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Systematic Review

Digital technology in informed consent for surgery: systematic review

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Abstract

Background: Informed consent is an ethical and legal requirement in healthcare and supports patient autonomy to make informed choices about their own care. This review explores the impact of digital technology for informed consent in surgery.

Methods: A systematic search of EBSCOhost (MEDLINE/CINAHL), Embase, Cochrane Central Register of Controlled Trials and Web of Science was performed in November 2021. All RCTs comparing outcomes of both digital and non-digital (standard) consent in surgery were included. Each included study underwent an evaluation of methodological quality using the Cochrane risk of bias (2.0) tool. Outcomes assessed included comprehension, level of satisfaction and anxiety, and feasibility of digital interventions in practice.

Results: A total of 40 studies, across 13 countries and 15 surgical specialties were included in this analysis. Digital consent interventions used active patient participation and passive patient participation in 15 and 25 studies respectively. Digital consent had a positive effect on early comprehension in 21 of 30 (70 per cent) studies and delayed comprehension in 9 of 20 (45 per cent) studies. Only 16 of 38 (42 per cent) studies assessed all four elements of informed consent: general information, risks, benefits, and alternatives. Most studies showed no difference in satisfaction or anxiety. A minority of studies reported on feasibility of digital technology in practice.

Conclusion: Digital technologies in informed consent for surgery were found to have a positive effect on early comprehension, without any negative effect on satisfaction or anxiety. It is recommended that future studies explore the feasibility of these applications for vulnerable patient groups and busy surgical practice.

Introduction

Informed consent to treatment is a fundamental human right that was proclaimed in Article 3 of the United Nations Universal Declaration of Human Rights in 1948, stating that 'everyone has the right to life, liberty, and security of person'[1]. In healthcare, it remains an ethical and legal requirement, whereby the healthcare provider communicates comprehensible information to their patient to help them decide to accept or refuse an intervention. Consent is an essential part of respect for patient autonomy and without it, treatment of an individual would constitute a trespass or battery[2]. Consent given must be 'valid' consent, whereby sufficient information is delivered to a competent patient for them to make a voluntary decision free from any coercion. The reasonable patient standard considers what the average patient needs to know to be an informed participant in the decision and underpins shared decision-making in modern healthcare. In the UK, the 2015 Montgomery *versus* Lanarkshire Health Board case[3] reiterated that treatments should be determined by what the reasonable patient considers important and not what the reasonable physician considers important[4,5]. This standard has been widely adopted internationally[4]. Despite this, there is evidence that the process of gaining informed consent is not performed well in the field of surgery, resulting in low satisfaction, poor treatment adherence, and increased litigation and complaints[6,7].

Good communication bolsters the consent process, which is not a one-off event or simply a signature on a consent form[8]. Several barriers exist to good communication, including patients' varying knowledge gaps, which need to be overcome, use of medical jargon, lack of physician training, time pressures, and patient factors such as culture, education, language barriers, and frailty[9–12]. Conventional consent practices in healthcare settings continue to have inherent flaws, where discussion remains unstandardized and at the discretion of the physician. This can easily introduce personal bias and lead to omission of key information[13]. Thus, a search for solutions to support and improve the consent process, particularly in the field of surgery, is needed.

Interventions to improve and standardize consent for surgical procedures have been considered in a number of studies and range from standard patient information leaflets (PILs) to multimedia (MM) interventions[14,15]. PILs have shown mixed results for improving patient recall and satisfaction[16,17] and are

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often unstandardized, with poor readability, and are overly complex[18]. Digital health technologies have been rapidly integrated into healthcare settings during the COVID-19 pandemic and have an ever-growing role in healthcare delivery[19]. Digital technologies to improve the informed consent process for surgical procedures have been increasingly under investigation over the last 10–15 years but have not yet superseded standard consent processes. Previous reviews have been published on the topic of informed consent in healthcare. Glaser *et al.* reported the results of comparative studies for medical and surgical procedures using written, audio-visual, interactive digital, verbal discussion with test-back and multicomponent informed consent interventions[20]. They identified that, overall, two-thirds of the variety of interventions described, aimed at improving communication, result in improved comprehension. Similarly, Kinnersley *et al.* reported the results of multiple interventions to improve informed consent across surgical, medical, radiological, anaesthetic, paediatric, and screening procedures[21]. Twenty-two studies were combined in a meta-analysis for the outcome 'immediate knowledge' that showed a statistically significant increase in knowledge compared with the control groups, but with substantial heterogeneity. Less than half of the interventions pertained to digital interventions and the patient cohort, as well as studies, were too heterogenous to combine in a meta-analysis[21]. The most recent review by Gesualdo *et al.* specifically looked at digital tools to improve consent in biomedical/clinical research but included both clinical research and clinical procedure (surgical and medical) studies in adult, adolescent, and paediatric populations[22]. All of these previous reviews are heterogenous in patient populations, study design (randomized and non-randomized), indication for consent (surgery, research, diagnostic test, screening test), and the range of interventions under investigation.

Therefore, the aim of this systematic review was to compare digital consent interventions to standard consent in the field of surgery alone, in terms of comprehension, satisfaction, and anxiety, where evidence suggests that improvement is required. Furthermore, to answer the research question with the most robust evidence available, only randomized clinical trial (RCT) study designs are included. Finally, this review will be the first to look specifically at the feasibility of digital interventions in surgical practice.

Methods

Statement of design

This review was carried out in accordance with the PRISMA guidelines[23] and was registered prospectively (PROSPERO ID CRD42021276879).

Study eligibility

All English-language RCTs that compared the level of comprehension about the intended surgical procedure and/or the level of satisfaction or anxiety in patients who underwent a digital consent intervention with those who underwent standard consent were included. Feasibility and pilot studies using an RCT design were also included. Disclosure and discussion around the four key elements of informed consent (risks, benefits, alternatives, and general procedure information) was considered for each group and whether understanding of these was assessed for comprehension. Surgical procedure was defined as any procedure using manual and instrumental techniques on a person, which involved a therapeutic procedure such as cutting of a person's tissues or closure of a wound sustained through injury. Both elective and emergency surgical procedures were included. Digital consent was defined as the use of any electronic technology such as DVD, multimedia files, and audio-visual presentations presented on a screen (hand-held, desktop computer, television, projection screen). Examples of multimedia include combinations of text, audio, graphics, video, and animation. Digital interventions with and without patient participation (such as test-back and self-navigation) were included. Standard consent interventions consisted of verbal face-to-face discussion between a clinician and the patient with or without the addition of written information in the form of a document, handout, or pamphlet to take home. Unstandardized discussions and standardized versions of consent processes (for example use of a script or checklist for key discussion points) were both considered as standard consent. Excluded studies were studies evaluating informed consent for adolescents or children (under 18 years of age), interventional medical procedures, clinical trial participation, patients not consenting for themselves, and for consent for anything other than a surgical procedure. No limitation was set as per the date, journal, or quality of the study.

Population, intervention, comparator, and outcome

The research question was formulated using the population, intervention, comparator, and outcome framework. The population of interest was those undergoing a surgical procedure. The intervention groups consisted of patients who were consented using a digital consent intervention as described above. Patients who received standard verbal consent (SVC) were used as comparators. The primary outcome was overall patient comprehension at early and delayed time points. Also reported was whether studies assessed comprehension of all elements of informed consent, including comprehension of the procedure, risks, benefits, and alternatives. The secondary outcomes included patient satisfaction, anxiety, and the feasibility of digital interventions, defined as the time taken for the intervention compared with controls and/or any documented challenges to feasibility. Eligible studies were required to report on any or all the outcomes in both the intervention and control groups.

Search methodology

A systematic search of EBSCOhost (MEDLINE/CINAHL), Embase, Cochrane central register of controlled trials, and Web of Science was conducted. Searches used medical subject headings and text words for 'consent', 'digital', 'surgery', and 'patient education' linked by the Boolean operator AND. The names of authors, with a previous review published on this topic, were searched in Scopus. The search strategy was developed with the assistance of a medical librarian (Appendix S1). A comprehensive literature search was carried out in November 2021 by two reviewers (A.K. and B.F.). The initial search was performed without language restriction but only full-text articles in English were considered for inclusion. Reference lists of included studies and earlier reviews on this topic were also interrogated for studies meeting the inclusion criteria.

Study selection

All citations, after duplicates were removed using EndNote, were uploaded into COVIDENCE[24], a software systematic review manager for screening by two independent reviewers (A.K. and B.F.). A.K. and B.F. screened all titles and abstracts, followed by full texts identified as potentially relevant. The members of the study team (A.K., S.S.G., F.D., and D.H.) developed and approved a standardized data extraction Microsoft® Excel file. Any disagreements regarding inclusion and data were resolved in consultation with the senior authors (S.S.G., F.D., and D.H.). One study had missing data of interest and the required data were unavailable from the trial registry[25]. Primary authors were not contacted for any missing raw data.

Grouped interventions

Interventions were divided into two naturally occurring categories *post hoc*. Audio-visual media with active patient participation (APP) included audio-visual media delivered on a desktop computer, hand-held computer, or mobile phone application with any interactive features. Features that allowed patients to navigate through educational modules, such as skip sections using thumbnails, request more information, record questions to ask, or test their knowledge were considered as APP. Audio-visual media with passive patient participation (PPP) included videos, graphics, and animations that omitted interactive activities. Group-two interventions could include discussion with the consenting clinician but no other interactive feature requiring APP.

Study populations

Extracted data were tabulated in Microsoft® Excel. The trial authors, year, country, sample size, surgical specialty, surgical procedure, participant's age, intervention, patient engagement, elements of consent included, timing of comprehension, group favoured, secondary outcomes, and risk of bias assessment were recorded.

Outcome measures

The primary outcome was the difference in patient comprehension between groups, as assessed by validated or unvalidated questionnaires. The difference between groups was measured by the mean score or mean percentage correct for independent questionnaires. The inclusion of the individual elements of informed consent (general knowledge about the procedure, risks, benefits, and alternatives) was recorded by reviewing the comprehension questionnaires where available. Timing of comprehension assessment was categorized as early (same day as consent intervention) and delayed (more than 24 h after consent intervention). The secondary outcomes included the effect on patient anxiety, as measured by either standardized scales or clinical interviews, and satisfaction with the intervention received after randomization, as measured by validated or unvalidated questionnaires. In addition, the feasibility of digital interventions was assessed based on the time taken for the intervention and/or the time face to face with the surgeon—these could be recorded electronically or by hand. Any other factors that were felt to be barriers to feasibility were recorded. Statistically significant results that resulted in improved comprehension or satisfaction, or reduced anxiety were considered to have resulted in a positive or improved effect and was therefore considered an advantageous intervention. Results that were statistically significant but in favour of the control group are reported as favouring standard consent and non-significant results were reported as having no advantage in improving consent.

Risk of bias

Bias was assessed using the Cochrane risk of bias 2 tool for the patient comprehension outcome in each trial[26]. Where comprehension was not assessed, bias was assessed for patient satisfaction outcome. Five domains assessing the randomization process, deviations from protocol, missing outcome data, measurement of the outcome, and the selection of reported results were examined to make overall risk-of-bias judgements.

Data analysis

Meta-analysis was considered by the authors of this review. It was felt that it would be inappropriate to combine results and to make interpretations, given the differences between studies, mainly the type of procedure and assessment tools used across studies. Furthermore, combining studies for meta-analysis when there was a high risk of bias reported for the majority of studies, may be seriously misleading and would simply compound the errors[27].

Results

Literature search

An initial search of online databases yielded 1654 results. After duplicates were removed, 919 potentially relevant studies were included for abstract screening. A total of 79 full-text articles were retrieved, of which 44 were excluded. A total of 40 studies, 35 from initial database searches and a further five studies identified through manual search of the bibliographies of those studies and previous reviews, were included. These results are summarized as a PRISMA flow chart[23] (*Fig. 1*), with reasons for study exclusion.

Characteristics of included studies

Included studies were conducted in 13 countries across North America (20 of 40; 50 per cent), Europe (10 of 40; 25 per cent), Oceania (6 of 40; 15 per cent), and Asia (5 of 40; 12.5 per cent), with dates between 2004 and 2021. A total of 3842 patients were included in studies. Comprehension was assessed in 38 studies[11,15,28–63], satisfaction in 24[28,31,33–39,43–45,47,49,50,52,54–56,58,59,63–65], anxiety in 16 studies[29,31–33,35,44,46,47,49,50,52,53,56,58–60,65], and time taken face to face with the treating clinician in seven studies[34–36,52,57,60]. Thirty-nine studies specified that the trial setting was for elective surgery and only one study was carried out for an emergency procedure[37]. Included studies described surgical procedures across 15 surgical specialities. One study had missing data of interest and the required data were unavailable from the trial registry[25].

Digital interventions with active patient participation

Fifteen studies reported results on digital consent with APP (*Table S1*). APP ranged from use of a hand-held computer and navigation thumbnails, to comprehension checkpoints throughout the consent programme (*Fig. 2*). Patient self-navigation was used in 12 of 15 (80 per cent) studies[28,33,38,42,48,52,55,56,58,59,62,64]. Patients could decide the flow rate of the programme, skip between chapters, and fast-forward or rewind video content. The devices used to deliver interventions differed among studies. Hand-held computers were used in 6 of 15 studies (40 per cent)[33,34,38,42,55,62], desktop computers in 8 of 15 (53.3 per cent)[15,28,48,52,56,58,59,64], and mobile phone applications in 1 of 15 (6.6 per cent)[40]. Six

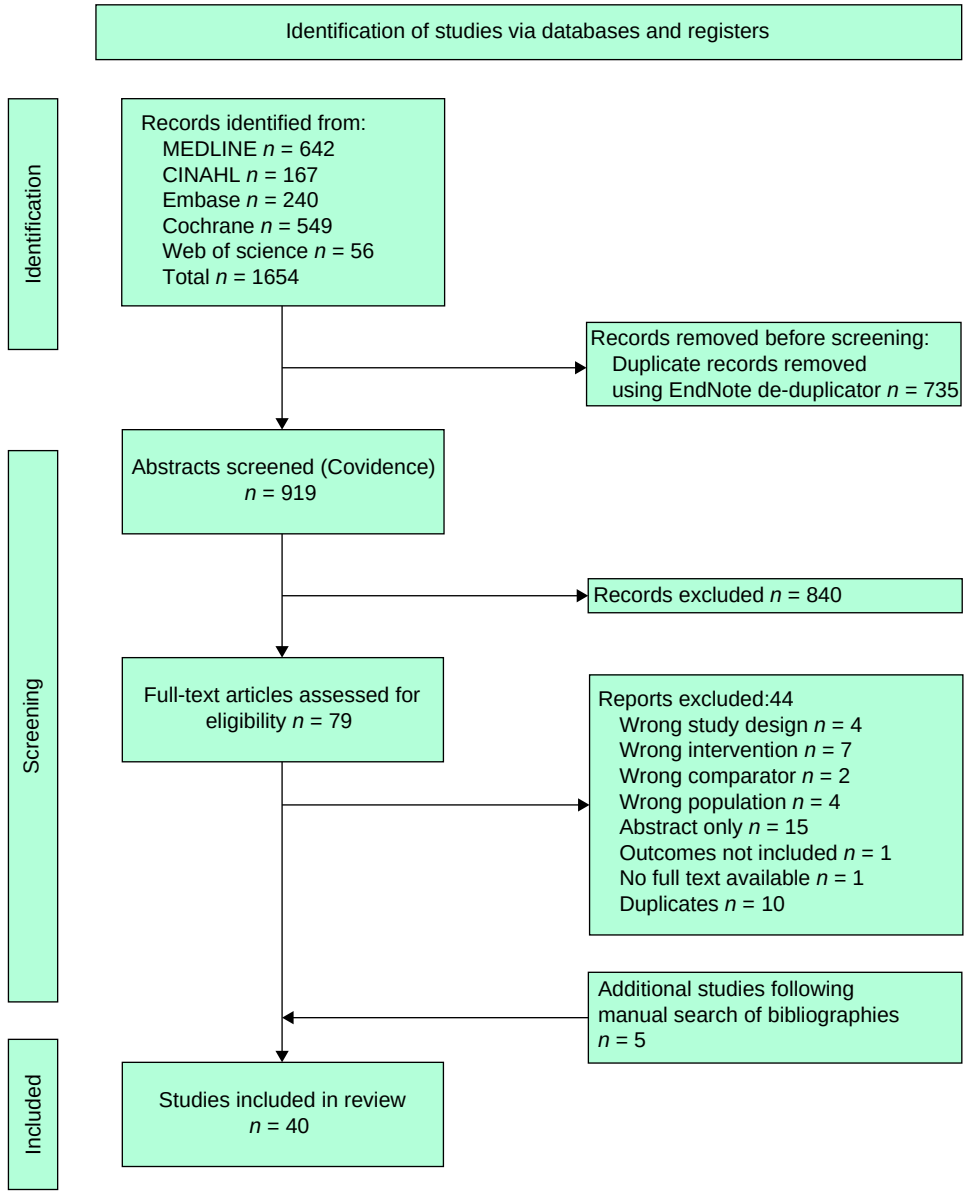

Fig. 1 PRISMA flowchart

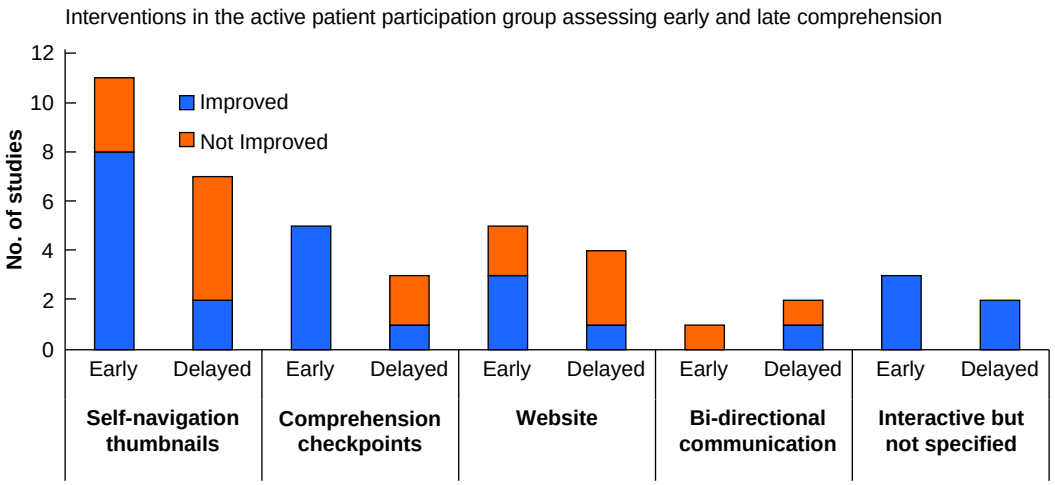

Fig. 2 Bar chart of the interventions that did and did not improve early and late comprehension in the active patient participation group

interventions were web-based programmes, delivered through a website where internet access was required[28,33,38,42,55,64]. The degree of APP varied among studies from minimum participation (self-navigation) to maximum participation (comprehension checkpoints, chat function to interact with clinician, and interaction with animations). Three studies used comprehension assessments embedded into the programme, where patients had to answer correctly to progress[15,42,48]. Two studies used checkpoints to confirm understanding before proceeding[28,55]. Most interventions were offered in hospital, except for two that were accessed at home[40,64] and two where the intervention was offered both onsite and at home[33,59] Further characteristics of interventions are detailed in *Table S1*.

Digital interventions with passive patient participation

Twenty-five studies reported results on digital consent with PPP (*Table S2*). Video-only interventions were reported in 15 of 25 (60 per cent) studies[29,36,37,39,41,44,45,50,51,53,57,60,61,63,65], non-interactive PowerPoint presentations with audio-visual content in 3 of 25 (12 per cent) studies[11,43,46], and via a website in 2 of 25 (8 per cent) studies[47,49]. Five studies (20 per cent) had multicomponent interventions[30–32,35,54] and all five used video and written pamphlets in the intervention group (*Fig. 3*). Interventions were completed onsite in hospital for studies except for three that were accessed and completed at home. One study provided patients with a DVD for viewing and two provided access to videos via the Cloud or a hyperlink, which required the internet[39,41,47]. Further study characteristics are detailed in *Table S2*.

Primary outcomes

Early comprehension

Among the 38 included studies reporting on comprehension, 31 reported on early comprehension, of which 21 of 30 (70 per cent) found that digital interventions had a positive effect. Ten (50 per cent) studies were in the APP cohort. These included the five studies with comprehension assessments or checkpoints embedded in the programme, four that used self-navigation thumbnails, and one that was interactive but the features were not specified. Ten (50 per cent) studies within the PPP digital group also significantly improved early patient comprehension. Included were seven studies using video media[37,44,45,50,51,61,63], two using multicomponent interventions[30,32], and one using a website-based intervention[49]. One study by Huber *et al.*, tested both subjective and objective knowledge using an interactive education module for patients undergoing prostatectomy. While there was no difference in risk recall between groups, the intervention group scored significantly higher for perceived knowledge using a Likert scale[52]. There was no significant difference between groups for three APP studies and eight PPP studies. There were no studies in which the control group was favoured over the digital intervention being tested in both the APP and PPP groups.

Delayed comprehension

Among the 38 studies, 20 reported on delayed comprehension, nine in the digital intervention with APP cohort and 11 in the PPP cohort. Nine of 20 (45 per cent) studies reported a positive effect on delayed comprehension, four in the APP group, none of which used the same interactive features[34,40,42,56], and five in the PPP group; three used video format[57,60,61], one used a website[47], and one was multicomponent[32]. Eleven of 20 (55 per cent) studies found no difference in delayed comprehension between groups, five in the APP groups and six in the PPP group. Of note two of the studies using comprehension checkpoints found no difference in delayed comprehension compared with controls[28,48]. There was one study that compared the early comprehension scores with the delayed scores between groups. Kinman *et al.* favoured the control group for retention of information at a delayed time point of 6 weeks[38]. The intervention used, involved an interactive tool that allowed the physician to visually demonstrate the patients pelvic floor exam findings and the available treatment options for pelvic organ prolapse surgery. Only 33.3 per cent of patients completed the delayed follow-up questionnaire for this analysis. Delayed comprehension was assessed from 1–6 weeks after surgery.

Elements of informed consent—general information, risks, benefits, and alternatives

Of the 38 studies reporting on comprehension, 16 (42 per cent) assessed all four elements of informed consent[11,28–30,32,34,36–38,42,49,51,54,55,61,62], 17 (44.7 per cent) assessed comprehension of the general/procedure information alone, risks alone or combination of both[15,33,35,39–41,44–47,52,53,56,57,60,63], a further two (5 per cent) also included the benefits of surgery in the comprehension

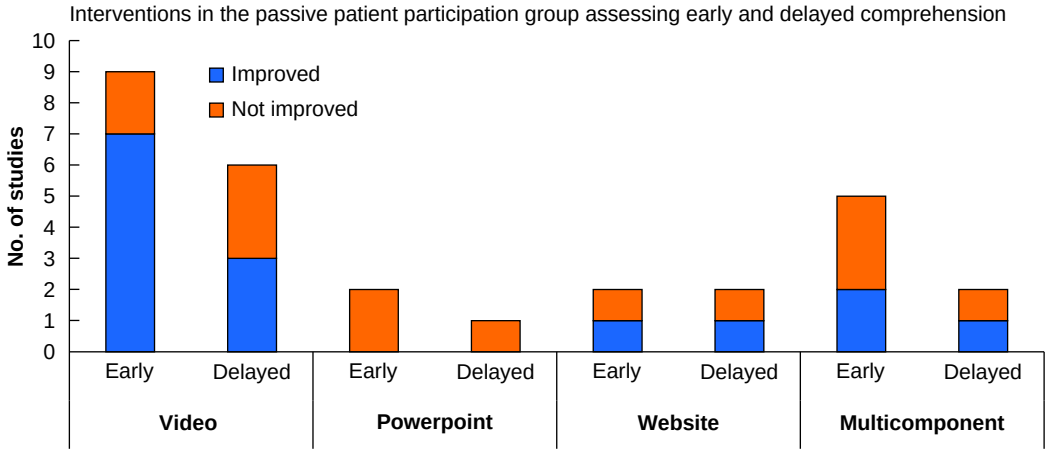

Fig. 3 Bar chart of the interventions that did and did not improve early and late comprehension in the passive patient participation group

Table 1 Results of secondary outcomes from trials comparing digital consent interventions with standard verbal consent

Study, country	*n*	Group	Intervention	Satisfaction intervention *versus* control, effect size (*P*)	Anxiety intervention *versus* control, effect size (*P*)	Time (s)
Zevin *et al.*[28], Canada	51	APP	SVC + audio-visual, web-based education programme	Satisfaction (CSQ-8), early NS difference between groups; $P = 0.36$		Time (face to face) 358 s (198) *versus* 751 s (212); $P < 0.01$
Penn *et al.*[29], USA	77	PPP	SVC + audio-visual, video			Time taken 275 s (193–444) *versus* 310 s (245–406); $P = 0.608$
Truong *et al.*[33], Australia	75	APP	SVC + audio-visual web-based education programme	Satisfaction (Likert), delayed NS difference between groups	Anxiety (STAI-6), DOS NS difference between groups	
Delcambre *et al.*[31], USA	231	PPP	SVC + audio-visual video + written pamphlet	Satisfaction (Likert 5-point), early NS difference between groups; $P = 0.065$	Anxiety (STAI 40—trait only), early NS difference between groups; $P = 0.626$	
Zhang *et al.*[32], USA	77	PPP	SVC + audio-visual video + written pamphlet		Anxiety (STAI 80), baseline, early, delayed (1 week) Favoured intervention group (early) 26.4 ± 5.1 *versus* 41.1 ± 10.3; $P < 0.001$	
Baenninger *et al.*[35], Switzerland	113	PPP	SVC + audio-visual, video + written pamphlet	Satisfaction (Likert 4-point), early NS difference between groups; $P = 0.915$	Anxiety (STAI-6), early NS difference between groups; $P = 0.159$	Time taken shorter with intervention group −4.96 min (95% c.i., −9.50 ,−0.43 min); $P = 0.032$
Kinman *et al.*[38], USA	57	APP	SVC + audio-visual, web-based education programme	Satisfaction counselling (Likert 5-point), early NS difference between groups; $P = 0.81$		
Pallett *et al.*[34], USA	116	APP	Audio-visual, multimedia	Satisfaction (CSQ-8), early NS difference between groups		Time (face to face) Shorter time with doctor for those that had intervention 8 *versus* 12 min; $P = 0.003$
Van Eck *et al.*[64], USA	177	APP	SVC + audio-visual, web-based	Satisfaction (OAS CAHPS survey) Validated First post-op. visit Intervention group 97 (5) *versus* 94 (8); $P = 0.019$		
Vo *et al.*[36], USA	63	PPP	SVC + audio-visual, video	Satisfaction (Likert 5-point), early NS difference between groups; $P = 0.43$		Time taken with surgeon shorter for intervention group 117.5 s (10.9) *versus* 241.6 s (13); $P < 0.001$
Lin *et al.*[37], Taiwan	142	PPP	SVC + audio-visual, video	Satisfaction (Likert 5-point) Satisfaction for intervention groups for all 3 questions; $P < 0.001$		
Sharma *et al.*[39], USA	40	PPP	SVC + audio-visual, web-based	Satisfaction overall process (Likert 5-point) Post-op. visit weeks 1 and 4 NS difference between groups		

(continued)

Table 1 (continued)

Study, country	*n*	Group	Intervention	Satisfaction intervention *versus* control, effect size (P)	Anxiety intervention *versus* control, effect size (P)	Time (s)
Tipotsch—Maca *et al.*[44], Austria	123	PPP	SVC + audio-visual, video	Satisfaction (Likert 5-point), early NS difference between groups; $P = 0.287$	Anxiety (STAI (80)), early NS difference between groups; S anxiety; $P = 0.305$, T anxiety; $P = 0.680$	
Ham *et al.*[43], South Korea	40	PPP	SVC + audio-visual, PowerPoint (non-interactive)	Satisfaction (VAS (mean)), early Favoured intervention 8.5 (1.5) *versus* 7.4 (1.7); $P = 0.033$		
Winter *et al.**[45], Australia	88	PPP	SVC + audio-visual, video	Satisfaction (CSQ—8) early, crossover NS difference between groups SVC had increase in satisfaction after crossover to intervention 29.07 *versus* 30.27; $P = 0.006$		
Choi *et al.*[46], Korea	51	PPP	SVC + audio-visual, PowerPoint (non-interactive)		Anxiety (STAI (80), DAS, VAS), early, week 1 NS difference between groups for STAI, DAS Lower anxiety scores for intervention group at 1 week for VAS; $P < 0.05$	
Bowers *et al.*[63], Canada Pilot RCT	93	PPP	SVC + audio-visual, video	Satisfaction (Likert), early ANOVA F value = 44.06; $P < 0.000$ Intervention favoured		
Fraval *et al.*[49], New Zealand	211	PPP	SVC + audio-visual web-based	Satisfaction (CSQ-8), early Favoured intervention, 20.59 (2.34) *versus* 19.71 (3.76); $P = 0.045$	Anxiety (STAI 80), early NS difference between groups 35.75 (12.19) *versus* 38.98 (12.70); $P = 0.195$	
Yin *et al.*[47], USA	55	PPP	SVC + audio-visual web-based	Satisfaction (Likert 10-point) Delayed (DOS and 1st post-op. visit) favoured intervention DOS 8.7 *versus* 7.7; $P = 0.04$, delayed, 9.2 *versus* 8.1; $P = 0.01$	Anxiety (Likert) NS difference baseline, DOS Favoured intervention at post-op. clinic 2 *versus* 3.5; $P = 0.03$	
Ellett *et al.*[50], Australia	41	PPP	SVC + audio-visual, video	Satisfaction (VAS), early NS difference between groups; $P = 0.64$	Anxiety (STAI-6), early, delayed (6 weeks) NS difference between groups at either time point	
Huber *et al.*[52], Germany	203	APP	SVC + audio-visual, education module	Satisfaction (Likert 6-point), early Per cent complete satisfaction 69% *versus* 52%; $P = 0.016$	Anxiety (STAI 80), early NS difference between groups; $P = 0.48$	Time taken NS difference between groups; $P = 0.89$
Mayilvaganan and Shivaprasad[65], India	60	PPP	SVC + audio-visual, video	Satisfaction (Likert 4-point), immediate, delayed (day of discharge) Intervention (video) group had significantly higher scores than other two groups; $P < 0.001$	Anxiety (self-reported 'feeling less anxious'), early NS difference between groups but 75% of video groups less anxious compared with 65% (3D model) and 50% (SVC)	
Wollinger *et al.*[55], Austria	90	APP	SVC + audio-visual, web-based	Satisfaction (VAS), early NS difference between groups		

(continued)

Table 1 (continued)

Study, country	*n*	Group	Intervention	Satisfaction intervention *versus* control, effect size (*P*)	Anxiety intervention *versus* control, effect size (*P*)	Time (s)
Wysocki *et al.*[53], Poland	58	PPP	SVC + audio-visual, video		Anxiety (VAS), baseline, delayed (24–36 h, 7 and 30 days) NS difference between groups at all time points	
Cornoiu *et al.*[56] (3-arm), Australia SVC, SVC + pamphlet	61	APP	SVC + audio-visual, multimedia education module	Satisfaction (Likert 5-point), early Favoured intervention and SVC compared with SVC + pamphlet; $P < 0.05$	Anxiety (STAI 80), early, DOS, delayed (6 weeks) NS difference between groups at any time point	
Johnson *et al.*[54], USA	151	PPP	1: SVC + audio-visual, video + written pamphlet	Satisfaction (Likert), early, DOS, delayed (6 weeks) NS difference at any time point between groups		
Bollschweiler *et al.*[58], Germany	76	APP	SVC + audio-visual, education module	Satisfaction (VAS), early NS difference between groups	Anxiety (KASA), early NS difference between groups	
Heller *et al.*[59], USA	133	APP	SVC + audio-visual, education module	Satisfaction (Likert 5-point), early Favoured intervention (96.9% *versus* 86.4%; $P = 0.03$	Anxiety (STAI 80), baseline, early, delayed NS difference between groups	
Danino *et al.*[60], France	80	PPP	SVC + audio-visual, video		Anxiety (STAI 80), baseline, DOS B: 42 (37.1–46.3) *versus* 41 (35.2–44.3); NS difference DOS: 45 (38.2–46.3) *versus* 55 (49.9–63.8); $P < 0.001$	Time taken 45.7 *versus* 47.6 min NS difference between groups

APP, active patient participation; PPP, passive patient participation; CSQ-8, client satisfaction questionnaire; DAS, Corah dental anxiety scale; DOS, day of surgery; KASA, cognitive—autonomic—somatic anxiety symptoms; OAS CAHPS, Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers & Systems; NS, not significant; STAI, state trait anxiety inventory; SVC, standard verbal consent; VAS, visual analogue scale. *Crossover study design.

assessment[31,50]. The alternatives to surgery were not assessed in 21 (55 per cent) studies. Two (5 per cent) studies did not state which elements were assessed for comprehension[43,59] and one assessed subjective comprehension alone[58].

In terms of the instruments used to measure comprehension the majority were not validated (30 of 38; 79 per cent). Six instruments were piloted or internally validated before commencement of the respective RCTs, one study was piloted among medical students[60], and the remainder among patients[37,38,44,55,61]. Wollinger *et al.* was the only study to perform Rasch analysis to validate their questionnaire[55]. Two studies adapted questionnaires from previous studies[32,41]. The format of the comprehension assessments also varied. Open-ended questions, true/false, or yes/no, multiple choice questionnaires (MCQs), risk recall, and combinations of these were used. Two studies assessed both subjective and objective comprehension[52,53], where subjective comprehension was measured using a visual analogue scale (VAS) and Likert scales. One study only reported 'self-reported knowledge' measured as good/average/poor[58]. Three studies did not report the format of the comprehension assessment[29,43,49].

Secondary outcomes

The secondary outcomes included patient satisfaction, anxiety, and feasibility of digital interventions based on the time taken for the intervention and/or the time face to face with the surgeon.

Satisfaction with the digital intervention content and interface was assessed. Fourteen of 24 (58.3 per cent) studies reported no difference between groups; six (33.33 per cent) in the APP cohort and eight (25 per cent) in the PPP cohort. Two studies with higher APP found no difference in satisfaction between groups[28,55]. Eleven (45.8 per cent) studies reported that the digital intervention had a positive effect on satisfaction. Four studies in the APP group reported significantly higher satisfaction compared with controls, three provided only minimal interactivity with self-navigation features alone[52,56,59], and one provided bidirectional communication through a chat function that kept the patient connected to their physician between visits[64]. Of note, a study by Van Eck *et al.* used a validated survey that assessed the overall patient experience of the outpatient surgical care that patients received. Satisfaction with the preoperative education was only one of five core care measures included in the survey. Within the PPP group, four studies used video interventions[37,45,63,65], two used web-based programmes[47,49], and one used a non-interactive PowerPoint slideshow[43]. The study by Winter *et al.* was a crossover design and increased satisfaction was only found in the control group once participants had crossed over to the digital intervention[45]. There were no studies that favoured the control group in terms of satisfaction. These findings are displayed in *Table 1*.

The majority (12 of 16; 75 per cent) of studies measuring anxiety reported no difference between groups, seven (43.7 per cent) studies in the APP cohort, and five (62.5 per cent) studies in the PPP cohort. Two of the four studies reporting a positive effect on anxiety levels reported on patient anxiety measured at

Table 2 Quality assessment using Cochrane risk of bias tool 2.0

Study ID	Experimental	Comparator	Outcome	D1	D2	D3	D4	D5	Overall
Baenninger *et al.*[35]	Digital	SVC	Comprehension	!	+	+	−	!	−
Bethune *et al.*[62]	Digital	SVC	Comprehension	!	+	+	!	!	−
Bollscweiler *et al.*[58]	Digital	SVC	Comprehension	+	+	+	−	!	−
Bowers *et al.*[63]	Digital	SVC	Comprehension	+	+	+	−	!	−
Choi *et al.*[46]	Digital	SVC	Comprehension	!	+	+	−	!	−
Clark *et al.*[11]	Digital	SVC	Comprehension	−	+	+	−	−	−
Cornoiu *et al.*[56]	Digital	SVC	Comprehension	!	+	+	−	!	−
Danino *et al.*[60]	Digital	SVC	Comprehension	+	!	+	−	!	−
Delcambre *et al.*[31]	Digital	SVC	Comprehension	!	+	−	!	!	−
Ellett *et al.*[50]	Digital	SVC	Comprehension	!	+	!	−	!	−
Fasulo *et al.*[41]	Digital	SVC	Comprehension	+	+	!	!	!	!
Fraval *et al.*[49]	Digital	SVC	Comprehension	+	−	+	−	!	−
Gordon *et al.*[42]	Digital	SVC	Comprehension	+	!	+	−	!	−
Gyomber *et al.*[15]*	Digital	SVC	Comprehension	+	− +	+	−	!	!
Ham *et al.*[43]	Digital	SVC	Comprehension	!	!	+	!	!	!
Heller *et al.*[59]	Digital	SVC	Comprehension	!	−	−	−	!	!
Huber *et al.*[52]	Digital	SVC	Comprehension	+	!	+	!	!	!
Kinman *et al.*[38]	Digital	SVC	Comprehension	+	+	+	+	!	!
Kim *et al.*[40]	Digital	SVC	Comprehension	!	!	+	−	!	−
Lin *et al.*[37]	Digital	SVC	Comprehension	+	!	+	+	!	!
Pallett *et al.*[34]	Digital	SVC	Comprehension	!	!	+	−	!	!
Penn *et al.*[29]	Digital	SVC	Comprehension	!	+	+	−	!	!

(continued)

Table 2 (continued)

Study ID	Experimental	Comparator	Outcome	D1	D2	D3	D4	D5	Overall
Rossi *et al.*[61]	Digital	SVC	Comprehension	!	+	!	+	!	!
Saglam *et al.*[30]	Digital	SVC	Comprehension	!	+	+	–	–	–
Sharma *et al.*[39]	Digital	SVC	Comprehension	!	+	–	–	!	–
Shukla *et al.*[51]	Digital	SVC	Comprehension	!	+	+	–	!	–
Siu *et al.*[48]	Digital	SVC	Comprehension	!	!	!	–	!	–
Tipotsch-Maca *et al.*[44]	Digital	SVC	Comprehension	!	!	+	!	!	!
Truong *et al.*[33]	Digital	SVC	Comprehension	+	+	!	–	!	!
Vo *et al.*[36]	Digital	SVC	Comprehension	!	+	+	–	!	!
Wilhelm *et al.*[57]	Digital	SVC	Comprehension	–	!	!	–	!	–
Winter *et al.*[45]*	Digital	SVC	Comprehension	+	– +	+	–	!	–
Wollinger *et al.*[55]	Digital	SVC	Comprehension	+	!	+	!	!	!
Wysocki *et al.*[53]	Digital	SVC	Comprehension	+	!	+	–	!	–
Yin *et al.*[47]	Digital	SVC	Comprehension	!	!	+	–	!	!
Zevin *et al.*[28]	Digital	SVC	Comprehension	!	!	+	–	!	–
Zhang *et al.*[32]	Digital	SVC	Comprehension	+	!	+	!	!	!
Johnson *et al.*[54]	Digital	SVC	Satisfaction	–	!	!	–	!	–
Mayilvaganan and Shivaprasad[65]	Digital	SVC	Satisfaction	!	!	–	–	!	–
Van Eck *et al.*[64]	Digital	SVC	Satisfaction	!	+	+	+	!	!

+, low risk; !, some concerns; –, high risk; D1, randomization process; D2, deviations from the intended interventions; D3, missing outcome data; D4, measurement of the outcome; D5, selection of the reported result; SVC, standard verbal consent. *Crossover study design, contains domain S (first row in split cell for D2—risk of bias arising from interval and carryover effects).

a follow-up clinic[46,47]. The results of trials reporting on anxiety are tabulated in *Table 1*.

Of the seven studies reporting on the time taken face to face with the consenting physician, four of seven (57 per cent) favoured the intervention for the shorter time spent with the clinician[28,34–36]. Two of these studies reported improved early comprehension in the intervention group[28,34] and two reported no difference between groups[35,36]. There was no significant difference in satisfaction between groups in these four studies. Of the three studies that reported no difference in time spent with the clinician, Huber *et al.* reported improved satisfaction for the intervention group[52] and Danino *et al.* reported improved comprehension for the intervention group[60]. The study by Penn *et al.* found no difference in comprehension and did not measure patient satisfaction. The total time taken to complete the interventions was reported in only five studies. Two reported increased length of time for the digital intervention compared with standard consent[42,57] and the remaining three had no difference in length between groups[15,43,52]. Each study intervention was delivered onsite in hospital. One study did not compare duration of the consent process between groups but allocated a set timeframe of 7–10 min to the digital consent group to complete the iPad™ module[62].

Other challenges to feasibility

The majority of studies included only fluent English-speaking patients (21 of 40; 52.5 per cent). A further six studies (15 per cent) included only fluent native-language-speaking patients; the most common language was German, followed by Mandarin, and Korean in one study each. A study by Clark *et al.* included English and Spanish speakers, providing an interpreter for the face-to-face discussion and a translated PowerPoint presentation to Spanish speakers[11]. This study found that native Spanish speakers' comprehension of the procedure was worse than native English speakers. Bethune *et al.* also included non-English-speaking patients if an interpreter was available on the day[62].

Study inclusion and exclusion criteria were assessed to see how diverse the study populations were to determine how feasible digital interventions would be to introduce to practice and how generalizable the results are to the broader surgical community (*Table S3*). Populations that were excluded included patients with poor hearing (defined as documented hearing impairment or unable to hear the digital audio)[31,34,55,57], poor vision (defined as a surgical site that would interfere with vision or visual acuity less than 0.1 Snellen)[31,34,36,45,55], illiteracy[30,49,59], low health literacy[38,42], no access to digital devices (smartphone or DVD player)[40,41], inability to use devices (touchscreen)[55], or no access to the internet[47,64]. Finally, some studies excluded patients based on age. Four studies included only patients younger than 65 years[40,47,64,65], another study specified patients were less than 40 years old[32] and one included only patients older than 55 years[44]. The remainder included patients older than 18 years without any other age limits.

Quality assessment

None of the included studies assessed using the Cochrane risk of bias 2 tool had low overall risk of bias for the outcome patient comprehension. Most studies 23 of 40 (57.5 per cent) were deemed to have a high overall risk of bias, the remaining 17 of 40 (42.5 per cent) had some concerns. The areas that frequently increased the overall risk of bias were outcome measurement with unvalidated questionnaires, randomization, and allocation concealment and lack of prespecified statistical plan or detailed trial protocol. More detail on the overall risk of bias for each domain in individual studies is shown in *Table 2*.

Data analysis

Meta-analysis was considered by the authors of this review. It was felt that it would be inappropriate to combine results and to make interpretations, given the differences between studies (mainly the type of procedure and assessment tools used across studies). Furthermore, combining studies for meta-analysis when there is a high risk of bias reported for most studies, may be misleading and would simply compound the errors[27].

Discussion

Previous systematic reviews have shown that digital technology in addition to SVC may have some benefit for patient comprehension; however, it was not the primary intervention of interest in the reviews by Glaser *et al.* or Kinnersley *et al.*[20,21]. Furthermore, while Gesualdo *et al.* focused their review to digital tools in consent, their primary aim was specific to improving consent in clinical research. This systematic review represents the largest analysis of digitally supported informed consent interventions in surgical practice and builds on the results of those previous reviews[20,21]. Forty studies in the field of surgery were identified that evaluated interventions to improve the process of gaining informed consent, either by attempting to improve patient comprehension, satisfaction, or by reducing anxiety. Overall, this review found that digital interventions could have a positive effect on patient comprehension in informed consent most notably for interventions where there is APP. There was consistent evidence that educational interventions with active patient involvement through self-navigation, knowledge checkpoints, or play/rewind thumbnails improves patient comprehension of their procedure than audio-visual interventions alone or with supplementary written material. Maximum patient engagement and participation through continuous comprehension assessment, would seem to be the most beneficial intervention. Each study with these interactive features significantly improved early comprehension, whereas less APP resulted in more variable results.

There is still a large emphasis on comprehension of risks and general knowledge about a procedure but little emphasis on comprehension of the benefits or alternatives to treatments. Introduction of these communication interventions did not negatively affect patient anxiety or satisfaction with the consent process. A small proportion of studies reported that digital consent interventions reduced the time spent with the physician, but the time spent completing consent was similar in both groups. Overall, the quality of most studies was low, with a high risk of bias in 57.5 per cent. Despite this, the results show that communication and educational interventions could be advantageous for consent in surgical practice and that the current standard consent practices could be improved.

First, these findings suggest that there could be an advantage for patients who actively participate in education modules around consent to improve their understanding about their procedure, which aligns with learning theory[66], but that this may not be retained over time. Studies have shown that active participation increases attention and focus and improves critical and higher levels of thinking skills and memory[66,67]. In the studies that looked at delayed comprehension, there were equal numbers of studies with positive results where patients were

actively and passively engaging with digital interventions. This finding is in keeping with results from a previous review[20].

Second, there was limited assessment of comprehension around the benefits and alternatives of surgery and predominantly assessment of comprehension of risks for the procedure. This could be viewed as a defensive practice by physicians to mitigate against potential future claims. One could argue that managing patient expectations through discussion of potential benefits and alternatives of treatment is as important to mitigate against claims and should be included in all consent discussions. This is reiterated in the ethical guidance for doctors from regulatory bodies[68]. A collaborative shared decision-making process with patients can only be achieved by two-way communication of all the elements of informed consent. Further, adequately addressing all elements of informed consent both respects patient autonomy more fully and more robustly protects clinicians from litigation. It remains clear that practicing informed consent continues to be an exercise that challenges professional competence[69].

Third, this paper reports the numerous barriers to informed consent within surgery that need to be addressed. Patients were excluded from more than half of studies for one or more of the following: visual or hearing impairment, older age, poor health literacy, poor literacy, or limited English proficiency. These groups are at increased risk of poor comprehension[70,71]. Therefore, these results may only be generalizable to English-speaking adults, those younger than 65 years of age, and in higher-income countries. This is evidence that certain healthcare users are disadvantaged and potentially not receiving adequate communication for gaining informed consent.

Last, the main strength of this study is that only surgical procedures were included and the feasibility of implementing digital consent technologies was assessed, as evidence suggests that informed consent is predominantly inadequate in surgery[72,73]. Previous reviews have included informed consent for clinical research[22,74], which has much stronger governance and is generally performed in circumstances where there are fewer time constraints[73,75]. Nishimura *et al.* found that enhanced consent forms and extended discussions were most effective in improving patient understanding for consent in research, which would be difficult to implement in a busy surgical practice[74]. Furthermore, there was some evidence that digital technologies could reduce the time spent with the consenting physician without negatively impacting the consent process[28,34–36]. Further investigation is required but this advantage could potentially address the issue of time constraints, which is reported as a reason for suboptimal consent in surgery[73,76].

Future consent studies need to focus on those vulnerable patient groups that were excluded from studies. Specifically, there needs to be accurate translation of digital interventions, appropriate readability of written documents, and availability of interpreters to ensure that two-way communication is supported[77,78]. Feasibility measures should also be included in any future research, namely the time needed for delivery of a digital intervention, cost of interventions, additional staff or equipment required, or any legal or confidentiality concerns. Digital technologies have been under investigation for the last 15 years but they have not been applied universally in surgery. Future research needs to assess what the main barriers are for adoption. These conclusions relate to consent sought in elective circumstances, therefore further research is required to assess interventions for consent in emergency settings. Last, it is advisable that validated measures of patient comprehension, encompassing the four elements of consent are developed to improve the overall quality of future studies.

This systematic review has some limitations that need mentioning. The quality of the digital informed consent interventions and comprehension questionnaires presented remain unknown as the majority were unvalidated and derived predominantly by the physician team designing the study. This could have potentially introduced personal bias of the information delivered, misestimation of risk or inappropriate measures of patient comprehension. Second, the low quality of the studies introduces some uncertainty about the validity of the reported results; however, the findings are in keeping with previous reviews[20–22]. Third, one of the goals of this review was to assess the feasibility of adopting these interventions into practice. This review is unable to draw any firm conclusions around feasibility due to a lack of reporting of the time taken for interventions and for discussion with physicians. The two feasibility studies that were included[62,63] did not look at feasibility outcomes such as recruitment, retention, acceptability, barriers to completion of assigned intervention, or time taken for assigned intervention[79]. Time constraints are known to affect the quality of discussions with patients and can lead to junior members of the team being sent to obtain consent rather than senior registrars or consultants[73,76]. Information about timing of digital interventions and time spent with the consenting physician will be paramount to promote widespread adoption of these interventions in practice; however, time for delivery may not necessarily equate to feasibility and more studies investigating the barriers to implementation of digital consent are needed to fully answer this question. Furthermore, no studies reported the cost of interventions, additional staff, or equipment required.

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The authors declare no conflict of interest.

Supplementary material

Supplementary material is available at *BJS Open* online.

Data availability

Template of data extraction Microsoft®Excel file available as a supplementary file.

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