft© Windows version 10.

Patient and Public Involvement

Patients were not involved in the development or design of this pilot study. However we do plan to enlist patient help when disseminating our research findings. We aim to include patient involvement when designing subsequent studies involving OXIVCT.

RESULTS

Descriptive information

Over a four-month period, 20 participants (10:10, male: female) deemed suitable candidates for spinal procedures were recruited into the study. The mean age of participants was 56 years ($SD = 16.26$), range 27 years to 81years. Participant demographics can be seen in Table 1.

Patient satisfaction

The mean patient satisfaction score (CSQ-8) was 30.2 out of a maximum 32, indicative of high patient satisfaction. The CSQ-8 scores by gender and age can be seen in Table .2.

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3 A two-way between groups analysis of variance was conducted to explore the impact of
4 gender and age on patient satisfaction levels, as measured by the CSQ-8 scale.

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6 Participants were divided into five groups depending on their age (Group 1: 25-34 years,
7 Group 2: 45-54 years, Group 3: 55-64 years, Group 4: 65-74 years and Group 5: 75-99 years)

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9 The interaction effect between gender and age was not statistically significant .

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11 High patient satisfaction levels were reported across a broad range of spinal procedures, seen
12 in Table.3. These ranged from spinal nerve root blocks to complex deformity correction
13 surgery.
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17 The CSQ-8 responses generated several significant trends, a strong positive relationship
18 between meeting patients 'preoperative consenting needs and helping them to deal more
19 effectively with their preoperative concerns was reported ($p=.028$), with 80 % reporting that
20 the tool helped a great deal. All participants reported that they would recommend the video
21 consent tool to others preparing for surgery. When asked "if future treatment were required,
22 would you use the service again?", all participants said yes. A significant positive
23 relationship between the quality of the service participants received versus the service they
24 expected was observed ($p = 0.008$).
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32 **Engagement with the tool**

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34 All participants watched their consent video at least once prior to consenting for surgery, with
35 a mean number of viewings of 2-3 times. Eighty-five percent of the participants watched
36 their consent video with family and friends. Two participants sent their consent videos to
37 their children, who lived in the USA and Australia. 15% of participants reported watching
38 their video alone. Those who watched the video 4 to 5 times on average reported higher
39 satisfaction scores. Approximately 13 additional minutes were required compared to the
40 traditional process to complete the video recording process The mean recording time was 13
41 minutes and 15 seconds, with a range of 6 minutes and 21 seconds, to 20 minutes and 55
42 seconds. Introduction of the video consent tool did not endure any significant costs as the
43 technology already existed within the Trust.
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52 **DISCUSSION**

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54 The main findings of our study were that participants were overall 100% satisfied with the
55 tool and the service. All patients reported that that would use the service again, if needed and
56 100% of participants reported that would recommend the service to others requiring surgery.
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3 The mean CSQ-8 satisfaction score reported in this study was 30.2, with scores above 24
4 considered as achieving high levels of satisfaction (21) Compared to previous studies
5 examining multimedia consent processes (17, 23), the personalised consent tool used in the
6 present study is equal to, if not more effective than, the existing methods.
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10 Our preliminary results suggest that participants' age or gender did not affect patient
11 satisfaction levels with the use of the video consent tool in the preoperative setting. This
12 finding is consistent with studies (12, 24, 25). Busy preoperative clinics, poor communication
13 techniques, unanswered questions, anxiety and poor comprehension are all barrier to patients
14 not retaining information (26).
15

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17 Our study has shown that the use of personalised video tool can allow patients to process and
18 review complex information previously discussed by the surgeon, from the comfort of their
19 own home. Participants, had the opportunity to email the spinal service for further clarity of
20 the video content, two participants utilised this service.
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27 Introduction of the video consent tool did not require significantly more clinician time. The
28 ability to watch the video with family members, or even to securely send family members the
29 video, allowed for shared decision making and aided a person-centred approach to care,
30 empowering participants to manage their own medical information. This is important for
31 patients outcomes as shared decision making facilitates increased patient satisfaction levels
32 (27, 28). All patients engaged with their personalised consent adjunct twice on average before
33 consenting to surgery. To our knowledge, multiple interactions of a consent adjunct have not
34 been reported in the literature (29). This project found that, the more times participants
35 watched their consent video the more satisfied they became with their consent process. With
36 the highest satisfaction scores in those who engaged with the video tool the most (4 to 5
37 times). Moreover, as the majority of studies using multimedia tools as an adjunct to informed
38 consent do not personalise their content (27, 29), This is the first time that the use of a
39 personalised multimedia tool has been reported in the literature. Due to the relative ease in
40 setting up the pilot, other surgical disciplines within the trust have expressed interest in
41 rolling out OXIVCT across their departments.
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54 55 **CLINICAL IMPLICATIONS**

56 This study demonstrates that a personalised video consent tool is feasible to administer during
57 the preoperative consent process for spinal surgery procedures and that the intervention
58 produced high satisfaction scores. Overall, we found approximately thirteen additional minutes
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3 were required compared to the traditional process to complete the video recording process.
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5 This indicates that this procedure would be acceptable for use. Introducing OXIVCT into
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7 clinical practice has numerous benefits such as, documentary evidence of the clinician – patient
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9 consent conservation, which may reduce medicolegal cases associated informed consent.

10 It can be used as an educational tool for undergraduate medical teaching and could acts as a
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12 patient resource / decision aid, useful when analysing potential benefits and risks associated
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14 with surgery.

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17 While concerns over additional time, potential costs and practicality as to achieving this
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19 process are valid, we have found them not to be a significant barrier to delivering this service.
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21 Providing one has access to a digital recording device such as a smartphone that can transfer
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23 and store data securely, then the process is relatively simple. We recognise that patients need
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25 to have access to the internet and may require help if not familiar using this sort of technology;
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27 however, as 85% of UK adults have a smartphone (30) and access to the internet in this is not
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29 an insurmountable barrier. While we have not undertaken a cost analysis, for this pilot there
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31 have been no significant costs as the technology already exists within the NHS Trust. We would
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33 therefore recommend video consenting as a new bench mark in the consenting process. Based
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35 on this study, we recommend a randomised controlled trial and evaluate the full impact of this
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37 process on outcome measures such as information retention, length of stay and litigation
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39 claims.

40 **FUTURE RESEARCH**

41 The findings from this pilot provide a foundation for potential future research projects.
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43 A larger more diverse sample size to include younger (kids/teens) and older (75yrs +) people
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45 could add to the validity. There has been interest from other departments, further research
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47 could look at its utility in other surgical disciplines. Phase 2 of this pilot study has led to the
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49 development of a randomised controlled study to further evaluate the effects of OXIVCT on
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51 patients' retention of information, pre and postoperative anxiety, PROMS and length of stay.

52 **CONCLUSION**

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55 If patient satisfaction is a measure of quality (31) this study shows that the introduction of a
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57 personalised consent tool can have positive impact on the quality of service patients receive.
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59 The provision of informed care can be facilitated by the introduction of a personalised video
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3 tool, as it promotes patient autonomy, shared decision making and empowers patients to
4 manage their own health.
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8 **AUTHOR CONTRIBUTIONS:**
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10 GM, CT and JR made substantial contributions to the conception of the study. GM analysed
11 and interpreted the data for the study. GM, CT, DR and JR drafted the article and revised it
12 critically for important intellectual content. JR, gave final approval of the version to be
13 published and agreed to be accountable for all aspects of the article in ensuring that questions
14 related to the accuracy or integrity of any part of the article are appropriately investigated and
15 resolved. GM, JR and DR contributed to acquisition of the data.
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23

24 **Competing interests:** None
25

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27 Scientific Meeting of the Singapore Orthopaedic Association and at the Joint British
28 Scoliosis Society / Irish Spine Society Meeting, 2018.
29

30 **Patient consent:** Obtained
31

32 **Ethics approval:** Oxford Brookes University, Faculty of Health Sciences Research Ethics
33 Committee (FREC2016/57).
34
35

36 **Data sharing statement:** We welcome data-sharing requests from researchers interested in
37 OXIVCT. Please contact GM (gerard.mawhinney@ouh.nhs.uk) directly to explore further.
38

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40 spinal surgery department throughout the pilot and thank those who volunteered to take part
41 in the study.
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48 **WORD COUNT:** 2808
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8 **TABLES**
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10 Table.1. Demographics of Study Participants
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Demographic		N (%)
Gender	Male	10 (50%)
	Female	10 (50%)
	Mean age	56
	Range	27 -81
Participant Age (years)	25 - 34	2 (10%)
	35 – 44	0 (0%)
	45 – 54	6 (30%)
	55 – 64	5 (25%)
	65 – 74	4 (20%)
	75 – 99	3 (15%)
Frequency of viewing consent video	Once	7 (35%)
	2 to 3 times	10 (50%)
	4 to 5 times	3 (15%)
Video watched (with)	Alone	3 (15%)
	Next of Kin	11(55%)
	Children	2 (10%)
	Other family members	6 (30%)
	Friends	2 (10%)

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Table. 2. Mean CSQ-8 Scores by Age and Gender

Demographic	Mean CSQ-8 Score (Maximum score 32)	Range (<i>SD</i>)
Gender		
Male	30	26 – 32 (2.2)
Female	30.4	29 – 32 (1.07)
Total Mean	30.2	26 – 32 (1.70)
Participant Age (years)		
25 - 34	31	30 – 32
35 - 44	-	-
45 – 54	30.16	26 - 31
55 – 64	29	26 – 31
65 – 74	30.25	28 – 32
75 – 99	31.66	31 – 32

Table.3. Overview of consented surgical procedures

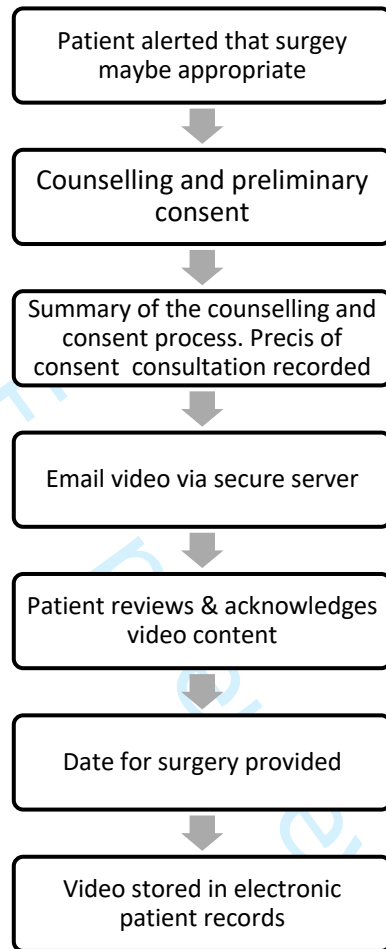
Variety of Surgical Procedures	N = 20
Deformity correction	3
Lumbar degenerative	6
Nerve root block	3
Removal of metalwork	1
Tumour surgery	7

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Figure.1. Summary of study procedure.



BMJ Open

THE OXFORD VIDEO INFORMED CONSENT TOOL (OXVIC): A PILOT STUDY OF INFORMED VIDEO CONSENT IN SPINAL SURGERY AND ITS IMPACTS ON PREOPERATIVE PATIENT SATISFACTION.

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Secondary Subject Heading:	Patient-centred medicine, Surgery
Keywords:	Video consent, Informed consent, Patient satisfaction, Spinal surgery

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5 THE OXFORD VIDEO INFORMED CONSENT TOOL (OXVIC): A PILOT STUDY
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7 OF INFORMED VIDEO CONSENT IN SPINAL SURGERY AND ITS IMPACTS ON
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9 PREOPERATIVE PATIENT SATISFACTION.
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For peer review only

ABSTRACT

Objectives: The British Association of Spinal Surgeons (BASS) has recently called for updates in consenting practice. This study investigates the utility and acceptability of a personalised video consent tool to enhance patient satisfaction in the preoperative consent giving process.

Design: A single centre, prospective pilot study using questionnaires to assess acceptability of video consent and its impacts on preoperative patient satisfaction.

Setting: A single National Health Service (NHS) centre with individuals undergoing surgery at a regional spinal centre in the UK.

Outcome measure: As part of preoperative planning, a self-administered questionnaire regarding patient satisfaction with the use of a video consent tool as an adjunct to traditional consenting methods was completed.

Participants: 20 participants with a mean age of 56 years ($SD = 16.26$) undergoing spinal surgery.

Results: Median number of video views were 2-3 times. 85% of patients watched the video with next of kin and family members.

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2
3 80% of participants reported that the video consent tool helped
4
5 to their address preoperative concerns. All participants stated
6
7 they would use the video consent service again. All would
8
9 recommend the service to others requiring surgery. Implementing
10
11 the video consent tool did not endure any significant time or
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13 costs.
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19 **Conclusions:** Introduction of a video consent tool was found to
20
21 be a positive adjunct to traditional consenting methods. Patient
22
23 - clinician consent dialogue can now be documented. A randomised
24
25 controlled study to further evaluate the effects of video
26
27 consent on patients' retention of information, pre and
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29 postoperative anxiety, patient reported outcome measures as well
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31 as length of stay may be beneficial.
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37 **Key Words:** Video consent, Informed consent, Patient
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39 satisfaction, Spinal surgery.
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ARTICLE SUMMARY

- Development of a personalised video informed consent tool.
- A novel method to document the patient - clinician preoperative consent conversation.
- Prospective data gathered from self-administrated patient satisfaction questionnaires.
- Participants recruited, 10 male, 10 female, mean age of 56, all undergoing spinal surgery.
- An individualised consent adjunct used to promote patient autonomy and shared decision making.

INTRODUCTION

Informed consent is a legal and ethical principle which is required prior to any intervention that may violate autonomy. The *Montgomery v Lanarkshire* judgement (1) initiated a change in how healthcare professionals obtain informed consent. *Montgomery* (1) confirms the shift from an already eroding paternalistic approach to consent set by *Bolam v Friem Hospital Management Committee*, (2), to the adoption and acknowledgment of a person-centred approach seen in *Sidaway v Bethlem Royal Hospital* (3), *De Freitas v O'Brien* (4) and *Bolitho v City & Hackney HA* (5). Others concur that *Montgomery* marked a decisive shift in the legal test of duty of care, from the perspective of the clinician to that of the patient (6).

Informed consent has gained accelerated momentum following the *Montgomery* judgement. In acknowledgement of the recent changes in consenting practice, the General Medical Council (GMC), the Royal College of Surgeons (RCS) and other professional organisations, such as The British Association of Spinal Surgeons (BASS), have issued best practice guidelines on obtaining informed consent (7). However, despite the release of updated guidelines there is currently a gap in consenting practice relating to documenting the preoperative consent conversation.

1
2
3 Preparing to undergo surgery can be a stressful event for
4
5 both patients and their families, often important information
6
7 discussed within the consent consultation is forgotten (8). By
8
9 providing patients access to a tool that captures their consent
10
11 conversation, it is thought that the video will provide patients
12
13 an opportunity to reflect and revisit the previously discussed
14
15 dialog, prior to consenting to treatment. It encourages a
16
17 bespoke individualised approach as indicated by Montgomery (1).
18
19 The addition of this step to the preoperative consenting process
20
21 may safeguard patients from medical coercion and promote
22
23 autonomy to make an informed decision about their care, while
24
25 reducing potential litigation claims.
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35 Enhancements in digital technology are driving changes in
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37 information practices, which has influenced how informed consent
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39 may be delivered (9), examples include the use of iPads to
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41 deliver consent information (10) to the use of a smartphone
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43 applications to assist informed consenting practice (11). The
44
45 acceptance of multimedia technology in preoperative consenting
46
47 has been demonstrated across a variety of surgical disciplines,
48
49 foot & ankle surgery (12), spinal surgery (13), vascular surgery
50
51 (14), ophthalmic surgery (15), gastrointestinal surgery (16) and
52
53 urological surgery (17). Notably, such preoperative multimedia
54
55 consent technologies are often generic and not patient specific.
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60 There is currently a lack of research regarding the use of

1
2
3 personalised multimedia consenting adjuncts within surgery.
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8 In order to improve service delivery and comply with the
9
10 updated guidelines, we piloted a video consent tool (OxVIC) as
11
12 an adjunct to traditional consenting methods for patients
13
14 attending a spinal Preoperative Outpatient Assessment Clinic
15
16 (POAC). Each consent video contained indications for surgery,
17
18 associated risks and benefits, alternative treatment options
19
20 and a section for patients to ask questions or clarify points.
21
22

23 To our knowledge, the use of a video informed consent tool has
24
25 not been used before in spinal surgery.
26
27 Our study aims were to evaluate acceptability of a novel consent
28
29 tool (OxVIC), as an adjunct to traditional (written and verbal)
30
31 consenting methods. Provide documentary evidence of the patient
32
33 - clinician consent conversation, which now forms part of the
34
35 medical notes. Improve patient experience and enhance patient
36
37 satisfaction within the preoperative consent process, while
38
39 generating an evidence base for future research.
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50 **METHODS**

51 Ethical approval for this project was obtained from the Health
52
53 and Life Sciences Faculty Research Ethics Committee (FREC)
54
55 Oxford Brookes University, Oxford, England (FREC2016/57). In
56
57 addition to the video consent process described below, written
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1
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3 informed consent was additionally obtained from all
4
5 participants.
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10 **Procedure**

11
12 We conducted a single centre, non-randomised, non-
13 comparative pilot study in patients undergoing a spinal
14 procedure at an NHS spinal centre in the UK. A flowchart of the
15 study procedure is outlined on Figure 1. Prior to consenting
16 to take part, all patients received a Participant Information
17 Sheet (PIS). The PIS outlined that if patients agreed to take
18 part they would receive the "gold standard" (verbal and
19 written) in consent information. In addition to this they would
20 also receive a consent adjunct in the form of a personalised
21 video. All participants who agreed to take part were consented
22 by fellowship trained Consultant Spinal Surgeons using verbal
23 and written consenting methods in addition to a summary of the
24 consent consultation being recorded. A researcher, independent
25 of the surgical team provided participants with patient
26 information sheets prior to consenting. Participants were all
27 informed that their participation was voluntary and they were
28 free to withdraw at any time. The summary was conducted in a
29 structured way and consisted of the following, a discussion
30 around the patients reasoning for choosing surgery, followed by
31 an overview of the surgical procedure, its intended benefits and
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3 associated risks ending with an opportunity for the patients'
4
5 to check their understanding by asking questions.
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8 A password protected email and a hospital trust approved
9
10 web transfer service was used to send the personalised consent
11
12 videos to study participants. Participants reviewed their
13
14 personalised consent consultations at home with their family or
15
16 friends. Participants had the option to forward their personal
17
18 consent videos to family members outside of the UK. All,
19
20 participants were invited to contact the spinal team, to seek
21
22 clarity or ask further questions regarding the video content
23
24 (two participants utilised this service). The recorded consent
25
26 was stored securely within the patient's electronic health
27
28 records, accessible only to the research team. Participants were
29
30 asked to contact the spinal team once they had reviewed the
31
32 consent conversation, acknowledging the risks and benefits of
33
34 the proposed treatment. Prospective data from patients was
35
36 obtained using a self-administered questionnaire regarding
37
38 patient satisfaction with the use of a video consent tool as an
39
40 adjunct to traditional consenting methods. Participants were
41
42 invited to complete the measure following the consent
43
44 consultation and after reviewing their personalised consent
45
46 video.
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52 **Participants**

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55 Participants were recruited over a four month period
56
57 (September to December 2017).
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3 Twenty two people were approached to take part, two declined,
4
5 twenty volunteered. (n=20). Participants did not receive a
6
7 honorarium for taking part in the study. Study inclusion
8
9 criteria were: all participants must be over the age of 18
10
11 years of age and have capacity to make informed decisions.
12
13 Participants were also required to have an active email
14
15 address with access to the internet. Participants were
16
17 excluded from the study if they lacked capacity to make
18
19 informed decisions or if they had any visual or hearing
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21 impairments which may inhibit their ability to review their
22
23 consent video.
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40 **Assessments**

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42 Electronic Self-Administered Questionnaires (SAQ) were
43
44 distributed via email to patients who agreed to partake in the
45
46 study by a researcher independent of the surgical team. Data
47
48 were collected at one point, post consent consultation.
49
50 Participant demographics, which included gender, age, number of
51
52 times the video consent tool was viewed and who they watched the
53
54 video with, were collected. In addition to this, participants
55
56 completed the validated CSQ-8 tool (18) online. The CSQ-8
57
58 consists of eight self-report questions, each constructed with
59
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1
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3 a four point Likert scale reply. The minimum achievable
4 satisfaction score is 8, indicating poor satisfaction, a maximum
5 score of 32 would indicate high levels of satisfaction (19, 20).
6
7 The CSQ-8 tool has been extensively tested for reliability and
8 validity (19-21), to date it has been translated into more than
9
10 30 languages since its first launch in the early 1980's (22).
11
12 The CSQ-8 has been found to be acceptable for use in previous
13 studies examining patient satisfaction with consenting methods
14
15 (17, 23).
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26 **Data analysis**

27
28 The data collection period finished once 20 completed
29 SAQ's were received. Normality of data were assessed using a
30 Kolmogorov-Smirnov test. Descriptive, bivariate and
31
32 inferential statistics were calculated and reported using two-
33
34 tailed methods with the assistance a statistical program from
35
36 IBM, SPSS 24 for Microsoft© Windows version 10.
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44 **Patient and Public Involvement**

45
46 Patients were not involved in the development or design
47 of this pilot study. However we do plan to enlist patient help
48 when disseminating our research findings. We aim to include
49
50 patient involvement when designing subsequent studies
51
52 involving the Oxford Video Informed Consent tool (OxVIC).
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RESULTS

Descriptive information

Over a four-month period, 20 participants (10:10, male:female) deemed suitable candidates for spinal procedures were recruited into the study. The mean age of participants was 56 years ($SD = 16.26$), range 27 years to 81years. Participant demographics can be seen in Table 1.

Patient satisfaction

CSQ-8 data were normally distributed. The mean patient satisfaction score (CSQ-8) was 30.2 out of a maximum 32, indicative of high patient satisfaction. The CSQ-8 scores by gender and age can be seen in Table .2.

A two-way between groups analysis of variance was conducted to explore the impact of gender and age on patient satisfaction levels, as measured by the CSQ-8 scale. Participants were divided into five groups depending on their age (Group 1: 25-34 years, Group 2: 45-54 years, Group 3: 55-64 years, Group 4: 65-74 years and Group 5: 75-99 years) The interaction effect between gender and age was not statistically significant . High patient satisfaction levels were reported across a broad range of spinal procedures, seen in Table1. These ranged from spinal nerve root blocks to complex deformity correction surgery.

1
2
3 The CSQ-8 responses generated several significant trends,
4 a strong positive relationship between meeting patients
5 'preoperative consenting needs and helping them to deal more
6 effectively with their preoperative concerns was reported
7 (p=0.028), with 80 % reporting that the tool helped a great
8 deal. All participants reported that they would recommend the
9 video consent tool to others preparing for surgery.
10 When asked "if future treatment were required, would you use
11 the service again?", all participants responded yes. A
12 significant positive relationship between the quality of the
13 service participants received versus the service they expected
14 was observed ($p = 0.008$).

31 32 **Engagement with the tool**

33 All participants watched their consent video at least
34 once prior to consenting for surgery, with a mean number of
35 viewings of 2-3 times. Eighty-five percent of the participants
36 watched their consent video with their next of kin, which
37 includes partners and other family members, their children or
38 friends. Two participants sent their consent videos to their
39 children, who lived in the USA and Australia. 15% of
40 participants reported watching their video alone. Those who
41 watched the video 4 to 5 times on average reported higher
42 satisfaction scores. Approximately 13 additional minutes were
43 required compared to the traditional process to complete the
44 video recording process.

1
2
3 The mean recording time was 13 minutes and 15 seconds, with a
4 range of 6 minutes and 21 seconds, to 20 minutes and 55
5 seconds. Introduction of the video consent tool did not endure
6 any significant costs as the technology already existed within
7 the Trust.
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17 **DISCUSSION**

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19 The main findings of our study were that participants
20 were overall completely satisfied with the video consent tool
21 and the service. All patients reported that that would use the
22 service again if needed and that they would recommend the
23 service to others requiring surgery.
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30 The mean CSQ-8 satisfaction score reported in this study
31 was 30.2, with scores above 24 considered as achieving high
32 levels of satisfaction (21) While it was beyond the scope of
33 this exploratory pilot study to examine to how the video
34 consent tool compared to other methods of consent, such as
35 audio recording of consent, participant scores on the CSQ-8 in
36 the present study indicate that the personalised video consent
37 tool may be equal to, if not more effective than, the existing
38 methods (e.g. audio recording alone) (17, 23). However,
39 additional research is needed to further explore this
40 possibility. Our preliminary results suggest that
41 participants' age or gender did not affect patient
42 satisfaction levels with the use of the video consent tool in
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3 the preoperative setting. This finding is consistent with
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5 previous studies (12, 24, 25).
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8 Busy preoperative clinics, poor communication techniques,
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10 unanswered questions, anxiety and poor comprehension are all
11
12 barrier to patients not retaining information (26). Our study
13
14 indicates that the use of personalised video tool may allow
15
16 patients to process and review complex information previously
17
18 discussed by the surgeon, from the comfort of their own home.
19
20 Participants had the opportunity to email the spinal service
21
22 for further clarity of the video content and two participants
23
24 utilised this service.
25
26 Introduction of the video consent tool did not require
27
28 significantly more clinician time. The ability to watch the
29
30 video with family members, or even to securely send family
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32 members the video, allowed for shared decision making and
33
34 aided a person-centred approach to care, empowering
35
36 participants to manage their own medical information. This is
37
38 important for patients outcomes as shared decision making
39
40 facilitates increased patient satisfaction levels and
41
42 potentially reduces illness uncertainty (27, 28).
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48 All patients engaged with their personalised consent
49
50 adjunct twice on average before consenting to surgery. To our
51
52 knowledge, multiple interactions of a preoperative consent
53
54 adjunct have not been reported in the literature (29). All
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56 patients were happy to recommend OxVIC to others requiring
57
58 preoperative surgical consent, indicating they were satisfied
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3 and it would be acceptable for further use. This project found
4 that, the more times participants watched their consent video,
5 the more satisfied they became with their consent process.
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10 With the highest satisfaction scores in those who engaged with
11 the video tool the most (4 to 5 times). Moreover, as the
12 majority of studies using multimedia tools as an adjunct to
13 informed consent do not personalise their content (27, 29),
14 this is the first time that the use of a personalised
15 multimedia tool has been reported in the literature.
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26 **Clinical implications**

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28 This study indicates that a personalised video consent tool is
29 feasible to administer during the preoperative consent process
30 for spinal surgery procedures and that the intervention
31 produced high satisfaction scores. Overall, we found
32 approximately thirteen additional minutes were required
33 compared to the traditional process to complete the video
34 recording process. This suggests that this procedure would be
35 acceptable for use. Particularly in complex consultations
36 where decision-making and communication might be more
37 challenging for both the clinician and the patient.
38
39 While concerns over additional time, potential costs and
40 practicality as to achieving this process are valid, we found
41 them not to be a significant barrier to delivering this service.
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43 Provided one has access to a good quality digital recording
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3 device, such as a smartphone that can transfer and store data
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5 securely, then the process can be straightforward.
6

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8 We recognise that patients need to have access to the internet
9
10 and may require help if not familiar using this sort of
11
12 technology; however, as 85% of UK adults have a smartphone (30)
13
14 and access to the internet in this is not an insurmountable
15
16 barrier. While we have not undertaken a cost analysis, for this
17
18 pilot there have been no significant costs as the technology
19
20 already exists within the NHS Trust.
21
22

23
24 Introducing OxVIC into clinical practice has numerous benefits
25
26 such as, documentary evidence of the clinician - patient consent
27
28 conservation, which may reduce medicolegal cases. It may be used
29
30 as an educational tool for medical teaching and could act as a
31
32 patient resource / decision aid, useful when analysing potential
33
34 benefits and risks associated with surgery.
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40 We would therefore suggest video consenting as a new bench mark
41
42 in the consenting process. Based on this study, we recommend a
43
44 randomised controlled trial to evaluate the full impact of this
45
46 process on outcome measures such as information retention,
47
48 length of stay and litigation claims.
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53 **Strengths and limitations**

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55 This study has several strengths and weaknesses. Among the
56
57 strengths was the development of a novel method to document the
58
59 patient - clinician consent conversation. To our knowledge, this
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1
2
3 study is the first of its kind to provide preoperative patients
4 with a personalised multimedia consent adjunct (OxVIC).
5
6 Furthermore, OxVIC allows patients to review their consent
7
8 conversation with family members and friends away from the
9
10 clinical area, promoting shared decision making and patient
11
12 autonomy. Among the weaknesses is the limited diversity of the
13
14 sample (e.g. spinal surgery patients). Further studies could
15
16 include the patient perspectives from other surgical
17
18 specialities. In addition, quantitative data gathered within
19
20 this pilot could be supported by the addition of qualitative
21
22 research methods. While a standard NHS/Trust surgical consent
23
24 form was used to promote surgeon adherence to standard
25
26 information giving, the consent videos were not independently
27
28 reviewed for validation purposes prior to patient access. The
29
30 potential for standardisation should be considered in future
31
32 studies of multimedia consenting. Finally, concerns regarding
33
34 cost and additional consenting time could be perceived as a
35
36 potential limitation. However, the ability to document the
37
38 patient-clinical conversation and its potential application to
39
40 medio-legal practice may outweigh such concerns. This needs to
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42 be considered in future feasibility studies.
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57 **Future research**

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3 The findings from this pilot provide a foundation for potential
4 future research projects.
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7 A larger more diverse sample size to include younger (<25
8 years) and older (75yrs +) people could add to the validity.
9
10 Moreover, there is scope for the tool to be included in other
11 specialities and further research should examine the
12 acceptability of video consenting tool in multiple surgical
13 disciplines. A double blinded, randomised control trial to
14 definitively test the efficacy of OxVIC across different
15 surgical specialities is in process.
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30 **Conclusion**

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32 If patient satisfaction is a measure of quality (31) this
33 study indicates that the introduction of a personalised consent
34 tool may have a positive impact on the quality of service
35 patients receive. The provision of informed care could be
36 facilitated by the introduction of a personalised video tool,
37 as it promotes patient autonomy, shared decision making and
38 empowers patients to manage their own health.
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AUTHOR CONTRIBUTIONS:

GM, CT and JR made substantial contributions to the conception of the study. GM analysed and interpreted the data for the study. GM, JR and DR contributed to acquisition of the data. GM, CT, VW, DR and JR drafted the article and revised it critically for important intellectual content. All authors gave final approval of the version to be published and agreed to be accountable for all aspects of the article in ensuring that questions related to the accuracy or integrity of any part of the article are appropriately investigated and resolved.

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Competing interests: None

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Patient consent: Obtained

Ethics approval: Oxford Brookes University, Faculty of Health Sciences Research Ethics Committee (FREC2016/57).

Data sharing statement: We welcome data-sharing requests from researchers interested in OxVIC. Please contact GM (gerard.mawhinney@ouh.nhs.uk) directly to explore further.

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WORD COUNT: 3155

Table.1. Demographics of Study Participants

		Sample
Demographics		statistics
Gender, N(%)	Male	10 (50%)
	Female	10 (50%)
Participant age (years) <i>SD</i> =		
16.26	25 – 34	2 (10%)
Mean age – 56 years	35 – 44	0 (0%)
	45 – 54	6 (30%)
	55 – 64	5 (25%)
	65 – 74	4 (20%)
	75 – 99	3 (15%)
Range	27 – 81	
		3
Deformity		6
Variety of Surgical Procedures correction		3

	Lumbar	1
	degenerative	7
	Nerve Root block	
	Removal of	
	metalwork	
	Tumour surgery	
Frequency of viewing consent		
video	Once	7 (35%)
	2 to 3 times	10 (50%)
	4 to 5 times	3 (15%)
Video watched (with)		
	Alone	3 (15%)
	Next of Kin	11 (55%)
	Children	2 (10%)
	Other family	
	members	6 (30%)
	Friends	2 (10%)

Note. *SD* = standard deviation.

Table. 2. Mean CSQ-8 Scores by Age and Gender

Demographic	Mean CSQ-8 Score	(Maximum score Range (<i>SD</i>))
Gender		
Male	30	26 - 32 (2.2)
Female	30.4	29 - 32 (1.07)

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3 Total Mean 30.2 26 - 32 (1.70)
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6 Participant Age (years)
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12 45 - 54 30.16 26 - 31
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14 55 - 64 29 26 - 31
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16 65 - 74 30.25 28 - 32
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42 Figure legend: Figure.1. Provides an overview of the Oxford
43 Video Informed Consent Tool (OxVIC).
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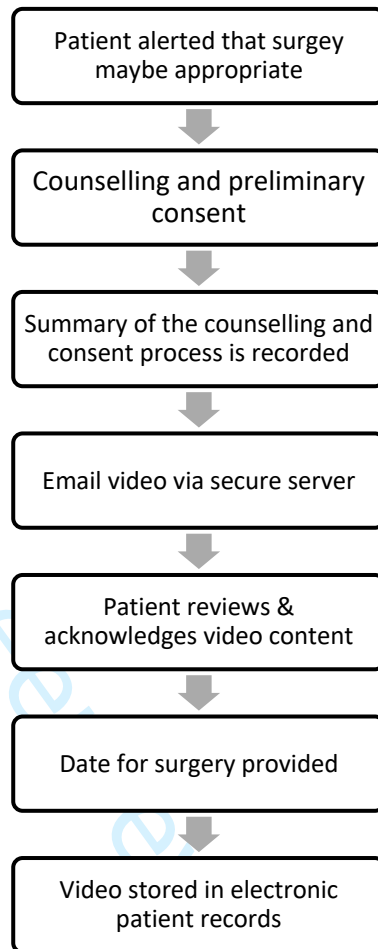
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Figure.1. An overview of the Oxford Video Informed Consent Tool (OxVIC) process



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BMJ Open

THE OXFORD VIDEO INFORMED CONSENT TOOL (OXVIC): A PILOT STUDY OF INFORMED VIDEO CONSENT IN SPINAL SURGERY AND PREOPERATIVE PATIENT SATISFACTION.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-027712.R2
Article Type:	Research
Date Submitted by the Author:	12-Mar-2019
Complete List of Authors:	Mawhinney, Gerard; Oxford University Hospitals NHS Foundation Trust Nuffield Orthopaedic Centre, Spinal Surgery; Nuffield Department of Clinical Medicine Division of Experimental Medicine, Thakar, Chrishan; Oxford University Hospitals NHS Foundation Trust Nuffield Orthopaedic Centre, Spinal Surgery Williamson, Victoria; King's College London, Rothenfluh, Dominique; Oxford University Hospitals NHS Foundation Trust Nuffield Orthopaedic Centre, Spinal Surgery Reynolds, Jeremy; Oxford University Hospitals NHS Foundation Trust Nuffield Orthopaedic Centre, Spinal Surgery
Primary Subject Heading:	Surgery
Secondary Subject Heading:	Patient-centred medicine, Surgery
Keywords:	Video consent, Informed consent, Patient satisfaction, Spinal surgery

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7 **THE OXFORD VIDEO INFORMED CONSENT TOOL (OXVIC): A PILOT STUDY OF**
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14 **PATIENT SATISFACTION.**
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ABSTRACT

Objectives: The British Association of Spinal Surgeons recently called for updates in consenting practice. This study investigates the utility and acceptability of a personalised video consent tool to enhance patient satisfaction in the preoperative consent giving process.

Design: A single centre, prospective pilot study using questionnaires to assess acceptability of video consent and its impacts on preoperative patient satisfaction.

Setting: A single National Health Service (NHS) centre with individuals undergoing surgery at a regional spinal centre in the UK.

Outcome measure: As part of preoperative planning, study participants completed a self-administered questionnaire (CSQ-8), which measured their satisfaction with the use of a video consent tool as an adjunct to traditional consenting methods.

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4 **Participants:** 20 participants with a mean age of 56 years ($SD = 16.26$) undergoing
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7 spinal surgery.
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14 **Results:** Mean patient satisfaction (CSQ-8) score was 30.2 / 32. Median number of
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17 video views were 2-3 times. 85% of patients watched the video with family and friends.
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21 80% of participants reported that the video consent tool helped to their address
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24 preoperative concerns. All participants stated they would use the video consent
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27 service again. All would recommend the service to others requiring surgery.
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31 Implementing the video consent tool did not endure any significant time or costs.
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Conclusions: Introduction of a video consent tool was found to be a positive adjunct to
traditional consenting methods. Patient – clinician consent dialogue can now be
documented. A randomised controlled study to further evaluate the effects of video
consent on patients' retention of information, pre and postoperative anxiety, patient
reported outcome measures as well as length of stay may be beneficial.

Key Words: Video consent, Informed consent, Patient satisfaction, Spinal surgery.

ARTICLE SUMMARY

Strengths and limitations of this study

- The development of a personalised video consent tool used to promote patient autonomy and shared decision making.
- An exploratory pilot study in spinal surgery, future research will explore the use of OxVIC across different surgical specialities.
- Prospective quantitative data gathered from 20 participants, the introduction of a qualitative research element is planned for phase two of this study.
- A novel method to document the patient-clinician preoperative consent conversation.

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INTRODUCTION

Informed consent is a legal and ethical principle that is required prior to any intervention that may violate autonomy. The *Montgomery v Lanarkshire* judgement (1) initiated a change in how healthcare professionals obtain informed consent.

Montgomery (1) confirms the shift from an already eroding paternalistic approach to consent set by *Bolam v Friem Hospital Management Committee*, (2), to the adoption and acknowledgment of a person-centred approach seen in *Sidaway v Bethlem Royal Hospital* (3), *De Freitas v O'Brien* (4) and *Bolitho v City & Hackney HA* (5).

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4 Others concur that *Montgomery* marked a decisive shift in the legal test of duty of
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7 care, from the perspective of the clinician to that of the patient (6).
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10 Informed consent has gained accelerated momentum following the Montgomery
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13 judgement.
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21 In acknowledgement of the recent changes in consenting practice, the General
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24 Medical Council (GMC), the Royal College of Surgeons and other professional
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27 organisations, such as The British Association of Spinal Surgeons, have issued best
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30 practice guidelines on obtaining informed consent (7). However, despite the release
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33 of updated guidelines there is currently a gap in consenting practice relating to
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38 documenting the preoperative consent conversation.
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45 Preparing to undergo surgery can be a stressful event for both patients and their
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48 families, often important information discussed within the consent consultation is
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51 forgotten (8). By providing patients access to a tool that captures their consent
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54 conversation, it is thought that the video will provide patients an opportunity to reflect
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59 and revisit the previously discussed dialog, prior to consenting to treatment. It
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3 encourages a bespoke individualised approach as indicated by Montgomery (1). The
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7 addition of this step to the preoperative consenting process may safeguard patients
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10 from medical coercion and promote autonomy to make an informed decision about
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14 their care, while reducing potential litigation claims.
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17 Enhancements in digital technology are driving changes in information practices.

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21 Such enhancements have influenced how informed consent may be delivered (9),
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24 examples include the use of iPads to deliver consent information (10) and the use of
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27 a smartphone applications to assist informed consenting practice (11). The
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31 acceptance of multimedia technology in preoperative consenting has been
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34 demonstrated across a variety of surgical disciplines, including foot and ankle surgery
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37 (12), spinal surgery (13), vascular surgery (14), ophthalmic surgery (15),
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41 gastrointestinal surgery (16) and urological surgery (17). Notably, such preoperative
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44 multimedia consent technologies are often generic and not patient specific. There is
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48 currently a lack of research regarding the use of personalised multimedia consenting
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51 adjuncts within surgery.
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4 In order to improve service delivery and comply with the updated guidelines, we
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7 piloted a video consent tool (OxVIC) as an adjunct to traditional consenting methods
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10 for patients attending a spinal Preoperative Outpatient Assessment Clinic (POAC).
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14 Each consent video contained indications for surgery, associated risks and benefits,
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17 alternative treatment options and a section for patients to ask questions or clarify
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20 points. To our knowledge, the use of a video informed consent tool has not been
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24 used before in spinal surgery.
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31 Our study aims were to evaluate acceptability of a novel consent tool (OxVIC), as an
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34 adjunct to traditional (written and verbal) consenting methods. Aim to provide
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38 documentary evidence of the patient – clinician consent conversation, which now
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41 forms part of the medical notes. Improve patient experience and enhance patient
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45 satisfaction within the preoperative consent process, while generating an evidence
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49 base for future research.
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METHODS

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3 Ethical approval for this project was obtained from the Health and Life Sciences
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7 Faculty Research Ethics Committee (FREC) Oxford Brookes University, Oxford,
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10 England (FREC2016/57). In addition to the video consent process described below,
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14 written informed consent was additionally obtained from all participants.
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22 Procedure

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25 We conducted a single centre, non-randomised, non-comparative pilot study in
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28 patients undergoing a spinal procedure at an NHS spinal centre in the UK. A flowchart
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31 of the study procedure is outlined on Figure 1. Prior to consenting to take part, all
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35 patients received a Participant Information Sheet (PIS). The PIS outlined that if
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39 patients agreed to take part they would receive the “gold standard” (verbal and
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42 written) in consent information. In addition to this they would also receive a consent
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45 adjunct in the form of a personalised video.
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53 All participants who agreed to take part were consented by fellowship trained
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56 Consultant Spinal Surgeons using verbal and written consenting methods in addition
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3 to a summary of the consent consultation being recorded. A researcher, independent
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7 of the surgical team provided participants with patient information sheets prior to
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10 consenting. Participants were all informed that participation was voluntary and were
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13 free to withdraw at any time. The summary was conducted in a structured way and
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16 consisted of the following: a discussion around the patients reasoning for choosing
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19 surgery, followed by an overview of the surgical procedure, its intended benefits and
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22 associated risks ending with an opportunity for the patients to check their
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25 understanding by asking questions.
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31 A password protected email and a hospital trust approved web transfer service was
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34 used to send the personalised consent videos to study participants. Participants
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37 reviewed their personalised consent consultations at home with their family or friends.
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41 Participants had the option to forward their personal consent videos to family members
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44 outside of the UK. All, participants were invited to contact the spinal team, to seek
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47 clarity or ask further questions regarding the video content (two participants utilised
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50 this service). The recorded consent was stored securely within the electronic health
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53 record, accessible only to the research team.
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4 Participants were asked to contact the spinal team once they had reviewed the
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7 consent conversation, acknowledging the risks and benefits of the proposed
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10 treatment. Prospective patient data were obtained using a self-administered
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13 questionnaire regarding patient satisfaction with the use of a video consent tool as an
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16 adjunct to traditional consenting methods. Participants were invited to complete the
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19 measure following the consent consultation and after reviewing their personalised
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22 consent video.
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31 Approximately 13 additional minutes were required compared to the traditional
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34 process to complete the video recording process. The mean recording time was 13
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37 minutes and 15 seconds, with a range of 6 minutes and 21 seconds, to 20 minutes
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40 and 55 seconds. This was dependant of the complexity of the proposed treatment
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43 and its associated risks and benefits. Introduction of the video consent tool did not
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46 endure any significant costs as the technology already existed within the Trust.
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Participants

Participants were recruited over a four month period (September to December 2017).

Twenty two people were approached to take part, two declined, twenty volunteered (n=20). Participants did not receive a honorarium for taking part in the study. Study inclusion criteria were: over the age of 18 years of age; have capacity to make informed decisions; and have an active email address with access to the internet.

Participants were excluded from the study if they had any visual or hearing impairments which may inhibit the ability to review the consent video.

Assessments

A researcher independent of the surgical team distributed electronic Self-Administered Questionnaires (SAQ) to participants who agreed to partake in the study, data were collected at one point, post consent consultation. Participant demographics, which included gender, age, number of times the video consent tool was viewed and who they watched the video with, were collected. In addition to this, participants completed

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2
3 the validated CSQ-8 tool. The CSQ-8 tool consists of eight self-report questions, each
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7 constructed with a four point Likert scale reply (18). The minimum achievable
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10 satisfaction score is 8, indicating poor satisfaction, a maximum score of 32 would
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13 indicate high levels of satisfaction (19, 20). The CSQ-8 tool has been extensively
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16 tested for reliability and validity (19-21); to date it has been translated into more than
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21 30 languages since its first launch in the early 1980's (22). The CSQ-8 has been found
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24 to be acceptable for use in previous studies examining patient satisfaction with
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28 consenting methods (17, 23).
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42 **Data analysis**

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45 The data collection period finished once 20 completed SAQ's were received.
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49 Normality of data were assessed using a Kolmogorov-Smirnov test. Descriptive,
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52 bivariate and inferential statistics were calculated and reported using two-tailed
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56 methods with the assistance a statistical program from IBM, SPSS 24 for Microsoft©
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59 Windows version 10.
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Patient and Public Involvement

Patients were not involved in the development or design of this pilot study. However, following this preliminary pilot study, patient involvement will be included in the development of subsequent studies utilising OxVIC.

RESULTS

Descriptive information

Over a four-month period, 20 participants (10:10, male: female) deemed suitable candidates for spinal procedures were recruited into the study. The mean age was 56 years ($SD = 16.26$), range 27 to 81 years. Participant demographics can be seen in Table 1.

Patient satisfaction

CSQ-8 data were normally distributed. High patient satisfaction levels were reported across a broad range of spinal procedures. The mean patient satisfaction score (CSQ-8) was 30.2 out of a maximum 32, indicative of high patient satisfaction.

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7 The CSQ-8 scores by gender and age can be seen in Table .2. A two-way between
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10 groups analysis of variance was conducted to explore the impact of gender and age
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13 on patient satisfaction levels, as measured by the CSQ-8 scale. Participants were
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16 divided into five groups depending on their age (Group 1: 25-34 years, Group 2: 45-
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18 54 years, Group 3: 55-64 years, Group 4: 65-74 years and Group 5: 75-99 years)
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24 The interaction effect between gender and age was not statistically significant ($p =$
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28 0.155).

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35 The CSQ-8 responses generated several significant trends, a strong positive
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38 relationship between meeting patients 'preoperative consenting needs and helping
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41 them to deal more effectively with their preoperative concerns was reported ($p =$
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44 0.028), with 80 % reporting that the tool helped a great deal. All participants
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48 reported that they would recommend the video consent tool to others preparing for
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52 surgery. When asked "if future treatment were required, would you use the service
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55 again?", all participants responded yes. A significant positive relationship between
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3 the quality of the service participants received versus the service they expected was
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7 observed ($p = 0.008$).
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13 14 **Engagement with the tool** 15

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17 All participants watched the consent video at least once prior to consenting for
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19 surgery, with a mean number of viewings of 2-3 times. Eighty-five percent of the
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21 participants watched the consent video with friends and family, which included next
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23 of kin, partners, children and other family members. Two participants sent the
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25 consent videos to their children living overseas. 15% of participants reported
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27 watching their video alone. Those who watched the video 4 to 5 times on average
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29 reported higher satisfaction scores.
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51 52 **DISCUSSION** 53

54 The main findings of our study were that participants were overall completely
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56 satisfied with the video consent tool and the service. All participants reported that
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58 that would use the service again if needed and that they would recommend the
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4 service to others requiring surgery. The mean CSQ-8 satisfaction score reported in
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7 this study was 30.2, with scores above 24 considered high levels of satisfaction (21).
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14 It was beyond the scope of this exploratory pilot study to examine how the video
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17 consent tool compared to other methods of consent, such as audio recording of
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20 consent. Nonetheless, participant scores on the CSQ-8 in the present study indicate
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23 that the personalised video consent tool may be equal to, if not more effective than,
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26 the existing methods (e.g. audio recording alone) (17, 23). However, additional
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29 research is needed to further explore this possibility. Our preliminary results suggest
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32 that participants' age or gender did not affect patient satisfaction levels with the use
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35 of the video consent tool in the preoperative setting. This finding is consistent with
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38 previous studies (12, 24, 25).
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Busy preoperative clinics, poor communication techniques, unanswered questions, anxiety and poor comprehension are all barrier to patients not retaining information (26). Our study indicates that the use of personalised video tool may allow patients to process and review complex information previously discussed by the surgeon,

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4 from the comfort of their own home. Participants had the opportunity to email the
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7 spinal service for further clarity of the video content and two participants utilised this
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10 service.
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17 Introduction of the video consent tool did not require significantly more clinician time.
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21 The ability to watch the video with family members, or even to securely send family
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24 members the video, allowed for shared decision making and aided a person-centred
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27 approach to care, empowering participants to manage their own medical information.
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31 This is important for patients outcomes as shared decision making facilitates
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34 increased patient satisfaction levels and potentially reduces illness uncertainty (27,
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38 28).
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45 All patients engaged with their personalised consent adjunct twice on average before
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48 consenting to surgery. To our knowledge, multiple interactions of a preoperative
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51 consent adjunct have not been reported in the literature (29). All patients were happy
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54 to recommend OxVIC to others requiring preoperative surgical consent, indicating
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58 they were satisfied and it would be acceptable for further use.
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7 This project found that, the more times participants watched their consent video, the
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10 more satisfied they became with their consent process. With the highest satisfaction
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13 scores in those who engaged with the video tool the most (4 to 5 times). Moreover,
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16 as the majority of studies using multimedia tools as an adjunct to informed consent
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19 do not personalise their content (27, 29), this is the first time that the use of a
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personalised multimedia tool has been reported in the literature.

Clinical implications

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35 This study indicates that a personalised video consent tool is feasible to administer
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38 during the preoperative consent process for spinal surgery procedures and that the
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42 intervention produced high satisfaction scores. Overall, we found approximately
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thirteen additional minutes were required compared to the traditional process to
complete the video recording process.

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This suggests that OxVIC would be acceptable for use, particularly in complex
consultations where decision-making and communication might be more challenging
for both the clinician and the patient.

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7 While concerns over additional time, potential costs and practicality as to achieving
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10 this process are valid, they did not appear to be a significant barrier to delivering this
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13 service. Provided one has access to a good quality digital recording device, such as a
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16 smartphone that can transfer and store data securely, then the process can be
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19 straightforward.
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24 We recognise that patients need to have access to the internet and may require help
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27 if not familiar using this sort of technology; however, as 85% of UK adults have a
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30 smartphone (30) and access to the internet in this is not an insurmountable barrier.
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34 Future studies exploring clinician experiences of obtaining patient consent via OxVIC
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37 would also be useful to ensure that any concerns or barriers to use that were not
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40 identified in the present study are considered and acceptably addressed.
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46 While we have not undertaken a cost analysis, for this pilot there have been no
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49 significant costs as the technology already exists within the NHS Trust. Introducing
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52 OxVIC into clinical practice has numerous benefits such as, documentary evidence
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55 of the clinician – patient consent conservation, which may reduce medicolegal cases.
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4 It may be used as an educational tool for medical teaching and could act as a patient
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7 resource / decision aid, useful when analysing potential benefits and risks associated
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10 with surgery.
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17 We would therefore suggest video consenting as a new bench mark in the consenting
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20 process. Based on this study, we recommend a large-scale study to evaluate the full
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23 impact of this process on outcome measures such as information retention, length of
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26 stay and litigation claims.
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42 **Strengths and limitations**

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45 This study has several strengths and weaknesses. Among the strengths was the
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48 development of a novel method to document the patient – clinician consent
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51 conversation. To our knowledge, this study is the first of its kind to provide preoperative
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54 patients with a personalised multimedia consent adjunct (OxVIC). Furthermore,
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57 OxVIC allows patients to review their consent conversation with family members and
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3 friends away from the clinical area, promoting shared decision making and patient
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7 autonomy.
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14 Among the weaknesses is the limited diversity of the sample (e.g. spinal surgery
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17 patients). Further studies could include the patient perspectives from other surgical
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20 specialities. In addition, quantitative data gathered within this pilot could be supported
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23 by the addition of qualitative research methods. While a standard NHS/Trust surgical
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26 consent form was used to promote surgeon adherence to standard information giving,
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29 the consent videos were not independently reviewed for validation purposes prior to
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32 patient access. The potential for standardisation should be considered in future
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35 studies of multimedia consenting.
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45 Finally, concerns regarding cost and additional consenting time could be perceived as
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48 a potential limitation. However, the ability to document the patient-clinical conversation
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51 and its potential application to medio-legal practice may outweigh such concerns. This
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54 needs to be considered in future feasibility studies.
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Future research

The findings from this pilot provide a foundation for potential future research projects.

A larger more diverse sample size to include younger (<25 years) and older (75yrs

+) people could add to the validity. Moreover, there is scope for the tool to be

included in other specialities and further research should examine the acceptability

of video consenting tool in multiple surgical disciplines. A larger study to definitively

test the efficacy of OxVIC across different surgical specialities is in process.

Conclusion

If patient satisfaction is a measure of quality (31) this study indicates that the

introduction of a personalised consent tool may have a positive impact on the quality

of service patients receive. The provision of informed care could be facilitated by the

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3 introduction of a personalised video tool, as it promotes patient autonomy, shared
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7 decision making and empowers patients to manage their own health.
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10 **AUTHOR CONTRIBUTIONS:**
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14 GM, CT and JR made substantial contributions to the conception of the study. GM
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16
17 analysed and interpreted the data for the study. GM, JR and DR contributed to
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19
20 acquisition of the data. GM, CT, VW, DR and JR drafted the article and revised it
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22
23 critically for important intellectual content. All authors gave final approval of the
24
25
26 version to be published and agreed to be accountable for all aspects of the article in
27
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29 ensuring that questions related to the accuracy or integrity of any part of the article
30
31
32 are appropriately investigated and resolved.
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43
44

45 **Competing interests:** None
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47

48
49 **Disclaimer:** This study has been presented via podium presentation at the 41st
50
51
52 Annual Scientific Meeting of the Singapore Orthopaedic Association and at the Joint
53
54
55 British Scoliosis Society / Irish Spine Society Meeting, 2018.
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59 **Patient consent:** Obtained
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Ethics approval: Oxford Brookes University, Faculty of Health Sciences Research

Ethics Committee (FREC2016/57).

Data sharing statement: We welcome data-sharing requests from researchers

interested in OxVIC. Please contact GM (gerard.mawhinney@ouh.nhs.uk) directly to

explore further.

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WORD COUNT: 3163

Table 1. Demographics of Study Participants

Demographics		Sample statistics
Gender, N(%)	Male	10 (50%)
	Female	10 (50%)
Participant age (years) <i>SD</i> = 16.26	25 – 34	2 (10%)
Mean age – 56 years	35 – 44	0 (0%)

	45 – 54	6 (30%)
	55 – 64	5 (25%)
	65 – 74	4 (20%)
	75 – 99	3 (15%)
Range	27 – 81	

Variety of Surgical Procedures	Deformity correction	3
	Lumbar degenerative	6
	Nerve Root block	3
	Removal of metalwork	1
	Tumour surgery	7
Frequency of viewing consent video	Once	7 (35%)
	2 to 3 times	10 (50%)
	4 to 5 times	3 (15%)
Video watched (with)	Alone	3 (15%)
	Family and friends	17(85%)

Note. *SD* = standard deviation.

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11 **Table 2. Mean CSQ-8 Scores by Age and Gender**
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Demographic	Mean CSQ-8 Score (Maximum score 32)	Range (<i>SD</i>)
Gender		
Male	30	26 – 32 (2.2)
Female	30.4	29 – 32 (1.07)
Total Mean	30.2	26 – 32 (1.70)
Participant Age (years)		
25 - 34	31	30 – 32
35 - 44	-	-
45 – 54	30.16	26 - 31
55 – 64	29	26 – 31
65 – 74	30.25	28 – 32
75 – 99	31.66	31 – 32

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35 Figure legend: Figure.1. An overview of the Oxford Video Informed Consent Tool
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38 (OxVIC) process
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Figure.1. An overview of the Oxford Video Informed Consent Tool (OxVIC) process

