

## DEFORMITY

# Adult Spinal Deformity Patients Recall Fewer Than 50% of the Risks Discussed in the Informed Consent Process Preoperatively and the Recall Rate Worsens Significantly in the Postoperative Period

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**Study Design.** Recall of the informed consent process in patients undergoing adult spinal deformity surgery and their family members was investigated prospectively.

**Objective.** To quantify the percentage recall of the most common complications discussed during the informed consent process in adult spinal deformity surgery, assess for differences between patients and family members, and correlate with mental status.

**Summary of Background Data.** Given high rates of complications in adult spinal deformity surgery, it is critical to shared decision making that patients are adequately informed about risks and are able to recall preoperative discussion of possible complications to mitigate medical legal risk.

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**Methods.** Patients undergoing adult spinal deformity surgery underwent an augmented informed consent process involving both verbal and video explanations. Recall of the 11 most common complications was scored. Mental status was assessed with the mini-mental status examination-brief version. Patients subjectively scored the informed consent process and video. After surgery, the recall test and mini-mental status examination-brief version were readministered at 5 additional time points: hospital discharge, 6 to 8 weeks, 3 months, 6 months, and 1 year postoperatively. Family members were assessed at the first 3 time points for comparison.

**Results.** Fifty-six patients enrolled. Despite ranking the consent process as important (median overall score: 10/10; video score: 9/10), median patient recall was only 45% immediately after discussion and video re-enforcement and subsequently declined to 18% at 6 to 8 weeks and 1 year postoperatively. Median family recall trended higher at 55% immediately and 36% at 6 to 8 weeks postoperatively. The perception of the severity of complications significantly differs between patient and surgeon. Mental status scores showed a transient, significant decrease from preoperation to discharge but were significantly higher at 1 year.

**Conclusion.** Despite being well-informed in an optimized informed consent process, patients cannot recall most surgical risks discussed and recall declines over time. Significant progress remains to improve informed consent retention.

**Key words:** adult spinal deformity, informed consent, video consent, recall, complications, shared decision making, mini-mental status examination.

**Level of Evidence:** 3

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Adult spinal deformity (ASD) surgery is technically challenging and poses significant risk to patients. The specific types and rates of complications vary with the type of procedure. However, complication rates reported

in the literature range from 8.4% to 59%.<sup>1-11</sup> Complication rates increase with older patient populations<sup>1,2,6,9,11</sup> and have been reported as high as 95% in patients older than 70 years.<sup>1</sup> Furthermore, higher preoperative American Society of Anesthesiologists grades are associated with an increase in complication rates.<sup>12</sup> The complications may lead to readmission or reoperation,<sup>13-18</sup> which may negatively impact health-related quality of life.<sup>16</sup> Despite the high rates of complications for ASD surgery, overall patients' health-related quality of life outcomes and functionality improve postoperatively.<sup>19</sup>

Given these high complication rates, it is very important that patients have a clear understanding of the likely surgical outcomes and the risk of complications. During the last decade, there has been a shift to a patient-centered model of health care.<sup>20</sup> Patients expect to be educated by their physician to participate in the shared decision-making process. This shift places a higher emphasis on informed consent to provide adequate patient comprehension and recall. Patients with limited comprehension or recall who experience complications from the procedure may be more dissatisfied and more likely to file legal claims.<sup>21-24</sup>

Despite a shift toward patient-centered care, multiple studies have shown that patients do not comprehend or recall the consent information well.<sup>25-35</sup> In a study of patients undergoing rectal surgery, 47% to 57% of patients could *not* recall the risks at the first postoperative visit.<sup>29</sup> One to 3 days after consenting for traumatic orthopedic surgery, patients had only 22% recall.<sup>35</sup> In an attempt to improve these rates, previous studies have attempted to augment the informed consent process with information sheets and videos but with limited success.<sup>27,36-40</sup> In the nondeformity spine literature, 72% of patients receiving spinal injections for lumbar radiculopathy or stenosis thought that they had sufficient information on the procedures, risk, and benefits.<sup>41</sup> Patients were able to recall 3 to 5 risks.<sup>41</sup> Video was suggested to improve consent retention.<sup>41</sup>

Despite high complication rates for ASD surgery, there is a paucity of data on informed consent. The present study sought to examine the ASD consent process in an optimum setting meant to maximize retention. We hypothesized that despite undergoing high-risk surgery, patients would forget key components of the informed consent process and that their recall would decline over time. We aimed to quantitate retention of key portions of the informed consent process as well as patients' and surgeons' perspective on the relative importance of common complications in ASD surgery.

## MATERIALS AND METHODS

Adult patients undergoing spinal deformity surgery and meeting International Spine Study Group (ISSG) criteria were eligible for this prospective study. ISSG inclusion criteria include 18 years of age or older and at least 1 of the following: diagnosis of adult degenerative or idiopathic scoliosis with a curvature of the spine measuring 20° or greater, sagittal vertical axis greater than 5 cm, pelvic tilt greater than 25°, and thoracic kyphosis greater than 60°. ISSG exclusion

criteria include diagnosis of scoliosis other than degenerative or idiopathic (*i.e.*, paralytic/neuromuscular, congenital), age less than 18 years at the time of surgery or initial consultation, and inability to return for specified follow-up. All patient enrollment and surgery completion took place in 2012. At the preoperative visit, participants underwent standard surgeon-guided informed consent discussion. When present at this visit, patient family members witnessed the entire consent process and were invited to participate in the study. A 20-minute video was also provided detailing occurrence rates of 11 possible complications: infection, new/worse pain, need for additional surgery, medical complications, new weakness, positioning-related complications, instrumentation malposition, cerebrospinal fluid (CSF) leak, need for transfusion, blindness, and death. After completion of the video, patients completed a written quiz assessing recall of complications. They were asked to list "11 possible risks of my surgery" and the percentage correct was calculated. Patients then subjectively rated the commonality ("common" *vs.* "rare") and assigned a relative importance to each possible complication: 0 (minor) to 10 (very severe). The informed consent video slides and quiz are shown in Supplemental Digital Content data (available at: <http://links.lww.com/BRS/A984> and <http://links.lww.com/BRS/A985>). Patients received a photocopy of the slides presented in the video. Ten ASD surgeon members of the ISSG were also independently polled and asked to rank the complications on the same severity scale.

After surgery, the recall test was readministered at 5 additional time points: hospital discharge, 6 to 8 weeks, 3 months, 6 months, and 1 year postoperatively. To correlate mental status changes with retention of the informed consent process, a 16-point mini-mental status examination 2—brief version (MMSE2-BV) was administered at each of the time points mentioned previously. Participating family members were tested for recall and MMSE-BV at the first 3 time points: preoperation, discharge, and 6 to 8 weeks postoperation. The MMSE is a systematic and quick tool to assess 5 areas of cognitive function including orientation, registration, attention and calculation, recall, and language. The MMSE2-BV consists of a total of 16 questions with a maximum score of 16 and a mean score of 14.68 for healthy controls.

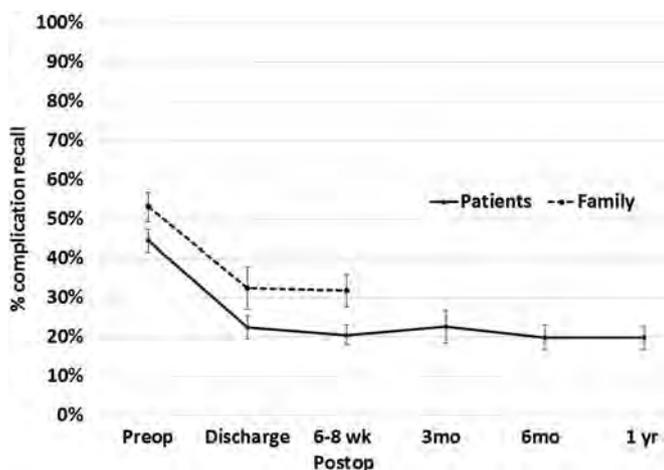
For recall and MMSE, postoperative time points were compared with preoperative within the same cohort (*i.e.*, patient or family) by Wilcoxon signed rank test. Wilcoxon signed rank test was also used to test for significant difference in patient recall of specific complications experienced *versus* not experienced. Patient recall and MMSE data were compared with the corresponding family data by Mann-Whitney *U* test. The association between continuous variables and complication recall was compared by linear regression. Categorical variables were assessed using analysis of variance. The level of significance was set to  $\alpha = 0.05$  for a single comparison with the Bonferroni-Holm correction for multiple comparisons. Statistical tests were calculated in Excel 2013 and SPSS 21.

**RESULTS**

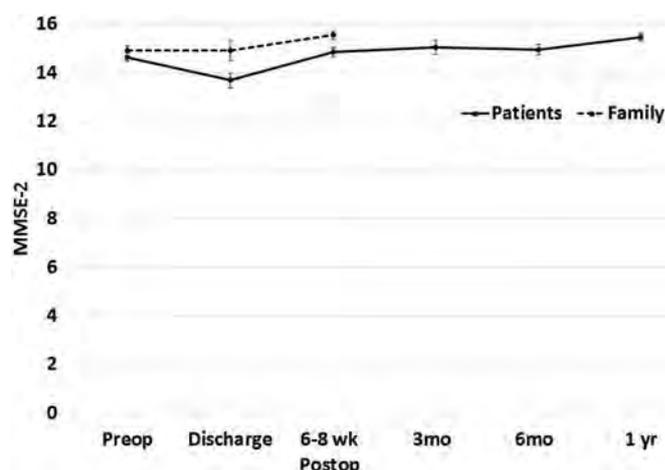
Fifty-six patients enrolled during the study period with a mean age of 61 years (range: 26–83 yr). There were a slight female patient predominance with 33 female (59%) and 23 male (41%) patients. Twenty-five family members enrolled, with a slight male family predominance with 10 female (40%) and 15 male (60%) participating family members. Preoperatively, patients thought that the informed consent process was important (median 10; scale 0–10) and the video was helpful (median 9). Surgeons also thought that the informed consent process was important (median 8,  $P = 0.06$ ).

The patients' perceived complication rate (median: 20%, range: 0%–90%) was similar to the reported complication rate. Patients thought that bleeding requiring transfusion was the most severe complication (median: 6) whereas blindness was the least (median: 3). New weakness (median: 5) was considered more severe than blindness and death (median: 4.5). Severity scores for infection, new/worse pain, positioning-related complications, and instrumentation malposition were similar (all  $P > 0.05$ ). Patient severity scores were lower than surgeon severity scores for need for additional surgery, medical complications, new weakness, blindness, and death (all  $P < 0.05$ ). Patient severity scores were higher than surgeon severity scores for transfusion and CSF leak (all  $P < 0.05$ ).

Immediate preoperative patient recall after video viewing was 45% (median,  $n = 56$ ). Compared with preoperation, median patient recall was significantly decreased at all postoperative time points: discharge (27%,  $n = 36$ ,  $P < 0.001$ ), 6 to 8 weeks (18%,  $n = 54$ ,  $P < 0.001$ ), 3 months (23%,  $n = 22$ ,  $P < 0.001$ ), 6 months (18%,  $n = 36$ ,  $P < 0.001$ ), and 1 year (18%,  $n = 40$ ,  $P < 0.001$ ; Figure 1). Median family recall trended higher than patient recall preoperatively (55%;  $n = 25$  family *vs.* 45% for patients,  $P = 0.09$ ), at discharge (36%;  $n = 12$  family *vs.* 27%,  $P = 0.11$ ), and at 6 to 8 weeks postoperatively (36%;  $n = 20$  family *vs.* 18%,  $P = 0.024$ ). Using the Bonferroni-Holm correction for repeated measures,



**Figure 1.** Recall of possible surgical complications *versus* time. Postoperative recall was significantly decreased from preoperative at all time points. Patient recall was significantly worse than family recall at 6 to 8 weeks postoperatively.

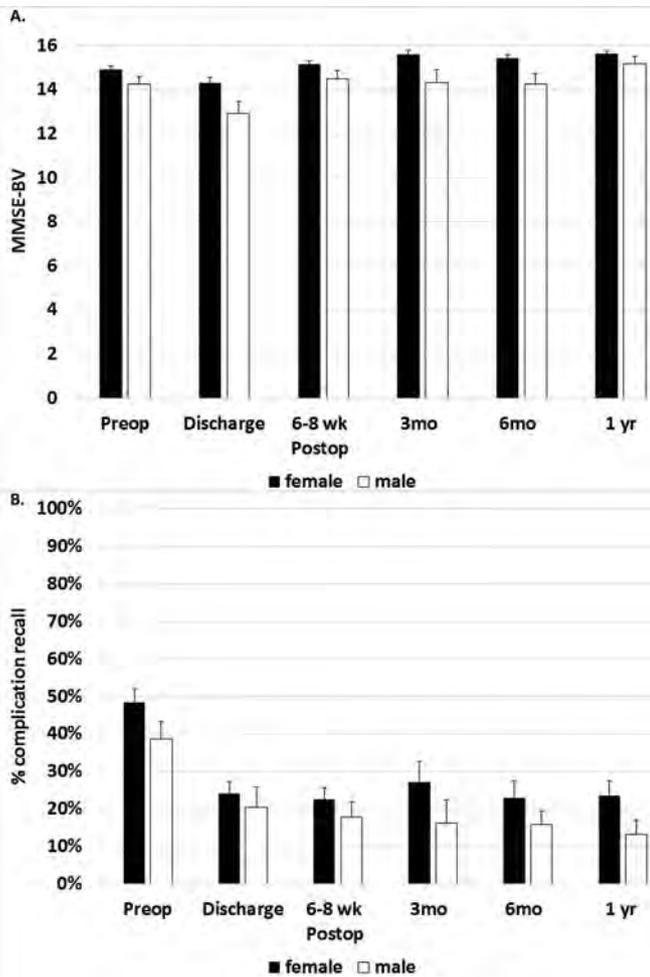


**Figure 2.** Mini-mental status examination 2-brief version (MMSE-BV) scores *versus* time. There was no significant difference between patient and family MMSE. MMSE indicates mini-mental status examination.

the null hypothesis of equal family and patient recall was not rejected.

Median preoperative patient MMSE-BV was 15 (mean: 14.6,  $n = 56$ ). There was a significant decrease in median patient MMSE at discharge (median: 14, mean: 13.7,  $n = 36$ ,  $P = 0.002$ ). At 6 to 8 weeks postoperation, median patient MMSE returned to a value (median: 15, mean: 14.9,  $n = 55$ ,  $P = 0.16$ ) not significantly different from preoperative baseline. Patient MMSE trended higher at 3 months (median: 16, mean: 15.0,  $n = 21$ ,  $P = 0.14$ ) and 6 months (median: 15.5, mean: 14.9,  $n = 36$ ,  $P = 0.032$ ). By 1 year postoperation, median patient MMSE (median: 16, mean: 15.5,  $n = 28$ ) was statistically significantly higher than preoperative baseline ( $P = 0.001$ , Figure 2). Median family MMSE was 15 preoperatively, 15.5 at discharge, and 16 at 6 to 8 weeks postoperatively. The latter 2 family time points were not significantly different from those preoperatively ( $P = 0.566$ ,  $P = 0.053$ , respectively). There was a statistically insignificant (after Bonferroni-Holm correction) trend toward higher family *versus* patient median MMSE preoperatively (15 *vs.* 15, respectively,  $P = 0.39$ ), at discharge (15.5 *vs.* 14,  $P = 0.021$ ), or at 6 to 8 weeks (16 *vs.* 15,  $P = 0.036$ ).

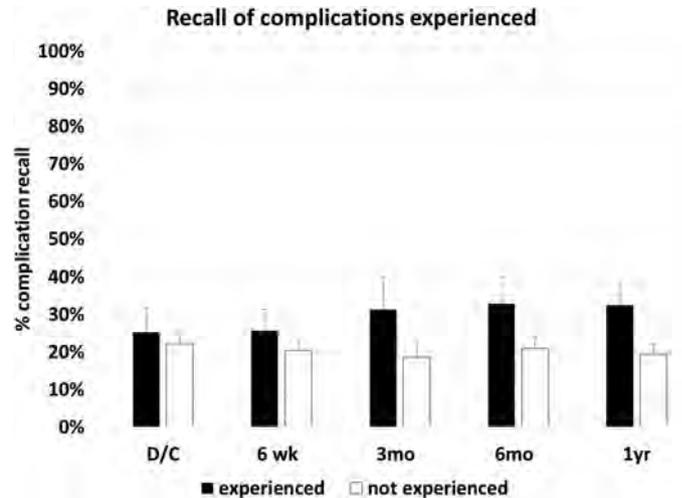
There was no association between subjective severity score and recall preoperatively, at discharge, or at 6 weeks ( $P = 0.56$ , 0.42, 0.51, respectively). Median MMSE scores trended higher in female *versus* male patients: 15 *versus* 14, respectively, preoperatively ( $P = 0.139$ ); 14.5 *versus* 13 at discharge ( $P = 0.053$ ); 15 *versus* 15 at 6 to 8 weeks postoperatively ( $P = 0.234$ ); 16 *versus* 15 at 3 months ( $P = 0.082$ ); 16 *versus* 14 at 6 months ( $P = 0.049$ ); and 16 *versus* 16 at 1 year ( $P = 0.404$ ). After Bonferroni-Holm correction, we retained the null hypothesis of no difference between female and male MMSE at any time points. There was a statistically insignificant trend toward higher median recall in female *versus* male patients (Figure 3): 55% *versus* 36%, respectively, preoperatively ( $P = 0.09$ ), 27% *versus* 18% at discharge ( $P = 0.58$ ), 18% *versus* 18% at 6 to 8 weeks postoperatively



**Figure 3.** Female versus male results. **A**, MMSE-BV scores versus time. **B**, Percent complication recall versus time. There was no significant difference between male and female recall. MMSE-BV indicates minimal status examination 2-brief version.

( $P = 0.23$ ), 27% versus 9% at 3 months ( $P = 0.26$ ), 18% versus 9% at 6 months ( $P = 0.39$ ), and 27% versus 9% at 1 year ( $P = 0.12$ ). Prior spinal surgery was not associated with recall at the 3 time points ( $P > 0.05$ ). There was an association between matched MMSE-2 and recall preoperatively ( $P < 0.001$ ) and at 6 week postoperatively ( $P = 0.02$ ) but not on discharge ( $P = 0.18$ ) or at 6 months ( $P = 0.72$ ). Recall did not seem related to duration of intensive care unit stay or total hospital stay ( $P > 0.05$ ). There was no significant difference between recall of specific complications experienced versus those not experienced. The median recall rate for complication experienced was 22% at discharge and 20% at 6 weeks, 3 months, 6 months, and 1 year ( $P = 0.76, 0.85, 0.18, 0.18, 0.06$ , Figure 4).

Patients rated the importance of the consent process at the highest possible level (10, scale 0–10). They scored the use of the video at the second highest level (9/10). Patient severity scores were lower than those of surgeons for need for additional surgery, medical complications, new weakness, blindness, and death (all  $P < 0.05$ ). Patient severity scores were higher than those of surgeons for transfusion and CSF leak



**Figure 4.** Patient recall of specific complications experienced versus recall of complications not experienced. There was no significant difference at any of the postoperative time points.

(all  $P < 0.05$ ). There was no association at any postoperative time point between recall and the following: subjective severity score, prior spinal surgery, intensive care unit stay, total hospital stay, American Society of Anesthesiologists class, MMSE-2, and postoperative complications ( $P > 0.05$ ).

## DISCUSSION

Informed consent is a highly important part of the shared decision-making process for patients and physicians. The consent process sets the stage for patient expectations and patient satisfaction with surgical treatment. This is especially important in ASD surgery as the complication rates are very high,<sup>3–5,7–10</sup> and patients’ understanding of these potential complications and their likelihood of occurrence is crucial in maintaining the patient portion of the shared decision making. In the present study, best efforts, including video augmentation and a take-home document, were made to improve retention of key risks associated with adult deformity surgery. This is an important issue that had not been previously studied and quantified for adult deformity surgery, which carries some of the highest complication rates within spine surgery. The degree to which potential complications were forgotten even in this optimal setting was remarkable. Only 45% of key risks were recalled immediately after discussion and video supplementation. Recall significantly and progressively worsened over time, reaching a nadir of 18% at 1 year. This is in line with many previous studies that have addressed this topic, with most having the same underlying theme of patients not comprehending and recalling the key aspects of the information provided during the process.<sup>25–35,37,38,40–42</sup> Having undergone a surgery or experiencing a complication from surgery did not improve patient recall. Patients and surgeons should be wary of this poor retention. Patients who were informed of specific surgical risks and who experience those specific complications without recalling the informed consent may feel

dissatisfaction with surgery and their surgeon. Detailed documentation of the consent discussion is clearly necessary.

Median preoperative MMSE-BV score was 15/16 (mean: 14.64, range: 10–16,  $n = 56$ ), very near the published test mean of 14.68 for healthy controls. For patients scoring at the lower end, there could possibly be age-related cognitive decline or other comorbidities, given a mean patient age of 61 years. Medical comorbidities are generally high in this age group and patient population. Diminished memory and cognition could be multifactorial. Interestingly, there was a significant decrease in median patient MMSE to 14 (mean: 13.7,  $n = 36$ ) at discharge and ultimately a significant increase to 16 (mean: 15.5,  $n = 28$ ) at 1 year. This increase could be due to undersampling because 64% and 50% of the original 56 patients underwent MMSE tests at the 2 later time points, respectively. Alternatively, an intriguing possibility is that their mental status initially decreased and then later improved because of initially high (immediately postoperatively) and later decreased narcotic use. Future studies should assess whether poor recall correlates with age, general health status, educational level, narcotic usage, or other comorbidities.

The adult deformity surgical community should evaluate innovative educational methodologies to improve on this disappointing recall rate. Despite the attempt to create a best case scenario for recall in this study, including the use of a PowerPoint-based video and subsequent take-home handout, the retention rate was poor.

When possible, spouses or additional family members should be present during the consent process. Family recall trended higher at all data points, with  $P = 0.024$  at 6 to 8 weeks postoperatively. The higher family recall was not fully explained by cognitive function because the trend for lower patient MMSE was not statistically significant. Although higher than patients, median family recall was still less than desired, ranging from 55% preoperatively to 36% at 6 to 8 weeks. These poor numbers emphasize the opportunity for improvement *via* other creative approaches to the consent process. As another example, the results of a recall examination could be used to optimize the consent process. In the present study, the recall examination was the main assessment and, therefore, was not used to direct teaching methods after the fact in order to not confound the results. However, response score to the initial recall test may be useful as a marker for recall issues in certain areas prompting use of additional educational resources and specific reinforcement. This would be an important area for future study.

Further use of multimedia such as animations of specific complications illustrating their causes and treatment might improve patient recall. Previous studies have demonstrated improvement in the informed consent process by using videos<sup>37–40</sup> to supplement the standard informed consent process. Rossi *et al*<sup>40</sup> found that video significantly improved consent comprehension in patients undergoing knee arthroscopy. Lurie *et al*<sup>38</sup> evaluated a video-aided consent process for lumbar disc herniations and stenosis, finding found no bias toward or away from surgery. Video and booklet supplements improved consent knowledge and satisfaction in

patients undergoing surgery for lumbar disc herniations and stenosis.<sup>37</sup> Fink *et al*<sup>42</sup> found that the strongest predictor of patient comprehension was the total amount of time spent on the consent process. These studies highlight the value and importance of supplementing the informed consent process with a video. Surgical consent videos might be standardized and made readily available online to allow for easy patient access. Another solution might be repeated viewings of a consent video pre and/or postoperatively that includes animations of the specific procedures and complications. Verbal and video consent style should be studied to determine optimum communication strategies.

A novel aspect to the present study was the evaluation of patient and surgeon perspectives on the importance of various ASD surgical complications. There was a discrepancy in the relative value assigned to specific complications by patients and surgeons. Patients ranked CSF leaks and transfusions as more severe complications than did surgeons. Spine surgeons should take note of these discrepancies and spend extra time on such potential complications deemed relatively more important by the patient. Teach-back (*i.e.*, asking a patient to repeat medical information back in his or her own words) is one established standard for improving consent communication. Perhaps teach-back should be made more pervasive and should involve reiteration of all major risks including the later postoperative periods when retention is extremely poor.

## CONCLUSION

Patients feel that the informed consent process and new technologies to augment it are highly important. In spite of this perceived importance, patient recall of key risks remains poor and declines over time, even with video-augmented consent and a written copy of key risks for their records. Significant progress remains to improve informed consent retention. Despite being well-informed in an optimized informed consent process, patients cannot recall most surgical risks discussed. With median informed consent risk retention declining to only 18% at 1 year, this is an important issue requiring future research in how to best educate our patients.

### ➤ Key Points

- ❑ Optimization of the informed consent process to maximize patient comprehension is highly important, especially in the context of high-risk surgery, yet achieving good patient retention remains challenging.
- ❑ In this prospective study of 56 patients undergoing adult spinal deformity surgery, median recall of common surgical complications was only 45% immediately after the informed consent discussion and declined to 18% at 6 to 8 weeks and 1 year postoperation.
- ❑ Family retention of informed consent was higher, with 55% median immediate recall and declining to 36% by 6 to 8 weeks postoperation.

- Patient MMSE scores significantly declined from baseline at the time of hospital discharge but improved to above baseline by 1 year postoperatively.

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