

THE ORTHOPAEDIC FORUM

MOON's Strategy for Obtaining Over Eighty Percent Follow-up at 10 Years Following ACL Reconstruction

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Abstract: The Multicenter Orthopaedic Outcomes Network (MOON) study of anterior cruciate ligament (ACL) reconstruction has achieved >80% follow-up for study subjects who were enrolled from 2002 to 2005; patient-reported outcome measures (PROMs) were reported at 2, 6, and 10 years through a carefully designed protocol that included surgeon involvement to encourage subjects to complete and return questionnaires. The process included emails and telephone calls from the central coordinating center, from research coordinators at each local institution, and lastly, from the subjects' surgeons for those who were less inclined to complete the follow-up. In order to quantify the effect of site and surgeon involvement, the enrollment year of 2005 was monitored for the 10-year follow-up (n = 516 subjects). In contact efforts made by the coordinating center, 73.8% (381) of study subjects were reached by the central site coordinator, contact information was verified, and questionnaires were subsequently sent, completed, and returned. An additional 54 subjects (10.5% of the overall study population) returned the questionnaire after local study site involvement, indicating the importance of individual surgeon and local site involvement to improve follow-up rates in multicenter studies in orthopaedic surgery. Follow-up rates were higher when a specific individual (the surgeon or the research coordinator) was given the task of final follow-up.

Achieving high rates of long-term follow-up in orthopaedic studies has proven to be challenging, with follow-up of approximately 80% required for Level-I evidence¹⁻⁵. Achieving that rate of follow-up is even more difficult with young patients, who generally relocate more frequently than older patients⁶⁻⁸. Age is a proven risk factor for greater loss to follow-up in anterior cruciate ligament (ACL) reconstruction⁶. Our multi-

center study of ACL reconstruction has achieved >80% follow-up with patient-reported outcome measures (PROMs) at 2, 6, and 10 years for study subjects who were enrolled from 2002 to 2005. This was accomplished through a carefully designed protocol that included surgeon involvement as a last resort to encourage subjects to complete and return questionnaires⁹⁻¹⁵. The process included emails and telephone calls from the

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central coordinating center, from research coordinators at each local institution, and from the subjects' surgeons for those who remained unresponsive and did not complete the follow-up. The purpose of this study was to determine the impact of each component of the overall strategy on follow-up rates so that other investigators can benefit from these strategies in order to increase their rates of long-term follow-up in future orthopaedic research.

Materials and Methods

Study subjects at each of the 7 study sites (Cleveland Clinic, Cleveland, OH; Hospital for Special Surgery, New York, NY; The Ohio State University, Columbus, OH; University of Colorado, Boulder, CO; University of Iowa, Iowa City, IA; Washington University, St. Louis, MO; and Vanderbilt University, Nashville, TN) who had ACL reconstruction in 2005 were eligible for the 10-year follow-up in this prospective cohort study. Any subjects who had subsequent total knee arthroplasty (TKA), were deceased, were incarcerated, withdrew from the study, or refused follow-up were excluded from further follow-up. Subjects who underwent TKA were not included because TKA is a reconstructive procedure with different outcome measures, and it is a clinical end point for ACL surgery patients, indicating severe osteoarthritis.

On the 10-year anniversary of the index ACL reconstruction surgery, subjects were contacted by a full-time research staff member from the central coordinating site (Vanderbilt University) via the telephone number and/or the email address that had been supplied at the most recent follow-up time point (i.e., baseline or the 2 or 6-year follow-up). One method of contact (i.e., telephone or email) was attempted each week until the subject had been reached or each method had been tried 4 times. If the subject was reached, his or her mailing address was confirmed or updated, subsequent surgery information was obtained, and the questionnaire was mailed to the confirmed address. A telephone call was made or an email was sent 1 week later to confirm the arrival of the questionnaire. The subject was then contacted once every 3 weeks and was reminded to complete the questionnaire. If the subject requested a replacement questionnaire, it was resent to his or her mailing address.

If a subject was not reached during the 4 attempts of each contact method, a questionnaire was mailed to their last confirmed address. Additional attempts to reach the subject were made once every 3 weeks, cycling through the different contact methods. If the subject was not reached after 4 months, the secondary contact that had been provided by the subject at a previous time point was called or emailed for updated subject contact information. Subjects were paid \$20 after the completion of the survey.

If the central coordinating center was unable to have the subject complete the follow-up forms, a list of subjects who had not been reached (or who had been contacted but had not returned the questionnaire) was sent to the local sites. The local sites then attempted to contact these patients and encourage completion of the questionnaire. The individual who made the contact attempts varied from site to site and was either the local

site research coordinator, the surgeon, or a combination of both. The local research personnel also were asked to check their medical record systems for updated contact information. The actions that were taken by these sites were documented. Each local site developed its own logistical flow for how to handle contacting the subjects. At some sites, the coordinator made a first pass prior to the surgeon, and at other sites, the coordinator was the sole contact person (calling on behalf of Dr. "XXX"). Sometimes, the surgeons took sole responsibility for contacting the subjects on their call list without the aid of the coordinator. Because of this mixed model, we reported it as contact by "surgeon/coordinator." We are not aware of any cases in which both the local coordinator and the surgeon called in parallel.

The local sites received bimonthly lists starting in January of the year after the start of the follow-up year. This means that the site was asked to get involved at different points of the follow-up cycle depending on what month the subject had been enrolled and how long it took to initially send the questionnaire. Subjects who had been enrolled in January and were reached quickly may have been contacted every 3 weeks for several months. Subjects who were enrolled in December may have just had the questionnaire mailed to them before the site was asked to get involved.

The central coordinating site continued to attempt to contact these subjects in parallel with the local sites. An updated list of subjects was sent to the local sites every 2 months for a year after the tenth-year anniversary of the index ACL reconstruction surgery, or until 1 year after the last day within the follow-up year. Hence, subjects who underwent surgery early in the follow-up year could have been contacted for follow-up for nearly 2 years. If subjects were reached but were unwilling or unable to complete the PROMs, they were asked if they had undergone any subsequent surgery on either knee, and this information was recorded (Fig. 1).

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Results

There were 553 patients enrolled in our study who had ACL reconstruction in 2005. Of these, 516 were eligible for the 10-year follow-up study. The 37 subjects who were excluded had undergone subsequent TKA ($n = 11$), were deceased ($n = 4$), were incarcerated ($n = 3$), had withdrawn from the study ($n = 2$), or had refused follow-up at some point over the 10-year period ($n = 17$; Fig. 2).

The mean age of the eligible subjects at the 10-year follow-up was 38.2 years, and 54.5% of the subjects were men. At the conclusion of the follow-up period, 84.3% of the subjects ($n = 435$) had been reached by telephone for

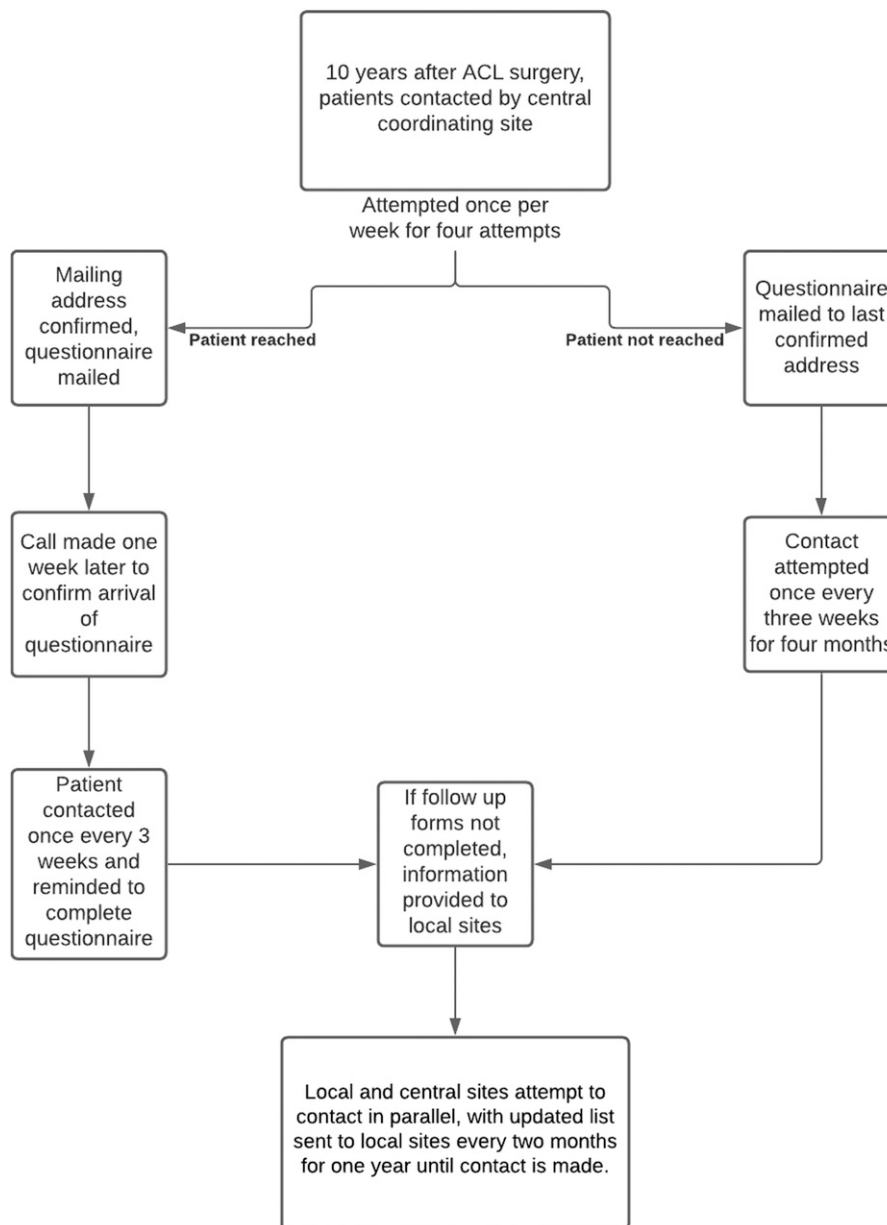


Fig. 1
Methods diagram.

subsequent surgery information and had returned the questionnaire. Another 32 subjects had not returned the questionnaire but were successfully reached for subsequent surgery information. Therefore, in addition to the 84.3% who completed the PROMs and subsequent surgery information, another 6.2% ($n = 32$) completed only the subsequent surgery questions, for a total of 90.5% (467) of all eligible subjects who were successfully reached for subsequent surgery information. The number of subjects and the overall questionnaire return rate by site are shown in Table I. The mean age of the subjects who returned the questionnaire was 38.7 years compared with a mean age of 35.4 years for subjects who did not return the

questionnaire ($p = 0.005$). Although this difference was found to be significant, the clinical relevance is questionable. Of subjects who returned the questionnaire, 47.6% were women. Conversely, 34.6% of the subjects who did not return the questionnaire were women ($p = 0.03$).

In the follow-up efforts that were made by the central coordinating site, 73.8% (381 subjects) were reached by the central site study coordinator, contact information was verified, and questionnaires were returned. The remaining 26.2% (135 subjects) who could not be reached or who were reached but did not return the questionnaire were placed on call lists. Some of the subjects who were reached but did not complete the

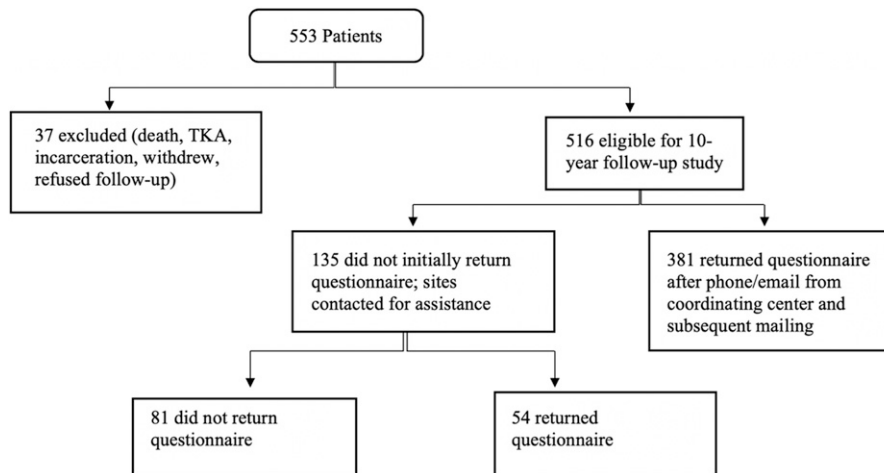


Fig. 2
Study flow diagram.

PROMs were able to provide information on subsequent knee surgery. The call lists were sent to the local sites for assistance in contacting the subjects and encouraging questionnaire completion. While the sites attempted to contact these subjects, the central site study coordinator continued follow-up efforts in parallel. The local sites successfully contacted 89 of the 135 subjects on the call lists by telephone, email, or both. A total of 54 (10.5% of the overall study population) of the subjects who were included on the call lists returned the questionnaire. Another 32 subjects (6.2% of the overall study population) did not return the questionnaire but were successfully reached by either the central site study coordinator or the local sites for subsequent surgery information.

At the local site level, of the 89 subjects with whom telephone contact was successfully made and/or an email was sent, the person who made telephone contact and/or sent the emails was the surgeon for 56 subjects, the coordinator for 8 subjects, and both the surgeon and the coordinator for 25 subjects. Questionnaires were returned by 29 (52%) of the subjects who were successfully contacted by telephone and/or emailed by the surgeon, 6 (75%) of the subjects who were contacted by the coordinator, and 4 (16%) of the subjects who

were contacted by both the surgeon and the coordinator. When a single individual (the surgeon or the coordinator) made telephone contact with and/or emailed the subjects, the follow-up rate was 55% (35 of 64) compared with 16% (4 of 25) when a specific individual was not identified ($p < 0.001$). Of the remaining 46 subjects on the call lists who were not successfully contacted by telephone or sent emails, 15 (33%) returned their questionnaires, even without being contacted.

Discussion

Loss to follow-up is common with cohort studies and often leads to bias¹⁶⁻²¹. To achieve high rates of follow-up in our multicenter study, we integrated local study site efforts only after the central site follow-up coordinator had exhausted his or her attempts to encourage the completion of the follow-up questionnaires. Through a very well-defined and specific protocol, we were able to receive follow-up in the form of completed PROMs from >80% of participants in the first 4 years of study enrollment (2002 to 2005) at 10 years. Overall, we achieved a questionnaire return rate of 84.3%, and the return rates from the individual local sites ranged from 77.3% to 89.4%. We also were able to collect subsequent surgery information on an additional 32 subjects by telephone, for a total of 467 subjects (90.5%) who were reached for subsequent surgery information.

The rate of follow-up at our site ranged from 77% to 89%, which demonstrates that there was not a vast difference among sites. Moving forward, we would emphasize that the more the surgeon touts the study at the time of enrollment (i.e., the importance of the study; wanting to know how the patient is doing, for good or for bad, after surgery; and how completing the follow-up questionnaire will help us to improve patient outcomes), the more successful the follow-up will be. It is essential to get “buy-in” from the patient early on. If the surgeon deems it important, then the patient will likely elevate its importance as well.

TABLE I Follow-up by Study Site

Site	Patients (no.)	Questionnaires Returned (%)
1	102	84.3
2	104	89.4
3	121	85.1
4	54	77.8
5	67	83.6
6	44	77.3
7	24	87.5

This longitudinal study opted for a priority of central follow-up over local site follow-up in order to maintain better study consistency. The majority of our local sites had research assistants and coordinators who changed annually over the course of the 2, 6, and 10-year follow-up periods. Conversely, the central site used only 2 individuals over the course of >15 years for subject follow-up. The subjects were alerted at the time of their enrolling that a central site (Vanderbilt University) would be contacting them at their 2, 6, and 10-year follow-up time points. Besides being familiar with the enrolling surgeon, these subjects were much more familiar with the follow-up coordinator at Vanderbilt than they would have been with a different local coordinator for each of their follow-up time points. With regard to study protocol on telephone call limits, there were no restrictions placed on the number of calls. At the start of the prospective cohort study in 2002, the institutional review board at each study site did not ask us to place a 3-call limit on follow-up.

The subjects who returned the questionnaire were slightly older than their counterparts who did not return the questionnaire, and there was a larger proportion of women in the group of subjects who returned the questionnaire. This latter finding is consistent with the work of Ramkumar et al., who reported that subjects who were men and non-White were at increased risk for loss to follow-up with PROMs at 2 years⁶.

It is also important to note that at the 2, 6, and 10-year follow-up time points of our cohort of $\geq 2,000$ subjects who underwent ACL reconstruction, to the best of our knowledge, there were not any complaints by the study subjects to any of the participating institutions regarding being contacted for follow-up. Therefore, institutional review boards can consider that this strategy for contacting subjects for follow-up after surgery for research purposes is not overly bothersome or intrusive to subjects.

A possible limitation to the study was that most telephone calls were made during business hours, and subjects may have been less likely to answer if they were occupied with work. Subjects may have been more likely to answer during free time on the weekends, when calls were made less frequently. The study also did not include documentation of why subjects did not complete their PROMs, which might have provided additional insights. Whether there was a notable difference in subject response rate depending on whether it was the research coordinator or the surgeon who reached out to the subject was not recorded for each site. It is also possible that subjects who were unhappy with their surgical outcomes may have been less likely to complete the PROMs, which may have influenced the study results on some level.

Additional changes to this study may also be made for the year 2021, given new opportunities to utilize alternative technological platforms. Electronic PROMs in REDCap (Research Electronic Data Capture) software would likely be easier for subjects to fill out rather than the paper forms that must be

mailed back. Using more convenient platforms may reduce the risk of the finding that young men have the highest risk rate of noncompliance. A secure application (app) for iPhone (Apple) or Android devices can be created that would automatically send notifications in the app to remind participants that it is time to follow up and complete the PROMs; additionally, the app could send reminders until the PROMs were completed. Younger people may be more likely to complete the PROMs in this format, and smartphone notifications would serve as a consistent reminder. Finally, text message reminders also can be utilized, and the addition of a link to the PROMs in a text message might encourage participants to complete the PROMs.

As detailed above, the efforts of the central site follow-up coordinator included multiple telephone calls and emails on a fixed schedule, verification of contact information, and regular reminders to complete the questionnaires. The questionnaires were returned by an additional 10.5% of subjects after the involvement of the local study sites, which included telephone calls and/or emails from surgeons and/or the research coordinators at these sites. This additional follow-up by the local sites, which was critical to achieving a total follow-up of >80%, was more successful when a single individual at the site was charged with the task of follow-up, which, in the majority of cases, was the surgeon who had cared for the subject.

In conclusion, in addition to our protocol as outlined above, we recommend assigning the final attempt at the time of follow-up to either the surgeon or a closely affiliated designee. We believe that contact by and engagement with the surgeon had a positive influence on the subjects and an important impact on our follow-up rate at 10 years following ACL reconstruction. ■

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