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## Minimal Clinically Important Difference of Shoulder Outcome Measures and Diagnoses: A Systematic Review

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### Abstract

**Objective:** Patient-reported outcome scales determine response to treatment. The minimal clinically important difference (MCID) of these scales is a measure of responsiveness: the smallest change in a score associated with a clinically important change to the patient. This study sought to summarize the literature on MCID for the most commonly reported shoulder outcome scales.

**Design:** A literature search of PubMed and EMBASE databases identified 193 citations, twenty-seven of which met the inclusion/exclusion criteria.

**Results:** For rotator cuff tears, a MCID range of 9–26.9 was reported for American Shoulder and Elbow Surgeons (ASES), 8 or 10 for Constant, and 282.6–588.7 for the Western Ontario Rotator Cuff Index (WORC). For patients who underwent arthroplasty, a MCID range of 6.3–20.9 was reported for ASES, 5.7–9.4 for Constant, and 14.1–20.6 for the Shoulder Pain and Disability Index (SPADI). For proximal humeral fractures, a MCID range of 5.4–11.6 was reported for Constant and 8.1–13.0 for Disability of the Arm, Shoulder, and Hand (DASH).

**Conclusion:** A wide range of MCID values was reported for each patient population and instrument. In the future, a uniform outcome instrument and MCID will be useful to measure clinically meaningful change across practices and the spectrum of shoulder diagnoses.

### Keywords

Minimal clinically important difference; rotator cuff; shoulder disease; outcome assessment

### Introduction

Patient-reported outcome scales are used to determine patients' response to treatment. These instruments capture change in a patient's clinical status over time, a property called responsiveness, which can be measured in multiple ways<sup>1</sup>. The minimal clinically important

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difference (MCID) is a measure of responsiveness defined as “the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient’s management”<sup>2</sup>. In other words, the MCID is the smallest change in an outcome score that is associated with a clinically important change to the patient. This value helps avoid changes in score that may be statistically significant but do not result in meaningful change for the patient<sup>2</sup>.

Outcome instruments such as the Shoulder Pain and Disability Index (SPADI) and the American Shoulder and Elbow Surgeons Standardized Shoulder Form (ASES) are frequently used in populations with shoulder disorders including rotator cuff disease and proximal humeral fractures, and many studies have determined MCID values for standardized instruments<sup>3,4</sup>. However, there is variation in MCID values presented across studies that analyze the same outcome measures and patient populations<sup>1</sup>. The purpose of this study was to determine the ranges of MCID values in the current literature for different shoulder outcome measures and shoulder diagnoses.

## Materials and Methods

A systematic literature search of PubMed and EMBASE databases was performed from their years of inception through March 2018. Keywords included “outcome scale,” “shoulder pain,” and “MCID.” The full search criteria can be found in Appendix A. A total of 193 citations were initially identified, and the titles and abstracts were reviewed for relevance. The full texts of 26 of these citations were then reviewed, and 9 were found to be relevant to the topic. Bibliographies of the full text articles were also reviewed, and an additional 18 papers were found to be relevant to the study. The inclusion criteria included studies that calculated the MCID of outcome measures for different shoulder diagnoses. Exclusion criteria were studies that analyzed non-English translated versions of an outcome instrument, did not calculate or explain how they calculated the MCID, or calculated a MCID value that included neck or distal upper extremity diagnoses (upper arm, elbow, forearm, wrist, or hand).

The Methodological Index for Non-Randomized Studies (MINORS) was used to assess the quality of the studies included in this review<sup>5</sup>. As these were non-comparative studies, the maximum possible score was 16. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) methodology was used for reporting this manuscript (see Supplementary Checklist)<sup>6</sup>.

## Results

Twenty-seven studies that met the inclusion and exclusion criteria were included in the final analysis (Figure 1, Appendix B). Some of the most commonly-used outcome instruments represented in these articles were ASES, the Constant Shoulder Score, the Simple Shoulder Test (SST), and SPADI (Table I). Four general outcome measures were represented as well: the Visual Analog Scale (VAS) for pain, the Numerical Pain Rating Scale (NPRS), the Short Form-12 (SF-12), and the Numerical Function Rating Scale (NFRS). Twenty-one studies

used an anchor-based method to calculate the MCID, thirteen used a distribution-based approach, and seven used a receiver operator curve (ROC) analysis. Many of these studies determined MCID values for different subgroups of their patient populations; however, only the overall results are included here to enable comparison.

Ten studies either did not specify the shoulder disorders of their subjects or calculated a single MCID for multiple disorders (Table II). Of these ten, one calculated a MCID for ASES of 6.4<sup>7</sup>. The Disability of the Arm, Shoulder, and Hand (DASH) had a MCID range of 3.9–15<sup>8,9</sup>. MCID values of 1.1 and 2.17 were calculated for NPRS<sup>10,11</sup>. SPADI had MCID values of 8, 10, and 13.2<sup>4,9,12</sup>.

Nine studies calculated a MCID for rotator cuff disease with or without a tear (Table II). ASES was found to have MCIDs of 6.2–17, 17.9, 21.9, and 26.9<sup>3,13,14</sup>; Constant of 8 and 10<sup>15,16</sup>; and the Functional Shoulder Score (FSS) of 24.7<sup>17</sup>. Tubach et al. in 2006 calculated separate MCID values for a numerical rating scale based on function and another based on pain, resulting in ranges of 15.1–37.3 and 34.3–62.5, respectively. A MCID of 2 was calculated for SST<sup>13</sup>.

Four studies calculated a MCID specifically for patients with rotator cuff tears (Table II). MCIDs of 6.2–13.9, 17.9, 21.9, and 26.9 were calculated for ASES<sup>3,14</sup>; 8 and 10 for Constant<sup>15,16</sup>; and 282.6, 392.5, and 588.7 for the Western Ontario Rotator Cuff Index (WORC)<sup>3</sup>.

Six studies calculated a MCID value for patients who underwent shoulder arthroplasty (Table III). A MCID range of 6.3–13.6 and 20.9 was reported for ASES<sup>14,18,19,20</sup> and 5.7, 8, and 9.4 for Constant score<sup>16,18</sup>. SPADI was found to have MCID values of 14.1 and 20.6<sup>18,19</sup> and SST of 1.5, 1.8, 2.4, and 3.0<sup>18,19,21</sup>.

Three studies calculated a MCID for patients with shoulder instability (Table III). The Oxford Instability Shoulder Score (OISS) was found to have MCIDs of 4.5 and 6.5<sup>22</sup> and the Rowe Score for Instability of 2.2, 5.6, and 9.7<sup>23</sup>. MCIDs of 4 and 5 were calculated for the Shoulder Rating Questionnaire (SRQ)<sup>22</sup>; and 60.7, 151.9, and 220 for the Western Ontario Shoulder Instability Index (WOSI)<sup>23,24</sup>.

Two studies calculated a MCID for proximal humeral fractures (Table III). Van de Water et al. in 2014 found MCID values of 5.4 and 11.6 for Constant, 8.1 and 13.0 for DASH, 5.1 and 11.4 for the Oxford Shoulder Score (OSS), 12.1 and 26.6 for the Subjective Shoulder Value (SSV), and 2.0 and 2.4 for the UCLA Shoulder Rating Scale. In 2016, the same authors calculated MCIDs of 10.3 and 11.7 for the Shoulder Function Index (SFInX).

The results of the MINORS criteria bias assessment are in Table IV<sup>5</sup>. All of the studies had a clearly stated aim, prospective collection of data, end points appropriate to the aim of the study, and a follow-up period appropriate to the aim of the study. Twenty-two studies included consecutive patients<sup>3,4,7,8,9,10,11,12,13,14,15,16,17,18,19,20,22,23,25,26,27,28</sup>, six stated they had unbiased assessment of the study end point<sup>9,10,21,23,27,28</sup>, four had less than 5% loss to follow-up<sup>13,15,16,23</sup>, and four had prospective calculation of the study size<sup>3,25,27,28</sup>. The lowest score was 9<sup>1,24,29,30</sup>, and the highest was 15<sup>27,28</sup>.

## Discussion

The MCID measures the responsiveness of a scale by capturing the smallest change representative of a clinically important difference to the patient<sup>2</sup>. This study is a systematic review of MCID values reported for commonly used outcome scales in shoulder disorders. The ASES, Constant, SST, and SPADI were the most commonly used instruments to assess MCID in patients with shoulder disorders. Patient populations with rotator cuff disease or tears, with proximal humeral fractures, and after shoulder arthroplasty were assessed using these outcome scales. A wide range of MCID was reported for these instruments for each of the patient populations.

Our results show that the MCID for the same outcome instrument varies with the shoulder diagnosis that was studied. For instance, the ASES score has a different MCID for rotator cuff tears versus shoulder arthroplasty. Hence, it is important that the specific shoulder diagnosis be considered when reporting the MCID in research and clinical settings. A given MCID may not be applicable to a very heterogenous shoulder patient population with varying diagnoses.

No method for calculating the MCID is considered the gold standard. Three methods are most commonly used: the anchor-based approach, receiver operator curve (ROC) analysis, and distribution-based approach. The anchor-based approach correlates the change in score of the outcome instrument with an external anchoring question that measures improvement<sup>2</sup>. These anchors include terms such as “a little better” or “slightly better” to assess improvement. A broader version of the term anchoring to changes on a 4-point scale or to terms such as a “satisfactory outcome,” “a good deal better,” “a great deal better,” or “much better” was also used by some studies. ROC curves are graphs of sensitivity versus 1-specificity, and the upper left-most point – as the most sensitive and specific – is considered the cut off that can best distinguish patients who have improved from those who have not<sup>7</sup>. Distribution-based methods use a statistical measurement such as the standard deviation or standard error of measurement of the sample<sup>8</sup>. A fourth approach is consensus-based, which involves surveying the opinions of experts to determine a reasonable value; however, this method is less frequently accepted.

In general, a relatively wide range of MCID values was observed for the outcome scales and shoulder diagnoses included in the study. This is likely because of the heterogeneity in patient populations recruited for the studies and variation in methodology used to calculate MCID. There is no identifiable pattern between the method used to calculate the MCID and the differences in results; however, none of the studies that examined rotator cuff disease, rotator cuff tears specifically, or proximal humeral fractures used an ROC curve.

This study had a couple limitations. This analysis had studies<sup>3,8,13,15,16,23,24,27,28,30</sup> that included patients who improved and those who worsened in their anchor-based MCID calculations as well as studies<sup>1,9,14,17,18,22,25,29</sup> that only included patients who improved, leading to variations in MCID scores across studies. In addition, many of these studies determined MCID values for different subgroups of their patient populations, but only the

overall results were included here to enable comparison. Analysis of the subgroup MCID values may alter the results.

## Conclusions

We present existing data on MCID for commonly used outcomes instruments for shoulder disorders and discuss some of the methodologies used in the studies. The ASES, Constant, SST, and SPADI were the most commonly used instruments to assess MCID in patients with shoulder disorders. Patient populations with rotator cuff disease or tears, with proximal humeral fractures, and after shoulder arthroplasty were assessed using these outcome scales. A wide range of MCID values was reported for these instruments for each shoulder patient population. Information from our study can be used by professional agencies to determine whether available evidence is sufficient to recommend uniform outcomes instrument(s) with acceptable MCID for various shoulder disorders.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

## Source of Funding

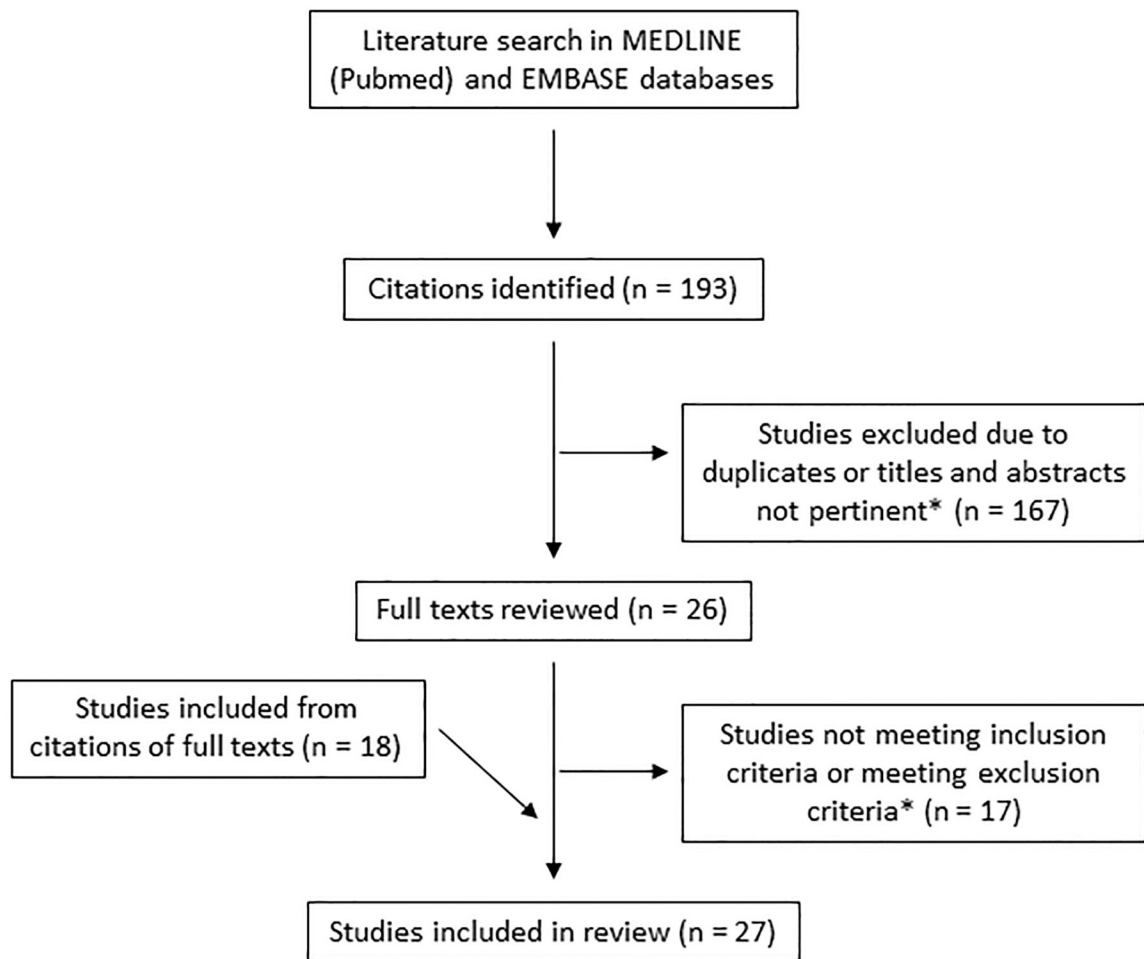
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**Figure 1.**

PRISMA diagram of the literature search and study selection

\*Inclusion criteria: studies that calculated the MCID of outcome measures for different shoulder diagnoses. Exclusion criteria: studies that analyzed non-English translated versions of an outcome instrument, did not calculate or explain how they calculated the MCID, or calculated a MCID value that included neck or distal upper extremity diagnoses.



**Table I.**

The shoulder-specific questionnaires represented in the included studies, the interpretation of their scores, and the number of studies in which their MCID was calculated.

Outcome Instrument	Abbreviation	# of studies	Score Range	
			Worse shoulder function	Better shoulder function
American Shoulder and Elbow Surgeons Standardized Shoulder Form	ASES	7	0	100
Constant Shoulder Score	Constant	4	0	100
Simple Shoulder Test	SST	4	0	12
Shoulder Pain and Disability Index	SPADI	4	100	0
Disability of the Arm, Shoulder, and Hand	DASH	3	100	0
Shoulder Rating Questionnaire	SRQ	3	17	100
UCLA Shoulder Rating Scale	UCLA	2	2	35
Western Ontario Rotator Cuff Index	WORC	2	2100	0
Western Ontario Shoulder Instability Index	WOSI	2	2100	0
Shortened DASH	QuickDASH	1	100	0
Penn Shoulder Score	PSS	1	0	100
Rowe Score for Instability	Rowe	1	0	100
Oxford Instability Shoulder Score	OISS	1	0	48
Oxford Shoulder Score	OSS	1	0	48
Subjective Shoulder Value	SSV	1	0	100
Functional Shoulder Score	FSS	1	0	100
Flexilevel Scale of Shoulder Function	FLEX-SF	1	0	100
Shoulder Function Index	SFInX	1	0	100
Dutch Shoulder Disability Questionnaire	SDQ-NL	1	100	0
United Kingdom Shoulder Disability Questionnaire	SDQ-UK	1	100	0

**Table II.**

MCID values for unspecified shoulder disorder, rotator cuff disease, and rotator cuff tears specifically

Outcome Instrument	MCID	References
<b>Unspecified Shoulder Disorder</b>		
ASES	6.4	Michener et al. <sup>7</sup> (2002)
DASH	3.9–15	Beaton et al. <sup>8</sup> (2011) Schmitt et al. <sup>9</sup> (2004)
FLEX-SF	3.02	Cook et al. <sup>30</sup> (2003)
NPRS	1.1, 2.17	Michener et al. <sup>10</sup> (2011) Mintken et al. <sup>11</sup> (2009)
PSS	11.4	Leggin et al. <sup>1</sup> (2006)
QuickDASH	8	Mintken et al. <sup>11</sup> (2009)
SDQ-NL	14	Paul et al. <sup>4</sup> (2004)
SDQ-UK	4–8	Paul et al. <sup>4</sup> (2004)
SF-12 PCS	6.5	Schmitt et al. <sup>9</sup> (2004)
SPADI	8, 10, 13.2	Paul et al. <sup>4</sup> (2004) Schmitt et al. <sup>9</sup> (2004) Williams et al. <sup>12</sup> (1995)
SRQ	12, 13	L'Insalata et al. <sup>29</sup> (1997) Paul et al. <sup>4</sup> (2004)
<b>Rotator Cuff Disease</b>		
ASES	6.2–17, 17.9, 21.9, 26.9	Gagnier et al. <sup>3</sup> (2018) Tashjian et al. <sup>13</sup> (2010) Werner et al. <sup>14</sup> (2016)
Constant	8, 10	Kukkonen et al. <sup>15</sup> (2013) Torrens et al. <sup>16</sup> (2016)
FSS	24.7	Iossifidis et al. <sup>17</sup> (2015)
NFRS	15.1–37.3	Tubach et al. <sup>25</sup> (2006) *
NPRS	34.3–62.5	Tubach et al. <sup>25</sup> (2006) *
Pain VAS	1.37	Tashjian et al. <sup>26</sup> (2009)
SST	2	Tashjian et al. <sup>13</sup> (2010)
WORC	245.26, 282.6, 392.5, 588.7	Gagnier et al. <sup>3</sup> (2018) * Kirkley et al. <sup>24</sup> (2003)
<b>Rotator Cuff Tears</b>		
ASES	6.2–13.9, 17.9, 21.9, 26.9	Gagnier et al. <sup>3</sup> (2018) Werner et al. <sup>14</sup> (2016)
Constant	8, 10	Kukkonen et al. <sup>15</sup> (2013) Torrens et al. <sup>16</sup> (2016)
WORC	282.6, 392.5, 588.7	Gagnier et al. <sup>3</sup> (2018) *

\* MCID initially reported as negative because lower numbers indicated improvement but switched here for consistency and ease of comparison

**Table III.**

MCID values for shoulder arthroplasty, shoulder instability, and proximal humeral fractures

Outcome Instrument	MCID	References
<b>Shoulder Arthroplasty</b>		
ASES	6.3–13.6, 20.9	Simovitch et al. <sup>18</sup> (2018) Tashjian et al. <sup>19</sup> (2017) Werner et al. <sup>14</sup> (2016) Wong et al. <sup>20</sup> (2016)
Constant	5.7, 8, 9.4	Simovitch et al. <sup>18</sup> (2018) Torrens et al. <sup>16</sup> (2016)
SF-12 MCS	5.7	Wong et al. <sup>20</sup> (2016)
SF-12 PCS	5.4	Wong et al. <sup>20</sup> (2016)
SPADI	14.1, 20.6	Simovitch et al. <sup>18</sup> (2018)
SST	1.5, 1.8, 2.4, 3.0	Roy et al. <sup>21</sup> (2010) Simovitch et al. <sup>18</sup> (2018) Tashjian et al. <sup>19</sup> (2017)
UCLA	3.6, 8.7	Simovitch et al. <sup>18</sup> (2018)
VAS Pain	1.4, 1.6	Simovitch et al. <sup>18</sup> (2018) Tashjian et al. <sup>19</sup> (2017)
<b>Shoulder Instability</b>		
OISS	4.5, 6.5	Moser et al. <sup>22</sup> (2008)
Rowe	2.2, 5.6, 9.7	Park et al. <sup>23</sup> (2018)
SRQ	4, 5	Moser et al. <sup>22</sup> (2008)
WOSI	60.7, 151.9, 220	Kirkley et al. <sup>24</sup> (2003) Park et al. <sup>23</sup> (2018)
<b>Proximal Humeral Fractures</b>		
Constant	5.4, 11.6	Van de Water et al. <sup>27</sup> (2014)
DASH	8.1, 13.0	Van de Water et al. <sup>27</sup> (2014) <sup>*</sup>
OSS	5.1, 11.4	Van de Water et al. <sup>27</sup> (2014)
SFIInX	10.3, 11.7	Van de Water et al. <sup>28</sup> (2016)
SSV	12.1, 26.6	Van de Water et al. <sup>27</sup> (2014)
UCLA	2.0, 2.4	Van de Water et al. <sup>27</sup> (2014)

\* MCID initially reported as negative because lower numbers indicated improvement but switched here for consistency and ease of comparison

**Table IV.**

Methodological Index for Non-Randomized Studies (MINORS) scores

	A clearly stated aim	Inclusion of consecutive patients	Prospective collection of data	End points appropriate to the aim of the study	Unbiased assessment of the study end point	Follow-up period appropriate to the aim of the study	Loss to follow-up <5%	Prospective calculation of study size	Total
Beaton et al. <sup>8</sup> (2011)	2	2	2	2	0	2	0	0	10
Cook et al. <sup>30</sup> (2003)	2	0	2	2	0	2	1	0	9
Gagnier et al. <sup>3</sup> (2018)	2	2	2	2	0	2	1	2	13
Iossifidis et al. <sup>17</sup> (2015)	2	2	2	2	0	2	0	0	10
Kirkley et al. <sup>24</sup> (2003)	2	1	2	2	0	2	0	0	9
Kukkonen et al. <sup>15</sup> (2013)	2	2	2	2	0	2	2	0	12
L'Insalata et al. <sup>29</sup> (1997)	2	0	2	2	0	2	1	0	9
Leggin et al. <sup>1</sup> (2006)	2	0	2	2	0	2	1	0	9
Michener et al. <sup>7</sup> (2002)	2	2	2	2	0	2	1	0	11
Michener et al. <sup>10</sup> (2011)	2	2	2	2	2	2	0	0	12
Mintken et al. <sup>11</sup> (2009)	2	2	2	2	0	2	0	0	10
Moser et al. <sup>22</sup> (2008)	2	2	2	2	0	2	1	0	11
Park et al. <sup>23</sup> (2018)	2	2	2	2	2	2	2	0	14
Paul et al. <sup>4</sup> (2004)	2	2	2	2	0	2	1	0	11
Roy et al. <sup>21</sup> (2010)	2	1	2	2	2	2	1	0	12
Schmitt et al. <sup>9</sup> (2004)	2	2	2	2	2	2	1	0	13
Simovitch et al. <sup>18</sup> (2018)	2	2	2	2	0	2	1	0	11
Tashjian et al. <sup>26</sup> (2009)	2	2	2	2	0	2	0	1	11
Tashjian et al. <sup>13</sup> (2010)	2	2	2	2	0	2	2	0	12
Tashjian et al. <sup>19</sup> (2017)	2	2	2	2	0	2	1	0	11
Torrens et al. <sup>16</sup> (2016)	2	2	2	2	0	2	2	0	12
Tubach et al. <sup>25</sup> (2006)	2	2	2	2	0	2	1	2	13
Van de Water et al. <sup>27</sup> (2014)	2	2	2	2	2	2	1	2	15
Van de Water et al. <sup>28</sup> (2016)	2	2	2	2	2	2	1	2	15
Werner et al. <sup>14</sup> (2016)	2	2	2	2	0	2	1	0	11

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	A clearly stated aim	Inclusion of consecutive patients	Prospective collection of data	End points appropriate to the aim of the study	Unbiased assessment of the study end point	Follow-up period appropriate to the aim of the study	Loss to follow-up <5%	Prospective calculation of study size	Total
<b>Williams et al.<sup>1,2</sup> (1995)</b>	2	2	2	2	0	2	1	0	11
<b>Wong et al.<sup>20</sup> (2016)</b>	2	2	2	2	0	2	1	0	11