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Multimedia patient education to assist the informed consent process for knee arthroscopy

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Key words
arthroscopy, informed consent, multimedia, orthopaedics, patient education as topic.

Abbreviations
3-D, three-dimensional; MM, multimedia.

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Abstract

Background: In contemporary clinical practice, the ability for orthopaedic surgeons to obtain true 'informed consent' is becoming increasingly difficult. This problem has been driven by factors including increased expectations of surgical outcome by patients and increasing complexity of surgical procedures. Surgical pamphlets and computer presentations have been advocated as ways of improving patient education, but evidence of their efficacy is limited. The aim of this study was to compare the efficacy of a computer-based multimedia (MM) presentation against standardized verbal consent and information pamphlets for patients considering knee arthroscopy surgery.

Methods: A randomized, controlled prospective trial was conducted, comparing the efficacy of three methods of providing preoperative informed consent information to patients. Sixty-one patients were randomly allocated into MM, verbal consent or pamphlet groups 3–6 weeks prior to knee arthroscopy surgery. Information recall after the initial consent process was assessed by questionnaire. Retention of this information was again assessed by questionnaire at the time of surgery and 6 weeks after surgery.

Results: The MM group demonstrated a significantly greater proportion of correct responses, 98%, in the questionnaire at the time of consent, in comparison with 88% for verbal and 76% for pamphlet groups, with no difference in anxiety levels. Information was also better retained by the MM group up to 6 weeks after surgery. Patient satisfaction with information delivery was higher in the MM group.

Conclusion: MM is an effective tool for aiding in the provision and retention of information during the informed consent process.

Introduction

The process of ensuring that a patient is adequately informed prior to consenting to a surgical procedure has become an increasingly difficult task for the orthopaedic surgeon. This situation has been driven by several factors including increased expectations of surgical outcome by patients as well as increasing complexity of surgical procedures. This has made the process of educating patients about risks, benefits and alternatives to surgery a more complex process than in the past. Changes to the law have also occurred, with many countries having moved away from the long-standing belief (Bolam principle) that disclosure was at the discretion of the doctor.[1] In Australia, legal cases such as Rogers versus Whittaker (1992) have found that 'a doctor has a duty to warn a patient of a material risk inherent in the proposed treatment', thus raising the standard of information supplied to patients contemplating a surgical procedure.[2]

There has been a trend in the courts towards an ever-increasing demand for greater technical detail to be provided to patients, and in some countries, there is also a legal requirement that patients demonstrate a full comprehension of all relevant data prior to giving consent. The problem has also been exacerbated by an increase in medico-legal activity in many parts of the world in recent decades.[3]

Traditionally, the process of obtaining consent from a patient has involved discussing the risks and benefits of the proposed surgery. Additional techniques to enhance patient comprehension that may be used by a clinician include anatomical models, information pamphlets, videos, and both interactive and non-interactive computer programs. The extent of the patient understanding and recall with these different methods of providing information is variable.[4–6] More

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recently, improvements and broader accessibility of personal computers has facilitated the development of multimedia (MM) patient education software.

Professional surgical bodies around the world, including the Royal Australasian College of Surgeons, have promoted pamphlets as a useful adjunct to the process of informed consent. It has been our experience that many patients find these unhelpful, as often they have been written with excessive medical terminology and not in plain language. In addition, these pamphlets rarely have been validated for their educational efficacy and their ability to facilitate the informed consent process.

We therefore believe that the available methods of providing information to patients required closer evaluation. The aim of this study was to compare the efficacy of standardized verbal consent for knee arthroscopy surgery, with the same information provided via pamphlet or via a computer-based MM presentation.

Methods

A literature review was performed of the published complications relating to knee arthroscopy. Based on this review, consensus between the authors determined the average risk for each complication that was presented in the preoperative information. A focus group of patients who had previously undergone knee arthroscopy surgery was undertaken to determine what information they would like to have been told about knee arthroscopy prior to their surgery. From this, a list was constructed containing all information that would form the core content in the development of the verbal, pamphlet and MM presentations. The study and associated forms were assessed and approved by the hospital ethics committee.

The standardized verbal consent script was created using the core information to ensure that all patients randomized to the verbal consent group received the same quality and amount of information. This verbal consent presentation was undertaken by orthopaedic residents in the pre-admission clinic, according to the guidelines specified in the verbal consent script. Each resident was trained to follow the script, and parity was assured by the checking off of each section as discussed. This method of standardizing the verbal consent process was chosen to ensure no information was overlooked. We believe this would represent the best that could be achieved with such a method, understanding that without some guidance, the information provided by orthopaedic residents would vary greatly in quality and importance. At no stage did any of the study researchers have direct involvement with the information presented to patients during the consent process.

Using the same core information, a pamphlet using plain English at (grade school) year 8 level or less was carefully developed to provide an outline of the procedure and post-operative course, with most of the detail clarifying the possible risks and complications of the procedure. Each pamphlet comprised a single page of information, using 12 point Arial font, but did not include pictures.

An MM education module for knee arthroscopy was created and included a mixture of voice, text, photographs, and three-dimensional (3D) computer animation and then revised after piloting. Using 3D Studio Max 4.0 (Autodesk, San Rafael, CA, USA), a 3D graphics creation software program, specific 3D animations were created covering all aspects of the core information. The text included in the module was identical to the script developed for the verbal consent arm of the trial. The speech (audio) in the module reflected the text being displayed and offered no extra information. The animation and audio tracks were integrated with appropriate text into an interactive linear program that allowed patients to progress and review information provided and prepared in QuickTime (Apple, Cupertino, CA, USA) and Macromedia Flash (Adobe Systems Inc, San Jose, CA, USA) software programs.

Demographic data that were collected included age, gender, highest educational level achieved and computer skills assessed as number of hours used per week. This is presented in Table 1. A plain English-language statement regarding the nature of the study was provided to patients before consenting to their involvement in the trial.

A knowledge questionnaire was developed from the core information with the assistance of professional medical educators and evaluated through a number of revisions. The final selection of 10 questions was achieved with a balance between the overall time required to complete the questionnaire and ease of understanding. Seven of the questions specifically related to possible complications of the proposed surgery.

A four-question survey was also developed to assess patient satisfaction with the amount, method and content of the information provided during the consent process. These questions were constructed using a Likert scale with five possible responses. Mental state was assessed with the Abbreviated Mental State Score, and the State-Trait Anxiety Index questionnaire was administered before and after consent information.

Over an 18-month period, the three methods of providing consent information to patients were compared side by side at the pre-admission clinic of a large metropolitan public hospital.

Patients on a waiting list for knee arthroscopy surgery were completely randomized, by a numbered ball method, to the Verbal Only,

Table 1 Study demographics

	MM group	Verbal group	Pamphlet group
Participants	22	18	21
Gender (M/F)	10/12	12/6	17/4
Age	45+/–17	44+/–11	41+/–14
AMTS	9.0+/–0.8	8.9+/–0.6	9.0+/–0.9
Education level (grade level)	10.4+/–2.7	10.4+/–2.4	10.2+/–2.4
Computer experience (minimum hours use per week)	1.6+/–1.3	1.3+/–1.2	1.6+/–1.6

AMTS, abbreviated mental test score; MM, multimedia.

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MM Only or Pamphlet Only arms of the study. At the pre-admission clinic (Stage 1), 3–6 weeks prior to surgery, the knowledge questionnaires were administered to patients after the provision of consent information. Patients were then retested using the same questionnaire on the day of surgery (Stage 2) and at the 6-week post-operative review (Stage 3). The same questionnaire was used throughout the trial period to maintain relevance to the recall information.

Exclusion criteria included refusal to participate, inability to read the Plain English Language statement form, significant visual or auditory impairments and Abbreviated Mental State Scores of less than 7.

Statistical analysis

Results were analysed with Minitab software (Minitab Inc., State College, PA, USA). Both parametric (*t*-test, ANOVA) and non-parametric (Kruskal–Wallis) tests were used as appropriate. Gender versus recall analysis was performed using chi-square testing.

The required sample size was calculated using the two-sample *t*-test and retrospectively based on a power test of 0.8, an assumed difference between groups of 5 and 10%, and the standard deviation of the MM group recall data. The recommended sample size of 17 per group was surpassed in this study.

Results

During the study period, 100 patients were scheduled for knee arthroscopy at the hospital. Of these, 61 patients were recruited through the hospital pre-admission clinic to participate in the informed consent trial. The main reason for patient exclusion from the trial (39%) was poor English-literacy skills as assessed by the ability to read the standard Plain English Language statement.

Randomization resulted in 22 patients in the MM group, 18 patients in the verbal consent group and 21 patients in the pamphlet group. The average patient age was 44.2 years (range 20–74 years), and there were no significant differences ($P > 0.05$) between the groups in regard to treating surgeon and patient age. Other demographics assessed also showed no significant differences of measured parameters such as education level, mental test scores and previous computer experience. There were no significant differences ($P > 0.05$) in the anxiety scores (State-Trait Anxiety Index) between study groups or between different stages (Table 2).

Recall of information presented to the patients prior to surgery, and assessed by our questionnaire at different peri-operative stages, is illustrated in Figure 1. At all stages, patients in the MM group correctly answered a statistically higher proportion of questions ($P < 0.05$). This was best observed at Stage 1, where the MM group demonstrated a significantly greater proportion of correct responses (98+/–5%) in the questionnaire when compared with the verbal (88+/–14%) and pamphlet (76+/–28%) groups. The average duration from initial consent presentation to date of surgery was 30 (+/–5) days for the MM module group, 23 (+/–7) days for the verbal consent group and 18 (+/–12) days for the pamphlet consent group ($P > 0.05$ for all groups).

Of the 10 questions in the knowledge questionnaire, 7 directly related to possible complications of the procedure. The correct response rate of those specific questions mirrored the overall responses in the questionnaire with statistically significant differences ($P < 0.05$) between the MM group and both verbal and pamphlet groups at all stages.

The MM (6.6+/–1.5) and verbal consent (5.8+/–2.2) groups showed statistically higher satisfaction ($P < 0.05$) than the pamphlet group (3.9+/–1.8).

A potential source of uncontrolled bias was the amount of information provided by the treating surgeon during the initial consultation when the patient was placed on the surgical waiting list. During the trial phase of this study, there were 10 surgeons responsible for knee arthroscopy surgery at our institution. A retrospective review revealed an even spread of patients through all three consent groups with no correlation between surgeon and recall responses.

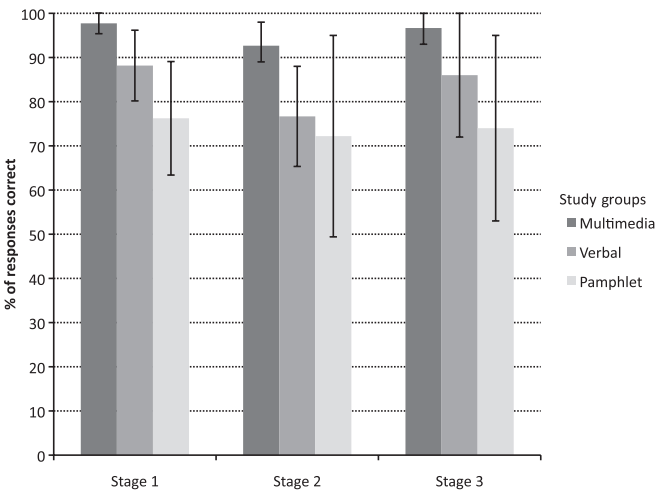

Fig. 1. Recall of information by patients as assessed by questionnaire at three stages. Data presented are mean and standard deviation (Stage 1 – 3–6 weeks prior to surgery, Stage 2 – day of surgery, Stage 3 – 6 weeks after surgery).

Table 2 State-Trait Anxiety Index Scores

	Stage 1 Pre-consent	Stage 1 Post-consent	Stage 2	Stage 3
MM group	31.2(+/–9.5)	28.8(+/–6.63)	31.6(+/–12.4)	33.5(+/–12.5)
Verbal group	31.8(+/–9.1)	33.7(+/–11.5)	32.6(+/–10.6)	30(+/–8.4)
Pamphlet group	35.9(+/–9.5)	31.9(+/–9.6)	37.1(+/–12.9)	34.7(+/–16.7)

$P > 0.05$ between all groups and stages. MM, Multimedia.

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Discussion

This trial showed a clear distinction between different methods of providing information to patients regarding knee arthroscopy surgery and its inherent risks. The MM group showed a statistically higher recall rate for questions related specifically to complications, as well as to non-complication-related questions. Not only was this demonstrated at the initial assessment, but it was also found that the patients viewing the MM program retained more information at the time of surgery and importantly, also at the 6-week post-operative review. We believe this is an important observation, as most complications related to knee arthroscopy surgery are likely to have occurred by this time. While all patients in the study group would have received variable verbal information at the time of their placement on the waiting list, often many months to years earlier, they all received standardized information at the time of attending the pre-admission clinic. This differed only in its delivery format to the patient, that is, verbal, written or MM presentation.

It is not entirely clear why the study showed a preponderance of males in the pamphlet group. The unrestricted nature of the method of randomization, and small overall sample sizes, could have contributed to imbalance in numbers; however, it would not have biased the effect of the method of consent. The difference in gender breakdown is statistically significant only between the MM and pamphlet groups ($P = 0.015$); however, there was no correlation between gender and recall ($P > 0.05$). In fact, the recall of female participants in the pamphlet group was lower, although not statistically significant, than male participants in the same group.

The Duty of Care of health professionals involves the provision of information as well as treatment. The delivery of appropriate informed consent is a requirement of EQuIP 4 from the Australian Council of Healthcare Standards. It states that 'adequate information is provided to consumers/patients regarding their illness and treatment options. This should be in plain language, and available in verbal and written form, where practicable'. The guide also states that consent to treatment should follow the provision of this information and that the information should include an explanation of expected outcomes and possible complications.[7]

A number of studies have evaluated the satisfaction of patients with the consent process as well as the degradation of information retention over time. Larobina *et al*.[8] evaluated patients undergoing coronary artery bypass surgery and percutaneous coronary intervention to assess their understanding of the risks of interventions. Although no patient identified any of the explained risks as a reason to reconsider having their procedure, 80% of patients wanted to be informed of all the risks and considered doctors obligated to discuss all risks of surgery. Knowledge of medical concepts of their disease and possible complications was found to be poor. Hutson and Blaha[9] studied patients' recall of information provided during the informed consent process 6 months after total joint replacement surgery and compared them with the understanding that had been demonstrated preoperatively. There was a large deficit in patient recall of the risks, with only 25% of patients remembering the risk of infection and only 3% remembering that there was a risk of damage to a nerve or artery.

Patients today are exposed to a large amount of health information. There is a critical link between health literacy, patient understanding and patient safety.[10] Doctors have sought other methods to improve the informed consent process, and these include information pamphlets, video, and both interactive and non-interactive computer programs and MM. Studies that have evaluated the efficacy of information delivery to patients using pamphlets have demonstrated variable results.[11,12] The usefulness of information pamphlets can be adversely affected by the use of complex medical terminology. Pamphlets may also be less useful as an educational tool for patients with a low level of education,[13,14] patients with poor language comprehension or elderly patients with poor eye sight.

The use of visual material can be particularly useful.[14,15] Video presentations have been tried as an adjunct to obtaining consent for colonoscopy, and the use has been well tolerated and accepted by patients.[16] They have been shown to improve information recall and can reduce anxiety and stress experienced by patients.[16,17] Improvement of information recall compared with other methods is uncertain. Ader *et al*.[18] compared videodisc information for dental surgery to verbal and pamphlet consent. While markedly better than verbal consent, videodisc did not show substantial improvement over less expensive pamphlet information.

Interactive computer programs have been used as early as the 1980s for patient education regarding the treatment of conditions such as rheumatoid arthritis and osteoarthritis.[19,20] Patient education utilizing MM is now employed for a large range of surgical procedures and medical treatments.[21–24] Surprisingly, there have been only a few studies incorporating MM into the consent process. Shaw *et al*.[25] studied the use of MM as an adjunct to standard consent information for colonoscopy rather than a direct comparison between different information delivery methods, as we have undertaken in this study. The MM group showed an increased comprehension that may have been due to information re-enforcement. To the author's knowledge, however, there has not yet been a randomized trial directly comparing different methods of providing information in a consent process as conducted in this study.

We acknowledge that a potential weakness of our study is that although care was taken with the construction of the knowledge questionnaire, this assessment tool has not been formally validated. To validate such questionnaires requires large numbers of patients, which was beyond the scope of this study.

Conclusion

We agree with Lemaire[26] that the best protection for medical litigation is a strong, healthy doctor–patient relationship. However, as practising surgeons, we also believe there are ways that we can improve the understanding of patients who are considering the risks and benefits of a surgical procedure. The delivery of information using a combination of high-quality computer animation, voice, and text in this study appeared to provide improved patient understanding of the surgery and its complications. This paves the way for further larger trials to evaluate standardized health information delivery using this format. It is not our intention that this technology in any way replaces the requirements for doctor–patient communication, but we have demonstrated that it is a powerful tool for assisting in the informed consent process.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Data S1 – Information sheet for knee arthroscopy.
Data S2 – Knee arthroscopy assessment questionnaire.
Fig. S1 – the use of multimedia to improve patient consent for knee arthroscopy: Study flowchart.

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