



The minimal clinically important difference for function and strength in patients undergoing reverse shoulder arthroplasty



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Hypothesis: Despite a statistically significant improvement in functional scores after receiving a reverse shoulder arthroplasty (RSA) in a cuff-deficient shoulder, not all patients perceive a minimal clinically important difference (MCID) in every functional domain of the score.

Methods: This was a prospective longitudinal study including 60 consecutive patients with a cuff-deficient shoulder treated with a RSA. The Constant score was recorded before surgery and at a 1-year follow-up assessment. At the 1-year follow-up, all patients also filled out a 15-item anchor questionnaire to assess their perception of change in their overall function, forward elevation, lateral rotation, internal rotation, and strength to determine the MCID.

Results: The mean Constant score was 30.1 (standard deviation, 10.7) before surgery and was 58.4 (standard deviation, 16.2) at the 1-year follow-up, with statistically significant improvement ($P < .001$). A statistically significant improvement was found in the domains of forward elevation ($P < .001$), lateral rotation ($P < .001$), and strength ($P < .001$) except for internal rotation ($P = .15$). The MCID for overall function, forward elevation, lateral rotation, internal rotation, and strength in the Constant score increased by 8, 6, 2, 2, and 11.5 points, respectively; only 46.7%, 20%, 50%, 45.8%, and 33.3% of the patients, respectively, exceeded the MCID on each domain after surgery.

Conclusions: A statistically significant improvement in the Constant score is expected after receiving an RSA in a cuff-deficient shoulder, but a considerable number of patients do not reach the MCID in the function and strength domains. A small improvement in rotation is perceived to be beneficial by patients, whereas large improvements in forward elevation are required for the improvement to be perceived to be beneficial.

Level of evidence: Development or Validation of Outcome Instrument.

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Keywords: Reverse shoulder arthroplasty; minimal clinically important changes; cuff-deficient shoulder; outcome

The Clinical Research Ethical Committee of the Parc de Salut Mar approved this study (2014/5930/I).

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Reverse shoulder arthroplasty (RSA) has been proven effective in the treatment of arthritis related to rotator cuff deficiency. After receiving a reverse shoulder prosthesis, patients' pain and function improve significantly.^{1,8,18,23,24} However, the functional improvement is mainly due to

forward elevation and abduction because the reverse system is less predictable in the restoration of external and internal rotation; the pattern of cuff tear and type of prosthetic device can greatly affect rotational motion.³ Nevertheless, RSA is associated with a significant number of complications, mainly including scapular notch development, dislocation, infection, and loosening of the components.²⁴

Statistically significant differences between before and after treatment scores mean that the differences obtained are not simply due to chance but do not reflect the clinical relevance of the differences found.^{9,11,12} In addition, the treatments used may differently affect the different domains of a score, making the determination of the clinical relevance of the treatment even more difficult.⁷ Any treatment option offers benefits and undesirable effects; it would be useful to know what patients experience as an important change or an important difference between the pretreatment and post-treatment status to properly balance the benefits and risks and make the right treatment decision.

The minimal clinically important difference (MCID) has been 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.”¹¹ Determining the MCID as perceived by the patient has become an important tool in interpreting the statistically significant differences found in outcomes as well as in determining their clinical relevance.^{5-7,9,11,12,21,22}

This measure has been widely used in medical diseases, such as asthma, but also in orthopedic disorders such as low back pain, ulnar neuropathy, subacromial pain, and rotator cuff tears.^{10,11,13-16,19,20} MCID values depend on the population selected, the treatment applied, and the score used to record changes, making them not suitable for general comparisons among different populations or diseases.^{5-7,21}

The objective of this study was to determine the MCID in the Constant score domains of function and strength in patients with irreparable massive rotator cuff tears treated with a RSA.

Materials and methods

This was a prospective longitudinal study including 60 consecutive patients with massive irreparable rotator cuff tears treated with RSA (Delta Xtend; DePuy, Warsaw, IN, USA). Before being included, all the patients underwent physical and imaging (X-ray and magnetic resonance imaging) examinations and were diagnosed with a massive cuff tear with or without arthritic changes. Inclusion criteria included age older than 65 years, a clinical and imaging diagnosis of a massive cuff tear, and an agreement to be enrolled in the study. Exclusion criteria included previous surgery on the affected shoulder, previous RSA in the opposite shoulder, and any other indication for RSA other than an irreparable massive rotator cuff tear, including acute and old fractures, revision surgery, and tumor surgery.

Patient assessment

All patients were functionally assessed using the Constant score before surgery.⁴ The Constant score is a 100-point scoring system that includes 4 domains: pain (0-15 points), activities of daily living (0-20 points), range of motion free of pain (0-40 points), and strength (0-25 points). Range of motion can be subsequently divided into forward elevation (0-10), abduction (0-10 points), lateral rotation (0-10 points), and internal rotation (0-10 points). Pain was recorded as the average between the value obtained with a visual analog scale (0-15 points) and the score obtained after categorizing pain as none (15 points), mild (10 points), moderate (5 points), and severe (0 points). Strength was assessed using a digital dynamometer (Lafayette Manual Muscle Testing System, Lafayette Instrument Co, Lafayette, IN, USA) as the mean value of the 3 registers.

At the 1-year postoperative follow-up, all patients were re-evaluated with the Constant score and with 5 questions to assess improvements in overall function, strength, forward elevation, lateral rotation, and internal rotation. The 5 questions were:

1. Compared to your presurgery state, how do you rate the overall function of your shoulder?
2. Compared to your presurgery state, how do you rate the strength of your shoulder?
3. Compared to your presurgery state, how do you rate the forward elevation of your arm?
4. Compared to your presurgery state, how do you rate the lateral rotation of your arm?
5. Compared to your presurgery state, how do you rate the internal rotation of your arm?

Fifteen-item anchor questions derived from those designed by Juniper et al¹² were used to answer each of the 5 anchor questions used to determine MCID (Table I). Cutoff points of the MCID for a Constant score improvement were determined for the overall function (the sum of forward elevation, abduction, lateral rotation, and internal rotation as recorded in the Constant score), strength, forward elevation, lateral rotation, and internal rotation.

Statistics

The change in the Constant score from baseline to the 1-year follow-up was calculated for each patient. The MCID was obtained using the anchor-based technique consisting of the 15-item questionnaire according to Juniper et al.¹² Patients who answered “no change,” “almost the same, hardly worse at all,” or “almost the same, hardly better at all,” were classified as having no change compared with their preoperative status. Patients who answered “a little worse, somewhat worse” or “a little better, somewhat better” were classified as having minimal change. Patients who answered “moderately worse, a good deal worse” or “moderately better, a good deal better” were classified as having a moderate change. Patients who answered “a great deal worse, a very great deal worse” or “a great deal better, a very great deal better” were classified as having a large change.¹²

Categoric variables are described with frequencies and percentages, and continuous variables are expressed as the mean and standard deviation (SD). Improvements in different Constant domains were assessed with the paired Student *t* test. To compare changes in Constant scores between MCID groups, 1-way analysis

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