Clinical Outcomes of SMILE and FS-LASIK Used to Treat Myopia: A Meta-analysis

Yingjie Zhang, MD; Qin Shen, MD; Yan Jia, MD; Dan Zhou, MD; Jibo Zhou, MD, PhD

ABSTRACT

PURPOSE: To assess possible differences in clinical outcomes when small-incision lenticule extraction (SMILE) and femtosecond laser-assisted LASIK (FS-LASIK) are used to correct myopia.

METHODS: A systematic review and meta-analysis. A systematic literature search was performed using Cochrane Collaboration methodology to identify randomized controlled trials and appropriate comparative studies comparing SMILE and FS-LASIK for myopia.

RESULTS: The authors identified 11 studies from a review of 102 articles, involving a total of 1,101 eyes, of which 532 eyes (48.32%) underwent SMILE and 569 eyes (51.68%) underwent FS-LASIK. No significant difference between the two procedures was evident in terms of final refractive spherical equivalent (P = .72), the proportion of eyes losing one or more lines of corrected distance visual acuity after surgery (P = .69), or the proportion of eyes achieving an uncorrected distance visual acuity of 20/20 or better (P = .35) and a refractive spherical equivalent within ±1.00 diopter of the target values (P = .70). The tear break-up time was longer in the SMILE group than the FS-LASIK group at 1 (P = .004) and 6 (P = .02) months after surgery. Corneal sensitivity was higher in the SMILE group than in the FS-LASIK group at 1 week (P < .00001) and 1 (P < .0001), 3 (P < .00001), and 6 (P < .003) months after surgery.

CONCLUSIONS: SMILE and FS-LASIK were comparable in terms of both safety and efficacy. SMILE may create fewer dry eye symptoms than FS-LASIK. Corneal sensitivity was greater after SMILE than FS-LASIK.

MATERIALS AND METHODS

Following generally accepted recommendations,17 we conducted a meta-analysis using the criteria outlined below.

SEARCH STRATEGY

Two reviewers independently searched the following electronic databases up to March 23, 2015: Cochrane Controlled Trials Register, PubMed, Medline, and EMBASE. To gather as much data as possible, and to identify all trials comparing SMILE and FS-LASIK, the following key words were used: “myopia,” “small-incision lenticule extraction” or “SMILE” or “ReLEx smile,” and “LASIK” or “femtosecond” or “laser in situ keratomileusis” or “keratomileusis.” We did not impose any date or language restriction.

We also searched the reference lists of retrieved articles to identify studies not found by the computerized search; we employed the “related articles” feature of PubMed to this end. We did not physically search either journals or conference proceedings. Any disagreement between the two reviewers was resolved by discussion; eventually, both reviewers agreed completely on final data interpretation.

INCLUSION CRITERIA

The selection criteria were: (1) controlled clinical studies, including prospective randomized controlled trials (RCTs) and nonrandomized comparative studies, (2) patient populations 18 to 60 years old with myopia of any degree of severity or myopia with astigmatism, no history of ocular surgery, and no systemic disease that might impair wound healing or render such healing abnormal, (3) all eyes treated via either SMILE or FS-LASIK, (4) at least one primary or secondary outcome reported, and (5) a follow-up period of least 3 months.

OUTCOME MEASURES

Primary Outcomes. The primary outcome parameters were safety, efficacy, and predictability. Safety measures included the final refractive spherical equivalent (SE) and the proportion of eyes losing one or more lines of corrected distance visual acuity after surgery. Efficacy measure was the proportion of eyes achieving an uncorrected distance visual acuity of 20/20 or better, and predictability measure was a refractive SE within ±1.00 diopter (D) of the target value.

Secondary Outcomes. The secondary outcomes were postoperative dry eye symptoms (including the Schirmer score, tear break-up time [TBUT], and tear film osmolarity [TFO]), postoperative corneal sensitivity, and postoperative subjective assessments. Because the follow-up times ranged from 1 week to 6 months and the number of relevant articles was small, data reported at the end of each follow-up were pooled.

DATA EXTRACTION

Data were independently extracted by two reviewers using preformatted sheets. The results were compared and any discrepancies resolved by discussion. A customized data extraction form, described in the Cochrane Handbook for Systematic Reviews of Interventions, was used to record the authors of each study, the year of the trial, the study design, the number of patients, patient age and gender, and study duration.

QUALITY ASSESSMENT

We used the Jadad scale18 to assess the quality of RCTs and the Newcastle–Ottawa Scale19 for quality nonrandomized comparative trials. The Jadad scale features three principal assessment domains: randomization, blinding, and participant withdrawal/dropout. Appropriate randomization and blinding scored 1 point each. The total score ranged from 0 to 5. Studies scoring less than 3 points were considered to be of low quality. The maximum Newcastle–Ottawa Scale score is 9, based on assessment of three areas: selection quality (maximum 4 points), comparability (maximum 2 points), and outcome measures (maximum 3 points). Studies scoring less than 6 points were considered to be of low quality.

STATISTICAL ANALYSIS

Quantitative primary and secondary outcome data were entered and analyzed separately using Cochrane RevMan Manager (RevMan) version 5.3 (http://tech.cochrane.org/revman/download). For continuous outcome data, means and standard deviations were used to calculate weighted mean differences (WMDs) with 95% confidence intervals (CIs). For dichotomous outcomes, risk ratios with 95% CIs were calculated. Statistical heterogeneity among studies was tested using chi-squared and I² statistics. Fixed-effects modeling employed the Mantel–Haenszel method unless significant evidence of statistical heterogeneity or clinical diversity was apparent. However, if heterogeneity was significant (P < .10 or I² > 50%), a random effects meta-analysis was performed using the DerSimonian–Laird method. All outcome measures were assessed on an intention-to-treat basis; the population included all dropouts.

Publication bias was assessed using the Egger linear regression test20 and the Begg rank correction test.21 Sensitivity analysis was performed by excluding studies that did not clearly meet the inclusion criteria (the
quality assessment scores were thus low). Because subgroup analysis is not appropriate if sample sizes are small, sensitivity analyses were performed to determine if conclusions were robust. A P value less than .05 was considered statistically significant.

In addition, if individual trial outcomes were not susceptible to meta-analysis because of data paucity, descriptive analysis was displayed.

RESULTS

SEARCH RESULTS
The selection process is summarized in Figure 1. The computer search identified 102 articles, including 29 studies potentially useful when seeking to compare SMILE with FS-LASIK. A total of 17 studies were excluded after systematic review of full texts: nine did not describe any usable outcome, five simple letters or comments, two animal experiments, and one was a protocol. Finally, 12 studies published from 2013 to 2014 were selected. Of these, two contained the same subjects but described different outcomes; we combined the data of these studies. Of the 11 studies included, two were RCTs, six prospective nonrandomized comparative works, and three retrospective studies.

STUDY CHARACTERISTICS AND QUALITY
Eleven studies involving a total of 1,101 eyes, of which 532 eyes (48.32%) underwent SMILE and 569 eyes (51.68%) underwent FS-LASIK, were included. The characteristics and quality assessments of these studies are shown in Table 1 and Tables A-B (available in the online version of this article). Follow-up ranged from 3 to 6 months. Masking of surgeons is impossible in RCTs, and no study reported that patients were masked. Both RCT studies scored less than 3. Of the prospective nonrandomized comparative studies and the retrospective studies, three matched the preoperative SEs of eyes in the SMILE and FS-LASIK groups, three studies did not match preoperative SEs, and the other three studies did not mention the preoperative SE. None of the factors of age, gender, preoperative TBUT, or corneal sensitivity differed significantly between groups in studies that measured these parameters. As shown in Table 1 and Tables A-B, six of the 11 studies were of high quality (Newcastle–Ottawa Scale scores ≥ 6).

PRIMARY OUTCOMES

Postoperative Mean Refractive SE. Of the 11 studies, six reported postoperative mean refractive SEs. The follow-up times varied from 1 day to 6 months. One study found that the postoperative mean SE was significantly higher in the SMILE group 1 day after surgery. One study found no significant difference in postoperative mean refractive SE between the groups at 6 months after surgery. One study did not feature statistical analysis.

Three studies found no significant difference in postoperative mean refractive SE between the groups at either 1 or 3 months after surgery. No difference was evident (WMD: 0.02; 95% CI: -0.07 to 0.10; P = .72) (Figure 2) between groups. Because publication bias was evident (Egger’s test, P < .05), a sensitivity analysis was performed to explore the effects of excluding studies with different follow-up times. The statistical data did not change (I² = 0; WMD: 0.00; 95% CI: -0.05 to 0.06; P = .92).

Proportion of Eyes Losing One or More Lines of Corrected Distance Visual Acuity. Three of the 11 studies reported the numbers of patients experiencing loss of one or more lines of corrected distance visual acuity (compared to preoperative levels) at a follow-up of 3 months. Forest plots indicated no significant difference between the groups. The proportion of eyes losing one or more lines of corrected distance visual acuity did not differ between the groups (risk ratio: 1.45; 95% CI: 0.23 to 9.24; P = .69) (Figure 3).

Proportion of Eyes With Uncorrected Distance Visual Acuity of 20/20 or Better. Two studies reported the proportions of eyes achieving uncorrected distance

![Figure 1. Results of the literature search.](image-url)
visual acuities of 20/20 or better at the end of the follow-up (3 months). The proportions of eyes attaining such uncorrected distance visual acuities did not differ between the two groups (risk ratio: 1.05; 95% CI: 0.95 to 1.16; \( P = .35 \)) (Figure 4).

**Proportion of Eyes With Postoperative Refractions Within \( \pm 1.00 \) D of the Targets.** Two studies\(^\text{12-14} \) reported refractive parameters at follow-up times of 3 months. The proportion of eyes attaining postoperative refractions within \( \pm 1.00 \) D did not differ between the two groups (risk ratio: 1.01; 95% CI: 0.97 to 1.04; \( P = .70 \)) (Figure 5).

**Secondary Outcomes**

**Schirmer Scores.** Four studies\(^\text{7-9,13} \) reported postoperative Schirmer test data at follow-up times of 1 week to 6 months; we analyzed the results obtained at different time points. Two studies\(^\text{8,9,13} \) contained Schirmer test data derived 1 week after surgery. Demirok et al.\(^\text{13} \) conducted Schirmer testing under anesthesia. Li et al.\(^\text{9} \) tested without anesthesia. Neither study found any significant difference between the groups 1 week after surgery. Four studies\(^\text{7-9,13} \) reported the results of Schirmer testing 1 month after surgery. No significant difference was evident between the groups (Figure 6A). Because publication bias was apparent (Egger's test, \( P < .05 \)), a sensitivity analysis was performed by omitting the study of Denoyer et al.;\(^\text{7} \) similar results were obtained (I\(^2 = 0 \); WMD: -0.46; 95% CI: -1.99 to 1.07; \( P = .55 \)). Schirmer test data obtained 3 and 6 months after surgery did not differ between the two groups (\( P > .05 \)) (Figures 6B-6C). Overall, we found no evidence of publication bias (Egger’s test, \( P = .19 \); Begg’s test, \( P = 1.0 \); Egger’s test, \( P = .42 \); Begg’s test, \( P = .308 \); analysis of 3- and 6-month data). Ganesh and

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### Characteristics of the 11 Included Studies

|------------------------|---------|--------------|---------|------------------------|--------------|---------|------------------------|--------------|---------|------------------------|--------------|---------|------------------------|--------------|---------|------------------------|--------------|---------|------------------------|--------------|---------|------------------------|--------------|---------|------------------------|--------------|---------|------------------------|--------------|---------|------------------------|--------------|---------|------------------------|--------------|
| Ganesh & Gupta\(^\text{10} \)(2014) | India   | RCT          | China   | Lin et al.\(^\text{12} \)(2014) | Prospective CT | China   | Li et al.\(^\text{9} \)(2014) | Prospective CT | China   | Xu & Yang\(^\text{8} \)(2014) | Prospective CT | China   | Wei & Wang\(^\text{14} \)(2013) | Prospective CT | China   | Shen et al.\(^\text{40} \)(2010) | Retrospective | China   | Li et al.\(^\text{11} \)(2013) | Taiwan       | China   | Denoyer et al.\(^\text{7} \)(2015) | Prospective CT | China   | Hu et al.\(^\text{24} \)(2013) | Taiwan       | China   | Li et al.\(^\text{15} \)(2014) | Retrospective | China   | SMILE = small-incision lenticule extraction; FS-LASIK = femtosecond laser-assisted LASIK; Pre SE = preoperative spherical equivalent; RCT = randomized controlled trials; CT = comparative trials; NR = not reported

**TABLE 1**

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Design</th>
<th>No. of Eyes</th>
<th>Pre SE (Degree)</th>
<th>Follow-up (m)</th>
<th>Quality Assessment</th>
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<tr>
<td>Ganesh &amp; Gupta(^\text{10} )(2014)</td>
<td>India</td>
<td>RCT</td>
<td>50</td>
<td>-4.99 ± 2.09</td>
<td>3</td>
<td>Jadad scale: 3</td>
</tr>
<tr>
<td>Demirok et al.(^\text{13} )(2013)</td>
<td>Turkey</td>
<td>RCT</td>
<td>28</td>
<td>-3.90 ± 1.50</td>
<td>6</td>
<td>Jadad scale: 2</td>
</tr>
</tbody>
</table>
| Lin et al.\(^\text{12} \)(2014)     | China   | Prospective CT | 60          | -5.13 ± 1.75    | 3             | Newcastle–Ottawa Scale: 7
| Xu & Yang\(^\text{8} \)(2014)       | China   | Prospective CT | 38          | -6.69 ± 1.34    | 3             | Newcastle–Ottawa Scale: 5
| Li et al.\(^\text{9} \)(2014)         | China   | Prospective CT | 32          | -4.56 ± 2.3     | 3             | Newcastle–Ottawa Scale: 6
| Shen et al.\(^\text{40} \)(2010)     | China   | Retrospective | 17           | -4.40 ± 1.22    | 3             | Newcastle–Ottawa Scale: 6
| Li et al.\(^\text{11} \)(2013)        | China   | Prospective CT | 60          | -4.63 ± 1.38    | 3             | Newcastle–Ottawa Scale: 5
| Denoyer et al.\(^\text{7} \)(2015)   | France  | Prospective CT | 60          | -4.63 ± 1.38    | 3             | Newcastle–Ottawa Scale: 5
| Hu et al.\(^\text{24} \)(2013)        | China   | Retrospective | 83           | -4.81 ± 1.29    | 3             | Newcastle–Ottawa Scale: 6
| Li et al.\(^\text{15} \)(2014)        | China   | Retrospective | 22           | -4.81 ± 0.90    | 3             | Newcastle–Ottawa Scale: 6

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Gupta found that 3-month Schirmer I and II test data were significantly lower in the LASIK group than the SMILE group (P < .0001).

**TBUT.** Four studies presented TBUT data at 1 week and 1, 3, and 6 months after surgery; the tests were performed at different time points. Two studies reported TBUT data 1 week after surgery; the two groups did not significantly differ (WMD: 0.38; 95% CI: 0.02 to 0.72; P = .61) (Figure 7A). Four studies reported TBUT data 1 month after surgery. Forest plots showed that the TBUT was longer in the SMILE group than in the FS-LASIK group (WMD: -0.27; 95% CI: 0.21 to 1.11; P = .004) (Figure 7B). No publication bias was evident upon either Egger’s or Begg’s testing (P = .159 and .296, respectively). Three studies reported TBUTs 3 months after surgery; no significant difference was evident between the groups at any time point. Denoyer et al. reported TBUTs at 1 and 3 months after surgery; the TBUTs were higher in the FS-LASIK group than in the SMILE group at both time points (Figure 7D).

**TFO.** Two studies reported TFOs after surgery. Demirok et al. reported TFOs 1 week and 1, 3, and 6 months after surgery. No significant difference was evident between the groups at any time point. Denoyer et al. reported TFOs at 1 and 3 months after surgery; the TFOs were higher in the FS-LASIK group than in the SMILE group at both time points (Figure 7D).

**Corneal Sensitivity.**

Four studies measured central corneal sensitivities at 1 week to 6 months after surgery. We analyzed the results obtained at different time points. At 1 week after surgery, the corneal sensitivity of the FS-LASIK group was significantly lower than that of the SMILE group (WMD: 9.19; 95% CI: 6.17 to 12.20; P < .00001) (Figure 8A).
At 1 month after surgery, analysis of four studies showed that the corneal sensitivity of the FS-LASIK group was significantly less than that of the SMILE group (WMD: 9.69; 95% CI: 4.88 to 14.50; $P < .0001$).
Individually, each of the four studies revealed significant differences between the groups. At 3 months after surgery, the corneal sensitivity of the FS-LASIK group was significantly lower than that of the SMILE group (WMD: 13.10; 95% CI: 7.74 to 18.73; \( P < .00001 \)) (Figure 8C).

At 6 months after surgery, one study\textsuperscript{13} found no significant difference between the groups. Two studies\textsuperscript{9,11} found significant differences between the SMILE and FS-LASIK groups. Forest plots showed that the corneal sensitivity was lower in the FS-LASIK group than in the SMILE group (WMD: 13.9; 95% CI: 7.47 to 18.73; \( P < .00001 \)) (Figure 8D).

Neither Egger’s nor Begg’s test yielded evidence of publication bias at any follow-up time (both \( P \) values > .05).

Demirok et al.\textsuperscript{13} measured superior and inferior corneal sensitivities at 1 week and at 1, 3, and 6 months after surgery. Sensitivities were lower in the FS-LASIK group than in the SMILE group at 1 week and 1 and 3 months after surgery. However, no significant difference in the sensitivity of either location was evident between the groups 6 months after surgery.

Wei and Wang\textsuperscript{16} not only reported overall central corneal sensitivity data but also the sensitivities of the superior, inferior, nasal, and temporal regions. Significant differences were evident between the groups at 1 week and 1 and 3 months after surgery at all locations. The corneal sensitivity of the FS-LASIK group was significantly lower than that of the SMILE group.

**POSTOPERATIVE SUBJECTIVE ASSESSMENT**

Three studies\textsuperscript{7,8,10} reported the postoperative subjective assessment. Xu and Yang\textsuperscript{8} used McMonnies questionnaire to assess subjective symptoms of dry eye syndrome. In the SMILE and FS-LASIK groups, the scores from McMonnies questionnaire recovered to the preoperative values at 3 and 6 months, respectively. In the results by Ganesh and Gupta,\textsuperscript{10} the mean complaint score on the subjective questionnaire for pain, redness, watering, and pricking sensation was higher in the FS-LASIK group than in the SMILE group. Meanwhile, Denoyer et al.\textsuperscript{7} showed that patient-reported vision-related quality of life was significantly impaired in the FS-LASIK group compared with the SMILE group.

**DISCUSSION**

Many clinical studies reported on postoperative outcomes after SMILE and FS-LASIK were used to
correct myopia, but no systematic comparison of such outcomes has appeared. Thus, we performed a meta-analysis to compare the safety, efficacy, dry eye symptoms, and corneal sensitivities after surgery, to guide the selection of a treatment mode appropriate for correcting myopia.

The pooled results revealed that the SMILE and FS-LASIK groups did not differ significantly in terms of safety or efficacy. Schirmer test data obtained at any time after surgery did not differ significantly between the two procedures. However, the TBUT was longer in the SMILE group than in the FS-LASIK group at 1 and 6 months after surgery. Also, the corneal sensitivity was lower in the FS-LASIK group than in the SMILE group at any time after surgery.

Our results should be interpreted cautiously, because the reviewed studies differ in detail and the number of retrieved studies are few. Following an accepted principle of meta-analysis, we included all data complying with our inclusion criteria to evaluate clinical outcomes objectively. Begg’s rank correction test and Egger’s linear regression test were used in efforts to detect publication bias. Also, we conducted sensitivity analysis when heterogeneity was evident among studies. One difficulty encountered when seeking to combine the results of RCTs and comparative studies is the considerable variation in follow-up times. Of the 11 included studies, only one study directly compared the different procedures for each eye in the same patient. The results from that study were close to this meta-analysis. The longest follow-up time of all 11 studies was 6 months, thus limiting our ability to comment on the long-term stability of refraction. Also, restoration of a normal tear film and recovery of corneal innervation after refractive surgery may take longer than 12 months, so the studies evaluated may not accurately reveal final outcomes. The follow-up times were not identical, and data collected at different follow-up times were pooled to allow comparisons to be made.

Changes in technology and technique may affect surgical results, as opposed to those of drug treatments. In other words, evolution of surgical technique is a problem when a systematic review is contemplated. SMILE was performed as described by Sekundo et al. in 2011 using the same machine in all 11 studies included in the analysis. However, the femtosecond-laser techniques used were not identical. Therefore, the effects of new technology and techniques on the reported outcomes are unclear. Also, clinical outcomes may be affected by the laser systems used, the surgical nomograms employed, and differences in intraoperative and postoperative procedures. To ensure the reliability and feasibility of our work, we applied strict study inclusion criteria to allow us to compare the outcomes of the two techniques performed by the same surgeon using the same nomogram and prescribing the same postoperative treatment.

The significant safety parameters of refractive surgery are the postoperative mean refractive SE and the proportion of eyes losing one or more lines of corrected distance visual acuity. We ran sensitivity analyses after excluding studies with different follow-up times when publication bias (Egger’s test, \( P < .05 \)) was evident. No difference in safety between the groups was noted. The results thus suggest that both SMILE and FS-LASIK are safe when used to correct refraction.

In terms of efficacy, we sought to assess the proportions with uncorrected distance visual acuities of 20/20 or better. The proportions of eyes with postoperative refractions within \( \pm 1.00 \) D of the targets were termed as predictability. Because only two studies reported these parameters, it was not possible to perform sensitivity or subgroup analysis. No significant difference was evident between the groups; both methods were equally effective and predictable.

Dry eye causes ocular discomfort associated with visual disturbance, which not only compromises visual outcomes but also reduces the quality of daily life. Thus, we separately analyzed Schirmer test data, TBUT, and TFO as measures of dry eye disease developing after refractive surgery. Because the follow-up time varied from 1 week to 6 months, we analyzed results obtained at different time points. Schirmer test data at 1, 3, and 6 months did not differ between the groups. No significant difference in TBUT was evident between the groups 1 week or 3 months after surgery. However, the TBUT was longer in the SMILE group than in the FS-LASIK group at 1 and 6 months after surgery, suggesting that tear film stability is better after SMILE than FS-LASIK. However, in both groups, the TBUTs after surgery were usually less than 10 mm, which is lower than the limit of normal, indicating that the TBUT fell after surgery in both groups but was greater in the FS-LASIK group than in the SMILE group.

The refractive surgery-induced TBUT decrease persisted for 6 months after surgery. Two studies reported TFOs after surgery. We did not subject these data to meta-analysis because the number of studies was so small, the follow-up times different, and the outcomes diverse.

Significant differences in central corneal sensitivity between the groups were evident at 1 week and at 1, 3, and 6 months after surgery, suggesting that corneal sensitivity was greater in the SMILE group, even 6 months after surgery. Corneal sensitivity is mediated by corneal...
nerve fibers, and a reduction in such sensitivity after resection surgery is inevitable because of amputation of nerve fibers during creation of a flap and subsequent laser ablation. In FS-LASIK procedures, both flap cutting and laser ablation contribute to corneal denervation. In SMILE, which is an “all-in-one” procedure, both the cap and the refractive lenticule are created by a femtosecond laser; no flap is needed. Corneal sensitivity was thus higher in the SMILE than the FS-LASIK group.

As a new surgical technique, SMILE has become an option when refractive surgery is planned only in some areas. The literature of the outcomes after this surgery are limited, and the follow-up time was not long enough, which may result in some biases, as we discussed above.

We found that SMILE and FS-LASIK were comparably safe and efficacious. However, SMILE may be associated with fewer dry eye symptoms than FS-LASIK. Corneal sensitivity was higher after SMILE than FS-LASIK. Further randomized, double-blinded, prospective, and longer follow-up studies are necessary to compare outcomes after SMILE and FS-LASIK in patients with myopia and myopia with astigmatism; such studies will allow us to better understand the benefits of SMILE and FS-LASIK and will provide useful guidelines when a type of surgery is to be chosen.

**AUTHOR CONTRIBUTIONS**

Study concept and design (YZ, QS, YJ, DZ, JZ); data collection (YZ, QS); analysis and interpretation of data (YZ, QS, YJ, DZ); writing the manuscript (YZ, QS, YJ, DZ); critical revision of the manuscript (YJ, DZ, JZ).

**REFERENCES**


### TABLE A

**Jadad Scale for Randomized Controlled Trials**

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<th>Randomization</th>
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### TABLE B

**Newcastle–Ottawa Scale for Non-Randomized Comparative Trials**

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<td>Xu &amp; Yang (2014)</td>
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<td>Li et al. (2014)</td>
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*aEach * equals 1 point.*