Comparison of Press Fit Versus Peripherally Cemented Hybrid Glenoid Components in Anatomic Total Shoulder Arthroplasty: Minimum 5-year Follow-up

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Running Title: Minimum 5 Year Uncemented Hybrid Glenoid

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Abstract

Background: A common complication of anatomic total shoulder arthroplasty (aTSA) is aseptic glenoid loosening. Monoblock polyethylene glenoid components with backside ingrowth or on-growth utilize hybrid fixation, with cementation of the peripheral pegs and central ingrowth or on-growth of bone have been designed to decrease glenoid loosening. However, there is a paucity of mid-term data comparing cementation of the peripheral peg holes versus all press-fit implantation for hybrid glenoid constructs. The purpose of this study is to compare the minimum five year clinical and radiographic outcomes of a press fit hybrid glenoid component to a peripherally cemented hybrid glenoid component in aTSA.

Methods: Between years 2013-2015, we reviewed a total of 169 primary aTSA patients, with follow-up data spanning a minimum of five years, from an international multi-institutional database. There were 61 press-fit and 108 peripherally cemented glenoids. Shoulders were evaluated for outcome measures, which included clinical outcome scores, radiographic outcomes, and complication rates.

Results: Postoperatively, there were no statistically significant differences in patient satisfaction, shoulder function, pain scoring, the Simple Shoulder Test, the Constant score, the American Shoulder and Elbow Surgeons score, the University of California–Los Angeles score, nor the Shoulder Pain and Disability Index, between the two cohorts. There were no significant differences in adverse events (p=0.791) or revision rates (p=0.592). At final radiographic follow-
up there were no significant differences between the two groups with regards to the incidence of radiolucent lines on the glenoid (p=0.210) or humeral side (p=0.282).

Conclusion: At a minimum of 5-year follow-up, aTSA with a press fit glenoid implant demonstrates no difference in clinical or radiographic outcomes when compared to a glenoid cohort where the peripheral pegs are cemented. Additionally, there is no increased rate of aseptic glenoid loosening or need for revision surgery between the two groups with a lower rate of radiolucency detected compared to prior mid-term data studies. Uncemented press fit glenoid fixation with a cage component appears to be a safe and effective treatment option for patients undergoing primary aTSA at a minimum of 5-year follow-up.

Level of Evidence: Level III; Retrospective Cohort Comparison; Treatment Study

Keywords: anatomic, shoulder, arthroplasty, press fit, glenoid, prosthesis, outcomes

Anatomic total shoulder arthroplasty (aTSA) was designed to provide improved function and pain relief for patients with symptomatic osteoarthritis and a functioning rotator cuff.3,13 Aseptic glenoid loosening with cemented glenoid implants remains one of the most frequent causes of pain and implant failure.2,6 A recent study showed 100% glenoid loosening at 20 years, suggesting that a cemented all polyethylene glenoid may not be the best choice in younger patients.7 Various glenoid constructs were developed to provide adequate long-term fixation, often with little success. Metal backed glenoid components were used for a brief period, but this transition was short lived as poor outcomes and complications arose.1,10,15 Over the past ten years, hybrid glenoid constructs consisting of a monoblock polyethylene glenoid melded with
metal on the backside, which allows for bony ingrowth/ongrowth, with a central cage/peg and cementation of peripheral pegs have been developed. Clinical trials found good clinical outcomes overall, however, with varying degrees (29%–93%) of osseointegration of the central peg.4, 5, 9, 14, 16, 20 All of the previous studies cemented the peripheral pegs.

More recently, surgeons employed a modified technique in which aTSA is performed with implantation of a monoblock hybrid glenoid without the use of peripheral cementation of the peripheral pegs.9, 11, 17 The theoretical advantages of this technique include less operative time, reduction in possible heat-induced necrosis, and potentially reduced complications in the revision setting. However, there is limited data regarding the clinical and radiographic outcomes when using a press fit uncemented technique. Additionally, there is little data thus far to support hybrid glenoids beyond five years, with existing data having mixed results.4, 11

The purpose of this study is to compare the minimum 5-year clinical and radiographic outcomes of cemented peripheral pegs versus press fit uncemented glenoid constructs in aTSA. We hypothesize that there will be no clinical or radiographic differences between the two cohorts. In addition, this study will document the clinical and radiographic outcomes of an uncemented glenoid component and cemented peripheral peg glenoid component with mid-term follow-up and determine how these results compare to previously published short term results.

Materials and Methods

An international multi-institutional database was queried between January 2013 and December 2015. One hundred and sixty-nine primary aTSA patients, with a minimum follow-up period of 5 years and an average age of about 65 years, were identified and included in the study. All patients underwent primary aTSA with a hybrid cage glenoid (Equinoxe platform shoulder
system; Exactech, Gainesville, FL, USA), which incorporates a titanium plasma coated central
cage that is clean room assembled with a 4-mm-thick molded, all polyethylene, 4-peg glenoid
component. The two glenoid implantation techniques utilized an identical peg pattern and were
prepared with the same instrumentation. All caged glenoids were implanted using the same
instrumentation. All patients received the same humeral component. These procedures were
performed by six different fellowship trained surgeons. The only difference during the
implantation process was whether cement was utilized in the three peripheral peg holes during
fixation of the glenoid component. Two of the surgeons performed only the uncemented press fit
technique, and four surgeons performed the hybrid cemented technique.

All patients underwent evaluation and scoring preoperatively for demographic
information including age, sex, body mass index, prior injections, and prior surgery. Pre- and
postoperative active range of motion (ROM) measures included forward elevation, active
abduction, external rotation, and internal rotation. Forward elevation and external rotation were
measured in degrees using a goniometer. Internal rotation was measured by the vertebral level
reached by the thumb using the scale of Flurin et al. This scale assigns the following
measurements to each score, 0=0 degrees , 1= hip, 2= buttocks, 3= sacrum, 4= L4-L5, 5= L1-L3,
6= T8-T12, and 7= T7 or higher. All measurements were performed in clinic by a member of the
research team. All patients underwent evaluation and scoring preoperatively and at latest follow-
up using the Simple Shoulder Test (SST), University of California Los Angeles (UCLA),
American Shoulder and Elbow Surgeons (ASES), Constant, and Shoulder Pain and Disability
Index (SPADI) scoring metrics. Subjective shoulder function was measured on a scale from 1-
10, with a score of 10 signifying an asymptomatic, fully functional shoulder. Each patient was
asked to rate the operative shoulder at latest follow-up relative to their preoperative condition as
“much better”, “better”, “unchanged” or “worse”. Pain was rated on a scale from 1 to 10, with 10 indicating severe pain. This data was analyzed to assess patient satisfaction between cohorts.

Standardized radiographs, including a Grashey and axillary lateral, were obtained preoperatively and at scheduled follow-up visits. Before surgery, CT scans and/or magnetic resonance images were also obtained to assess glenoid morphology. Radiographs were evaluated and graded by the operating surgeon for the presence and degree of glenoid radiolucent lines (RLL) according to the Lazarus scale. Additionally, postoperative complications and revisions were reviewed and documented as well.

All statistical analyses were performed using SPSS, version 27 (IBM, Armonk, NY, USA). Differences in preoperative functionality and pain scores, and postoperative outcomes, between the press fit glenoids and hybrid cemented glenoids were evaluated. Continuous dependent variables were analyzed using the t-test, or the Mann Whitney-U test when the data was nonparametric. Binary dependent variables were analyzed using the Chi-squared test, or Fisher’s Exact test when appropriate. P < 0.05 denoted a significant difference.

Results

There were 61 press fit glenoids and 108 peripheral cemented glenoids. The average age of the press fit group was 65 years, and there were 53% female. The average age of the hybrid cemented glenoid group was 65 years, with 48% being female. The mean follow-up was 6 years (range: 5-8 years) for both groups (p=0.557). All patients in the press fit group were indicated based on a diagnosis of osteoarthritis (100%). In the cemented group, 93% of patients had a diagnosis of osteoarthritis. There were no statistically significant differences between the two
groups in terms of age, gender, body mass index, previous shoulder surgery, primary diagnosis, and mean follow-up period (Table 1).

With regards to preoperative ROM, there were significant differences between the two groups in terms of active abduction (p = 0.003) and internal rotation (p = 0.004), with higher values in the press fit group. However, they did not exceed the minimal clinically important difference (MCID). Similarly, preoperative shoulder function, SST, ASES and SPADI scores were statistically significantly higher in the uncemented group, but these significant differences did not exceed the MCID deemed to be clinically relevant. There were no differences among Constant scores (p = 0.063), UCLA scores (p = 0.077), and pain scores (p = 0.349) between the two cohorts preoperatively (Table 2).

Postoperatively, both groups had statistically significant improvements that exceeded the MCID for all range of motion measurements, all five outcome scores, pain scores and shoulder function. When comparing the two groups, press fit aTSA had significantly higher active abduction (p < 0.001) and internal rotation (p < 0.001) that exceeded the MCID, likely reflecting the pre-existing preoperative differences. However, there were no statistically significant differences in patient outcome scores between the two cohorts for the SST (p = 0.790), Constant score (p = 0.288), American Shoulder and Elbow Surgeons score (p = 0.077), University of California Los Angeles score (p = 0.554), or Shoulder Pain and Disability Index scores (p = 0.204). There were no statistically significant differences in terms of pain scores, shoulder function or patient satisfaction postoperatively between the two cohorts (p = 0.083, p = 0.904 and 0.096, respectively) (Table 3).

At final radiographic follow-up, glenoid radiolucent lines (RLL) were present in 5.7% of the press fit glenoids with a mean RLL grade of 0.2, and 14.3% of the hybrid cemented cohort
with a mean RLL grade of 0.4 (p=0.210, and p=0.227, respectively). There was no significant
difference in the incidence of humeral RLL between the two cohorts (13.5% vs 6.1%, p=0.282)
(Table 4).

In the press fit aTSA group there were 5 complications, with three patients revised due to
aseptic loosening of the glenoid component, one patient had a dissociation of the components,
and one patient had a stroke postoperatively. In the cemented group, there were 6 complications.
Three patients were revised due to aseptic loosening of the glenoid component, one patient was
revised due to a deep prosthetic infection and one patient had radiographic findings and pain
suggestive of an acute rotator cuff tear and was subsequently revised to a reverse TSA. One
patient had continued pain along the lateral aspect of the upper arm, but no revision surgery was
performed on this patient. There were no significant differences in adverse events (p=0.791) or
revision rates (p=0.592) between the two groups (Table 4).

Discussion

Aseptic glenoid loosening remains an unsolved problem in aTSA. This is the largest
cohort of patients to date with a hybrid glenoid component in aTSA, with a minimum 5-year
follow-up, evaluating differences in clinical and radiographic outcomes between cementing the
peripheral pegs versus press fit fixation. This data shows that in direct comparison to a cemented
glenoid construct, there is no difference in clinical or radiographic outcomes compared to
patients who underwent an uncemented press fit cage glenoid in aTSA. In addition, there was no
increase in the incidence of aseptic glenoid loosening or need for revision surgery. Using press
fit glenoid components can be valuable as it can improve operative time and potential reduce
unwanted complications associated with a cemented technique.
This study builds upon the prior study by Friedman et al that evaluated a hybrid cage glenoid compared to a fully cemented glenoid of the same design in aTSA with a minimum of two year follow-up. That study demonstrated comparable clinical outcomes, a significant reduction in the incidence of glenoid RLL, and a significantly lower revision rate of hybrid cage glenoids compared to age matched, sex matched, and follow-up matched cemented glenoid cohort. The present study shows that those short term results, both clinical and radiographic, become non-significant 5 to 8 years after surgery. There were similar clinical ROM and patient reported outcomes scores, as well as no significant change in the radiographic appearance with regards to RLL or RLL grades. A high percentage of patients in both groups continued to rate their aTSA as much better or better compared to their preoperative status.

As hybrid and press fit glenoid components continue to gain popularity, there has been some controversial data emerging regarding the clinical and radiographic midterm outcomes. Chen et al reported on 55 aTSA using second generation hybrid trabecular metal implants with minimum 5-year follow-up. Patients were divided into two matched cohorts: peripheral peg cementation versus press fit glenoid fixation. Excellent clinical and patient reported outcomes were demonstrated in both cohorts; however, the press fit group demonstrated higher rates of RLL (64%) compared to the cemented group (24%). No patients in either group required revision surgery or had evidence of component fracture or gross loosening. The results in the current study reflect those seen by Chen et al, except for those regarding higher rates of RLL.

Jacxsens et al performed a cohort study of 35 aTSAs undergoing uncemented implantation of a cage glenoid component with a minimum 5-year follow-up and mean follow-up of 100 months. Their results demonstrated significant improvements in clinical outcomes that were comparable to their short-term data. However, 31% of the glenoid componenets were
considered radiographically loose.\textsuperscript{11} These rates of RLL are significantly higher than the rates in the current study, both for the uncemented press-fit group and the peripheral peg cemented cohort. No components in this study were radiographically loose.

Schoch et. al published a case series with patients who underwent pressfit implantation of the same cage glenoid component used in this study, with 51 patients over a 3 year period. They demonstrated that press fit glenoid components do not lead to early loosening, allowing time for bony ingrowth to occur. They concluded that press fit fixation is a safe option for those undergoing TSA.\textsuperscript{18} However, their study did not included a comparative group and mean follow-up was only 3 years, while the current study contains a cemented control cohort and a minimum follow-up of 5 years.

The present study is not without limitations. This study lacked randomization and utilized data from six different orthopedic surgeons which potentially introduces differences in surgical technique. However, the same shoulder arthroplasty implant was used, and the same instrumentation was used for each case, yet there may still be variability in technique. Additionally, the use of a single implant does not make these findings generalizable to all anatomic total shoulder arthroplasty. Furthermore, there is inherent bias in the operating surgeon evaluating their own radiographic results. In order for more critical, unbiased assessment, future work should include independent evaluators for radiographic analysis. There was a difference in the patient population between the two groups, with the cemented group having a higher incidence of patients with inflammatory arthritis. This may have accounted for the statistical differences seen preoperatively but did not appear to affect the postoperative clinical or radiographic outcomes. There was no preoperative assessment for humeral head subluxation or glenoid wear pattern evaluation, which may predict postoperative results in aTSA. Finally,
longer term clinical and radiographic follow-up will only provide better information in terms of long term implant survivorship.

Conclusion

At a minimum 5-year follow-up, there are equivalent clinical outcomes, radiographic outcomes, complication rates and revision rates using a hybrid cage glenoid with or without the use of cement in the peripheral pegs in aTSA. The clinical and radiographic outcomes are similar to previously published studies with a shorter follow-up period, demonstrating that the results continue over time. The incidence of glenoid RLL within this cohort is lower than other recently published studies with minimum 5 year follow-up. This study supports the continued use of a hybrid cage glenoid in aTSA, and that using cement for the peripheral pegs is not required. Longer-term clinical and radiographic follow-up is needed to determine whether these mid-term radiographic improvements will correlate with lower rates of aseptic glenoid loosening and better long-term implant survivorship.

References


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291 Table Legends
292 Table 1. Demographics
293 Table 2. Preoperative Functional Outcomes
294 Table 3. Postoperative Functional Outcomes
295 Table 4. Adverse Outcomes
### Table 1. Demographics

<table>
<thead>
<tr>
<th></th>
<th>AGE (YEARS)</th>
<th>GENDER</th>
<th>BMI</th>
<th>PREVIOUS SHOULDER SURGERY</th>
<th>PRIMARY DIAGNOSIS %</th>
<th>MEAN FOLLOW-UP (YEARS)</th>
</tr>
</thead>
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<tr>
<td><strong>UNCEMENTED</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>OA 100, RA 0, ON 0</td>
<td>6</td>
</tr>
<tr>
<td><strong>N=61</strong></td>
<td>65</td>
<td>53% female</td>
<td>31</td>
<td>16%</td>
<td>OA 100, RA 0, ON 0</td>
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<tr>
<td><strong>CEMENTED</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>OA 93, RA 6, ON 1</td>
<td>6</td>
</tr>
<tr>
<td><strong>N=108</strong></td>
<td>65</td>
<td>48% female</td>
<td>30</td>
<td>21%</td>
<td>OA 93, RA 6, ON 1</td>
<td>6</td>
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<tr>
<td><strong>P-VALUE</strong></td>
<td>0.513</td>
<td>0.510</td>
<td>0.279</td>
<td>0.490</td>
<td>0.124</td>
<td>0.557</td>
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</table>

OA = Osteoarthritis, RA = Rheumatoid Arthritis, ON = osteonecrosis, Uncemented = press fit glenoids, Cemented = hybrid cemented glenoids, N = number
### Table 2. Preoperative Functional Outcomes

<table>
<thead>
<tr>
<th></th>
<th>SHOULDER FUNCTION</th>
<th>PAIN SCORE</th>
<th>SST</th>
<th>CONSTANT</th>
<th>ASES</th>
<th>UCLA</th>
<th>SPADI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UNCEMENTED</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEAN +/- SD</td>
<td>4.9 ±2.1</td>
<td>6.6 ±2</td>
<td>5.1</td>
<td>41.2 ±12.5</td>
<td>38.3 ±13.9</td>
<td>14.9 ±3.4</td>
<td>75.3 ±20.6</td>
</tr>
<tr>
<td><strong>CEMENTED</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEAN +/- SD</td>
<td>3.9 ±1.9</td>
<td>6.8 ±2</td>
<td>3.7</td>
<td>36.5 ±13.0</td>
<td>32.1 ±17.1</td>
<td>13.7 ±4.0</td>
<td>88.0 ±28.1</td>
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<tr>
<td><strong>P VALUE</strong></td>
<td>0.025</td>
<td>0.349</td>
<td><strong>0.007</strong></td>
<td>0.063</td>
<td><strong>0.048</strong></td>
<td>0.077</td>
<td><strong>0.002</strong></td>
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SD, standard deviation; SST Simple Shoulder Test; UCLA, University of California, Los Angeles; ASES, American Shoulder and Elbow Surgeons; SPADI, Shoulder Pain and Disability Index

Bolded p-values are significant.
Table 3. Postoperative Functional Outcomes

<table>
<thead>
<tr>
<th>UN-CEMENTED</th>
<th>PATIENT SATISFACTION</th>
<th>SHOULDER FUNCTION</th>
<th>PAIN SCORE</th>
<th>SST</th>
<th>CONSTANT</th>
<th>ASES</th>
<th>UCLA</th>
<th>SPADI</th>
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</thead>
<tbody>
<tr>
<td>MEAN +/- SD</td>
<td>88%</td>
<td>8.1</td>
<td>1.7 +/- 2.5</td>
<td>9.8</td>
<td>71.3</td>
<td>80.5</td>
<td>29.7</td>
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<tr>
<td></td>
<td>+/-2.4</td>
<td>+/-3.2</td>
<td>+/-16.9</td>
<td>+/-21.4</td>
<td>+/-6.2</td>
<td>+/-26.6</td>
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<tr>
<td>CEMENTED</td>
<td>95%</td>
<td>8.4</td>
<td>1.2 +/- 2.1</td>
<td>10.3</td>
<td>68.9</td>
<td>85.6</td>
<td>30.5</td>
<td>18.0</td>
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<tr>
<td></td>
<td>+/-2.1</td>
<td>+/-2.3</td>
<td>+/-13.4</td>
<td>+/-19.1</td>
<td>+/-5.5</td>
<td>+/-23.6</td>
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<td></td>
</tr>
<tr>
<td>P VALUE</td>
<td>0.096</td>
<td>0.904</td>
<td>0.083</td>
<td>0.790</td>
<td>0.288</td>
<td>0.077</td>
<td>0.554</td>
<td>0.204</td>
</tr>
</tbody>
</table>

SD, standard deviation; SST Simple Shoulder Test; UCLA, University of California, Los Angeles; ASES, American Shoulder and Elbow Surgeons; SPADI, Shoulder Pain and Disability Index
Table 4. Adverse Outcomes

<table>
<thead>
<tr>
<th></th>
<th>PRESENCE OF HUMERAL RLL</th>
<th>PRESENCE OF GLENOID RLL</th>
<th>AVERAGE GRADE OF GLENOID RLL</th>
<th>COMPLICATIONS</th>
<th>REVISION SURGERY</th>
</tr>
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<tbody>
<tr>
<td>UNCEMENTED</td>
<td>13.5%</td>
<td>5.7%</td>
<td>0.2 ±0.90</td>
<td>8.2%</td>
<td>6.6%</td>
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<tr>
<td>CEMENTED</td>
<td>6.1%</td>
<td>14.3%</td>
<td>0.4 ± 1.24</td>
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<td>4.6%</td>
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<tr>
<td>P-VALUES</td>
<td>0.282</td>
<td>0.210</td>
<td>0.227</td>
<td>0.791</td>
<td>0.592</td>
</tr>
</tbody>
</table>

Uncemented = press fit glenoids, Cemented = hybrid cemented glenoids, RLL = radiolucent lines