Radiostereometric analysis of keeled versus pegged glenoid components in total shoulder arthroplasty: a randomized feasibility study

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Background: This study aimed to assess differences in the fixation and functional outcomes between pegged and keeled all-polyethylene glenoid components for standard total shoulder arthroplasty.

Methods: Patients were randomized to receive a keeled or pegged all-polyethylene glenoid component. We used model-based radiostereometric analysis (RSA) to assess glenoid fixation and subjective outcome measures to assess patient function. Follow-up examinations were completed at 6 weeks and 6, 12 and 24 months after surgery. Modifications to the RSA surgical, imaging and analytical techniques were required throughout the study to improve the viability of the data.

Results: Stymied enrolment resulted in only 16 patients being included in our analyses. The RSA data indicated statistically greater coronal plane migration in the keeled glenoid group than in the pegged group at 12 and 24 months. Functional outcome scores did not differ significantly between the groups at any follow-up. One patient with a keeled glenoid showed high component migration after 24 months and subsequently required revision surgery 7 years postoperatively.

Conclusion: Despite a small sample size, we found significant differences in migration between glenoid device designs. Although clinically these findings are not robust, we have shown the feasibility of RSA in total shoulder arthroplasty as well as the value of a high-precision metric to achieve objective results in a small group of patients.

Contexte: Cette étude avait pour objet d’évaluer les différences sur le plan de la fixation et des résultats fonctionnels entre les composants glénoïdiens à plots et à quille, tous deux en polyéthylène, dans une arthroplastie totale traditionnelle de l’épaule.

Méthodes: La répartition des composants glénoïdiens en polyéthylène à plots et à quille a été faite de façon aléatoire. Nous nous sommes servis de modèles d’analyses radiostéréométriques (ARS) pour évaluer la fixation glénoïdienne et les indicateurs de résultats subjectifs, ce qui nous a ainsi permis d’évaluer les résultats fonctionnels des patients. Quatre examens de suivi ont été réalisés après la chirurgie : à 6 semaines, puis à 6 mois, à 12 mois et à 24 mois. Tout au long de l’étude, des ajustements ont été apportés aux modèles d’ARS de la chirurgie, de l’imagerie et des analyses afin d’améliorer la viabilité des données.

Résultats: Des problèmes liés au recrutement ont fait en sorte que nous n’avions retenu que 16 patients dans le cadre de nos analyses. Les données d’ARS ont montré une migration statistiquement plus grande dans le groupe frontal que dans le groupe plots à 12 et 24 mois. Les résultats fonctionnels étaient sensiblement les mêmes d’un groupe à l’autre, peu importe le moment du suivi. Un patient du groupe quille a présenté une migration très importante du composant après 24 mois; il a dû subir une chirurgie de révision 7 ans après la chirurgie initiale.

Conclusion: Malgré la petite taille de l’échantillon, nous avons observé des différences significatives dans la migration des composants, selon le type utilisé. Même si ces observations ne permettent pas d’arriver à des conclusions robustes d’un point de vue clinique, nous avons montré qu’il est possible d’avoir recours aux ARS en contexte d’arthroplastie totale de l’épaule et démontré la valeur associée à l’utilisation de mesures de haute précision pour l’obtention de résultats objectifs chez un petit groupe de patients.
SUCCESSFUL RESULTS AFTER A TOTAL SHOULDER ARTHROPLASTY (TSA), AS DEFINED BY PATIENT SATISFACTION, FUNCTION AND THE ABSENCE OF PAIN, ARE REPORTED IN MORE THAN 90% OF CASES. ONE OF THE MOST COMMON REASONS FOR Revision TSA IS LOOSENING OF THE GLENOID COMPONENT. Glenoid component loosening can have serious detrimental effects, such as dislocation, osteolysis of the glenoid and glenohumeral instability; all of these factors can play a decisive role in long-term functional outcomes.

Several strategies have been introduced in recent years to improve the outcome of TSA, the most notable being a pegged polyethylene glenoid component. Several studies have assessed the stability and incorporation of pegged glenoids compared with the more traditional keeled glenoid components. Previous in vitro testing determined that pegged glenoid components have a greater pull-out strength than keeled components and that pegged components offer greater resistance to off-centre loads. Clinical studies have found that keeled components are more frequently unsupported at their posterior rim and are associated with a greater incidence of radiolucent lines than pegged glenoid components.

Although these initial results suggest that pegged components provide greater stability than the keeled counterparts, a very recent review by Vavken and colleagues has shown a significantly reduced risk of revision surgery with pegged glenoid components. Despite this finding, the authors reported that the difference in revision risk between pegged and keeled components was rather small and that there were no differences in the risk of radiolucency between component types.

Radiostereometric analysis (RSA) is a radiographic technique used to measure micromotion (< 1 mm) at the bone–implant interface. The amount of micromotion measured with RSA within 2 years of surgery can be used to reliably predict the long-term survival of total joint replacements. Although RSA has been used predominantly to assess micromotion of hip and knee prostheses, its use to detect micromotion in shoulder replacements has also been reported.

A consecutive series study determined that the glenoid predominantly experienced cranial forces, creating a shear force at the cement–bone interface and a tensile force at the inferior aspect of this interface. This mechanism of loosening is widely known as the “rocking horse phenomenon,” which appears as varus–valgus rotation in the coronal plane. Following these findings, Nuttall and colleagues determined keeled glenoid components to have significantly greater total translation and varus tilt (“rocking horse” loosening) than pegged components. Despite this seemingly positive finding, Rahme and colleagues observed no difference in micromotion between keeled and pegged glenoid component designs in a cohort of 25 patients (27 shoulders).

The findings of the aforementioned studies suggest that the pegged glenoid component is superior to the keeled component in terms of fixation and, concurrently, revision risk. However, at the time the present study was conceptualized, the question as to the optimum glenoid component design still remained. Our study was initiated in an attempt to measure and compare in vivo fixation of the pegged versus keeled glenoid component designs using RSA technology and to assess patient-reported quality of life and functional differences in a small cohort of patients.

METHODS

Clinical study

We initiated a prospective, randomized, parallel (1:1) single-blinded study after obtaining approval from the applicable research ethics board. One fellowship-trained surgeon (P.M.) identified potential patients from their local practice and performed the TSAs on all study patients based on presurgery consultation. We included patients undergoing TSA who were 18 years or older. We excluded patients requiring reverse TSA, those without an intact rotator cuff (including cuff tear arthropatis), patients with active Worker’s Compensation Board claims associated with the shoulder requiring surgery and those who had undergone previous shoulder joint replacement surgery. Study participants were enrolled between August 2008 and March 2011. Patients were randomized intraoperatively to receive either the pegged or keeled glenoid design preimplanted with RSA markers. A series of sequentially numbered opaque envelopes were created by a research assistant before study recruitment based on a computer-based randomization list in blocks of 10. Each envelope held an allocation to 1 of the 2 study arms, and the envelope was opened once the surgeon determined the patient was eligible based on intraoperative findings. The patient was not informed which implant was used, and clinical assessments were performed by a researcher (S.M.) who was also unaware of study allocation. The surgeon could not be blinded.

The primary outcome measure of this study was micromotion, as measured using RSA: namely, coronal plane translation and varus–valgus rotation. We also collected patient-reported outcome measures using the Simple Shoulder Test, the American Shoulder and Elbow Surgeons Questionnaire (ASES) and the Western Ontario Osteoarthritis Survey (WOOS). Complications, including the rate of loss of subsaculapris function as measured by a loss of internal rotation, aseptic loosening, glenohumeral (Gh) instability, rotator cuff tears, periprosthetic fractures, implant failures, infection, nerve injury and deltoid dysfunction were also documented. Follow-up examinations were completed at 6 weeks and 6, 12 and 24 months after surgery. Physical assessment, RSA
imaging and patient-reported outcome measures were completed at each follow-up visit.

Surgical technique, including surgical exposure, bony instrumentation and soft tissue balancing, was standardized for all patients. The procedure was performed with the patient under general anesthetic and in the beach chair position. Exposure involved an extended deltopectoral approach to the shoulder. All patients received a humeral stem and modular head in combination with pegged or keeled polyethylene glenoid components pre-marked with 0.8 mm diameter RSA markers (Biomedical, Biomet Orthopaedics). We inserted 5–10 RSA markers of 1.0 mm diameter into the glenoid, acromion and/or coracoid process during surgery. After initial difficulties with RSA image analysis, the number of implanted RSA markers was increased to 10–15 to improve results. The surgical procedure was no different between groups other than the type of glenoid component implanted and the respective glenoid preparation. We used a fourth-generation cement mixing technique and took extra care to ensure proper cementation of the glenoid components. There were no appreciable differences in postoperative care between study groups. Patients’ shoulders were immobilized in a sling for 3 weeks, and patients underwent posthospitalization rehabilitation.

**RSA examinations**

The configuration of the RSA equipment was the same as described in a 2012 study by Bohm and colleagues. The RSA exams were performed with the patient in the supine position with their affected arm held away from the body to improve visibility of RSA markers within the joint. The imaging technique was changed partway through the study from a medial–lateral direction to a superior–inferior direction to increase marker visibility, as suggested by a fellow RSA researcher (Dr. Charles Bragdon, Massachusetts General Hospital, Boston, Mass., personal communication, 2009). Glenoid component micromotion was measured with respect to the surrounding bone markers via model-based RSA (mbRSA) version 3.41 (Medis Specials B.V.).

Owing to difficulties with marker visibility on the radiographs, we used 2 advanced analysis techniques with the mbRSA software. The first technique was use of mathematical matrices of RSA marker locations to solve for occluded markers that were blocked by the humeral head, as described in a 2005 study by Kaptein and colleagues. The second technique involved computer-aided design (CAD) drawings of the glenoid prostheses with preimplanted marker locations obtained from the manufacturer. These CAD marker models were imported into mbRSA for each patient examination to help with visual distinction of RSA markers in the bone versus those in the prosthesis.

**Statistical analyses**

A sample size of 20 patients (10 per arm) was the initial target for this study based on previous RSA research of shoulder replacements in which a minimum detectable difference of 0.5 mm and standard deviation of 0.3 mm were reported. Nonparametric statistics were used for all comparisons as a result of the small sample size. We used Wilcoxon signed-rank tests to compare pre- and postoperative patient-reported outcome measures for each patient. Wilcoxon rank sum tests were used to compare patient-reported outcome measures and RSA migration data between the glenoid groups at each follow-up interval. For all comparisons, we considered results to be significant at \( p < 0.05 \).

**Results**

A total of 15 patients (16 shoulders) were recruited for this study: 10 men (1 bilateral TSA) and 5 women with a mean age of 64 (range 46–75) years at the time of surgery. There were no differences between the groups with respect to age, body mass index, or sex. Study recruitment was closed after 15 patients (16 shoulders), as the participating surgeon felt that continuing to randomize patients to receive the keeled implant was no longer appropriate based on clinical judgment and mounting published evidence indicating the keeled implant was not as successful as the pegged implant. Of the 16 patients enrolled, 11 were included in the 12-month postoperative analysis and 9 were included in the 24-month analysis owing to missed examinations and loss to follow-up. Figure 1 summarizes patient recruitment, loss to follow-up, outcome scores, and RSA analysis. All patients received the implant to which they were allocated via the randomization process (i.e., there were no study crossovers).

Most patient-reported outcome measures improved significantly for both glenoid groups from the preoperative to the 6- and 12-month postoperative follow-up (Table 1). However, no statistically significant improvement was found for the 24-month follow-up. Preoperative ASES and WOOS scores were significantly higher in the pegged group than the keeled group (Table 2). There were no postoperative differences between groups for all patient-reported outcome measures.

No differences were found between the glenoid groups for medial–lateral translation (Fig. 2), superior–inferior translation (Fig. 3), or coronal rotation (Fig. 4) at any follow-up. The magnitude of keeled glenoid translation in the coronal plane \( |\sqrt{(x_{T2}^2 + y_{T2})}| \) was significantly greater than that of the pegged group at the 12-month and 24-month follow-up periods (Fig. 5). Median values of glenoid component migration are presented in Table 3. One patient in the keeled glenoid group has undergone revision TSA as a result of aseptic loosening of the glenoid.
This patient showed the highest coronal plane migration of their glenoid (Fig. 4).

Altering the direction of RSA imaging marginally increased the number of RSA markers visible in each patient examination, as did increasing the number of beads implanted during surgery. Application of advanced RSA image analysis techniques resulted in a 2-fold increase in the amount of useable patient data at the 12- and 24-month follow-up compared with previous analysis efforts using traditional, non-model-based software (UmRSA version 6.0, RSA Biomedical).

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**Fig. 1.** Patient enrolment and analysis.
DISCUSSION

The small sample size achieved in our study limits its clinical relevance. However, we have shown the feasibility of RSA comparison between 2 all-polyethylene glenoid components used in TSA and described several strategies to improve the quality and viability of data gleaned in future studies of this kind. Furthermore, although our findings may not be at a level of clinical significance, we found a statistically significant difference in the magnitude of coronal plane translation between glenoid groups, which shows the value of high-precision metrics, such as RSA, in evaluating clinical success of orthopedic devices in small trials that can be implemented and completed quickly.

Our finding of significantly greater translation in the keeled glenoid group indicates a greater propensity for aseptic loosening of keeled glenoid components, which is consistent with published knowledge.11,12 This trend of coronal plane migration can also be seen in Figures 2 and 3, which show higher overall migration of the keeled components. The patient with the largest glenoid migration (Fig. 4) underwent revision surgery as a result of aseptic loosening of their keeled glenoid. The remaining patients in the keeled group will be monitored closely as they return for postoperative follow-up.

### Table 1. Median pre- to postoperative improvement in patient-reported outcome scores

<table>
<thead>
<tr>
<th>Metric; group</th>
<th>6-month</th>
<th>12-month</th>
<th>24-month</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Keeled</td>
<td>45.0*</td>
<td>51.3</td>
<td>41.2</td>
</tr>
<tr>
<td>Pegged</td>
<td>36.4*</td>
<td>34.2*</td>
<td>41.4</td>
</tr>
<tr>
<td>SST</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Keeled</td>
<td>3.0</td>
<td>6.0</td>
<td>4.0</td>
</tr>
<tr>
<td>Pegged</td>
<td>5.0*</td>
<td>5.5*</td>
<td>5.5</td>
</tr>
<tr>
<td>WOOS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Keeled</td>
<td>45.9*</td>
<td>48.3</td>
<td>58.9</td>
</tr>
<tr>
<td>Pegged</td>
<td>48.4*</td>
<td>47.9*</td>
<td>31.9</td>
</tr>
</tbody>
</table>

ASES = American Shoulder and Elbow Surgeons Questionnaire; SST = Simple Shoulder Test; WOOS = Western Ontario Osteoarthritis Survey.

*Significant improvement over preoperative score (p < 0.05).

### Table 2. Median patient-reported outcome scores showing improved preoperative scores in the pegged group

<table>
<thead>
<tr>
<th>Metric; group</th>
<th>Preoperative</th>
<th>6-month</th>
<th>12-month</th>
<th>24-month</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASES</td>
<td></td>
<td></td>
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<tr>
<td>Keeled</td>
<td>22.5</td>
<td>69.6</td>
<td>72.5</td>
<td>73.5</td>
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<td>Pegged</td>
<td>47.0*</td>
<td>93.3</td>
<td>97.1</td>
<td>96.4</td>
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<tr>
<td>SST</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Keeled</td>
<td>2.0</td>
<td>6.0</td>
<td>7.0</td>
<td>6.0</td>
</tr>
<tr>
<td>Pegged</td>
<td>4.5</td>
<td>10.0</td>
<td>11.0</td>
<td>10.5</td>
</tr>
<tr>
<td>WOOS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Keeled</td>
<td>80.2</td>
<td>34.6</td>
<td>34.7</td>
<td>18.5</td>
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<tr>
<td>Pegged</td>
<td>59.3*</td>
<td>7.2</td>
<td>7.15</td>
<td>22.3</td>
</tr>
</tbody>
</table>

ASES = American Shoulder and Elbow Surgeons Questionnaire; SST = Simple Shoulder Test; WOOS = Western Ontario Osteoarthritis Survey.

*Significant difference between groups (p < 0.05).
Although a small number of clinical studies of cemented TSA have shown no difference in micromotion or radiolucency between pegged and keeled glenoid components,\textsuperscript{1,17} a recent review by Vavken and colleagues,\textsuperscript{1} along with numerous other studies,\textsuperscript{4,8,16,23-25} showed that keeled glenoid components are inferior to pegged components in terms of fixation and patient outcomes. These findings are consistent with our study based on both the RSA and patient-reported outcome measures data.

Altering the direction of imaging improved marker visibility marginally, but the insertion of additional markers along with the use of advanced model-based RSA techniques were of much greater benefit. Our initial analyses of RSA radiographs resulted in only 6 patients at the 12-month follow-up and 4 patients at the 24-month follow-up compared with 11 and 9 patients, respectively, following application of the advanced techniques. These techniques enhanced the quantity and quality of RSA data as well as our confidence in the analysis. Although these techniques were extremely valuable for this study, improved marker placement and optimal imaging techniques are certainly preferable to labour-intensive analytic techniques. Recent studies have reported success when implanting RSA markers via predrilled holes and specialized delivery of the markers to position them away from the humeral head.\textsuperscript{17,26} In particular, the addition of markers to the acromion and coracoid process provides greatly improved spread and visibility.\textsuperscript{17,26} Such practices are recommended for future studies of glenoid component stability using RSA.

**CONCLUSION**

This research presents evidence of pegged glenoid components having improved fixation compared with keeled glenoid components in a small group of patients using a high-precision metric, RSA. One patient with a keeled glenoid underwent revision TSA 7 years after the index procedure as a result of aseptic loosening, which was captured by our radiographic analysis. Although our study was significantly limited by a small sample size, it showed both the feasibility and value of RSA in a TSA for comparison of different device designs. Improvements in the surgical, radiographic and analytical techniques of RSA described in this study will help with the feasibility of future studies of this kind.

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**Contributors:** M. Petrak, E. Bohn and P. MacDonald designed the study. T. Gascoyne, S. McRae, S. Parashin, E. Bohm, and P. MacDonald analyzed the data, which T. Gascoyne, S. McRae, S. Parashin, E. Bohm and P. MacDonald wrote the article, which all authors reviewed and approved for publication.

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