Humeral Fixation by Press-Fitting of a Tapered Metaphyseal Stem: A Prospective Radiographic Study

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A Prospective Radiographic Study

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Background: The technique of shoulder arthroplasty requires a method for securely and durably fixing the humeral component in the medullary canal of the proximal part of the humerus. As an alternative to fixation by cementing or tissue ingrowth, we explored the effectiveness of using a prosthesis with a metaphyseal taper from the anatomic neck to the diaphysis. This component is designed to obtain press-fit fixation in the cancellous bone of the metaphysis rather than in the cortical bone of the diaphysis. We tested the hypothesis that this press-fit humeral stem, designed to respect the taper of the proximal part of the humeral canal, would be associated with a low rate of loosening in patients managed with primary shoulder arthroplasty for osteoarthritis.

Methods: A prospective study was conducted to evaluate the prevalence of radiolucent lines around press-fit humeral prostheses. One hundred and thirty-one patients with glenohumeral osteoarthritis were followed for a minimum of two years. A zonal method of evaluating radiolucent lines was established. Shift in position and subsidence were judged qualitatively.

Results: No component showed subsidence or a shift in position. Fifty shoulders (39%) had no radiolucency. Two shoulders had radiolucency around the proximal part of the prosthesis, and seventy-five had radiolucency at the distal tip. Eleven radiolucencies were ≥1 mm in width. A neutral stem orientation was significantly less likely to be associated with radiolucency ($p = 0.026$). The prevalence of radiolucent lines did not differ between patients managed with hemiarthroplasty and those managed with total shoulder arthroplasty, and it did not increase with longer periods of follow-up.

Conclusions: In patients managed with shoulder arthroplasty, the fixation of a press-fit humeral component that has a tapered metaphyseal segment is comparable with that reported for cemented components and superior to that reported for press-fit cylindrical components.

Clinical Relevance: This type of fixation may provide an alternative to cementing of the humeral stem in individuals with glenohumeral osteoarthritis.

Level of Evidence: Therapeutic study, Level IV (case series [no, or historical, control group]). See Instructions to Authors for a complete description of levels of evidence.

The technique of shoulder arthroplasty requires a method for securely and durably fixing the humeral component in the medullary canal of the proximal part of the humerus. Historically, this fixation has been accomplished by the insertion of the component stem into unprepared bone, the insertion of the component stem into a medullary canal that has been reamed to the stem diameter, the insertion of the component body into a medullary space that has been reamed and then broached, the use of cement for fixation, and the use of a component with the capacity for tissue ingrowth. Each of these methods can be successful, but each also has limitations, such as the development of radiolucent lines around the implant, substantial rates of loosening, difficulty with component extraction for revision, and the risk of complications[1-17].

As an alternative to fixation by cementing or tissue ingrowth, we explored the effectiveness of inserting a prosthesis that has a metaphyseal taper from the anatomic neck to the diaphysis[13]. This component is designed to obtain a press-fit in the cancellous bone of the metaphysis rather than in the cortical bone of the diaphysis. We tested the hypothesis that this press-fit humeral stem, designed to respect the taper of the proximal humeral canal, would be associated with a low rate

Fig. 1-A

Fig. 1-B

Anterior (Fig. 1-A) and medial (Fig. 1-B) views of the broach used in the present study; note the taper in the medullary area.

of loosening in patients managed with primary arthroplasty for glenohumeral osteoarthritis.

Materials and Methods

A press-fit humeral component that incorporates a metaphyseal taper (Global; DePuy Orthopaedics, Warsaw, Indiana) was implanted without cement in 131 patients with glenohumeral osteoarthritis. The body of the prosthesis has a cylindrical diaphysis (ranging in size from 6 to 14 mm in 2-mm diametral increments) with proportionately sized metaphyseal elements[13]. The insertion technique includes the use of progressively larger cylindrical reamers until the first bite is achieved in the diaphysis. Reaming beyond this point is discouraged in order to minimize the risk of diaphyseal weakening and fracture. The metaphysis is then shaped with a broach that is scaled to the diaphyseal diameter (Figs. 1-A and 1-B). The rotational orientation of the broach is kept constant during broaching. This technique involves removal of only the amount of bone necessary to accommodate the prosthesis. During the study, if the prosthesis did not have sufficient stability after press-fitting (for example, if it could be moved with manually applied loads), cancellous bone harvested from the humeral head was added to the metaphyseal medullary space prior to insertion of the prosthesis.

The surgical procedures were performed by ten experienced shoulder surgeons, all of whom were members of a group of clinical investigators conducting prospective clinical research on shoulder arthroplasty performed with use of this particular prosthesis (Global; DePuy). The selection of patients for the present study was left to the discretion of the individual surgeons. The inclusion criterion was that, at the time of surgery, the surgeon concluded that the press-fit of the prosthesis was secure. The recommended criteria for confirming the initial security of fixation were (1) that the prosthesis required tapping with a mallet to drive it into its final position and (2) that the prosthesis could not be moved manually after insertion. All 131 arthroplasties that were performed by these ten surgeons and for which there was a minimum of two years of radiographic follow-up were included in this study.

The initial and follow-up radiographs for these 131 patients were submitted to an independent radiologist for zonal analysis of radiolucent lines with use of an adaptation of the system described by Gruen et al.[18]. Four patients (one of whom had had a total shoulder arthroplasty and three of whom had had a hemiarthroplasty) were excluded because the radiologist determined that the radiographs were inadequate for interpretation. The demographic data for the remaining 127 patients are shown in Table I. For the evaluation of radiolucent lines, the area of humeral fixation was divided into seven zones: zones 1 and 7 were the lateral and medial aspects of the proximal third of the area containing the stem; zones 2 and 6 were the lateral and medial aspects of the middle third of the area containing the stem; zones 3 and 5 were the lateral and medial aspects of the distal third of the area containing the stem; and zone 4 was the area at the tip of the stem. The maximum thickness of any radiolucent line in each of these zones was recorded as the radiolucency for that zone (Figs. 2, 3-A, and 3-B). The radiologist also made a qualitative assessment of whether the prosthesis was in an obvious varus or valgus position; otherwise, the position of the component was considered to be neutral. Postoperative and follow-up radio-

TABLE I Data on the Patients

No. of patients	127*
Age† *(yr)*	63.7 (40-91)
Male:female ratio	88:39
Duration of follow-up† *(mo)*	35.5 (24-84)
No. of hemiarthroplasties/no. of total shoulder arthroplasties	34/93

*Data are given only for the patients who had suitable radiographs for analysis. †The data are given as the average, with the range in parentheses.

Fig. 2
Radiograph of a well-fixed press-fit humeral component, showing no radiolucent lines at four years after surgery.

graphs were compared to enable the radiologist to make a qualitative judgment regarding whether subsidence or a shift in position had occurred. Any component with subsidence or a shift in position was deemed to be loose. An analysis of variance was conducted to compare the radiolucency rates among the shoulders with neutral, varus, and valgus components as well as between patients who had had a hemiarthroplasty and those who had had a total shoulder arthroplasty. The relationship between the radiolucency rate and the duration of follow-up was subjected to a correlation analysis.

Results

No component showed subsidence or a shift in position. Fifty (39%) of the 127 shoulders with suitable radiographs had no radiolucency. Of the seventy-seven shoulders that had some radiolucency, two had radiolucency in the proximal four zones and seventy-five had radiolucency only at the distal tip. Only eleven radiolucent lines were ≥ 1 mm in width (Fig. 4). A neutral stem orientation was significantly less likely to be associated with radiolucency (Table II). The rate of radiolucent lines was not different between patients who had had a hemiarthroplasty and those who had had a total shoulder arthroplasty (59% [twenty of thirty-four] compared with 61% [fifty-seven of ninety-three]). During the first four postoperative years, the duration of follow-up did not influence the radiolucency rate; specifically, the radiolucency rate was 60% (thirty-three of fifty-five) among patients who had been followed for at least twenty-four months, 69% (twenty-nine of forty-two) among those who had been followed for at least thirty-six months, and 50% (fifteen of thirty) for those who had been followed for at least forty-eight months.

Discussion

The technique of shoulder arthroplasty requires a method for securely and durably fixing the humeral component in the medullary canal of the proximal part of the humerus. The complexities of the shape of the proximal medullary canal include (1) a substantial metaphyseal canal at the anatomic neck of the humerus where the proximal end of the prosthesis rests, (2) a smaller canal in the diaphysis at the distal end of the prosthesis, and (3) a taper between the two. Robertson et al. recently pointed out that the shape of the canal is more complex than previously recognized in that the cross sections of the proximal part of the humerus are elliptical, with a spiraling major axis from proximal to distal[19]. Those authors also pointed out that the average taper is from a cross-sectional area of 1300 mm^2 at the surgical neck to 339 mm^2 in the diaphysis but that "proximal humeral morphology was extremely variable as highlighted by the large ranges of measurements seen for all variables."[19] In the early days of shoulder arthroplasty, only a few sizes of straight stems were available[9-11]. As a result, a secure press-fit of the stem

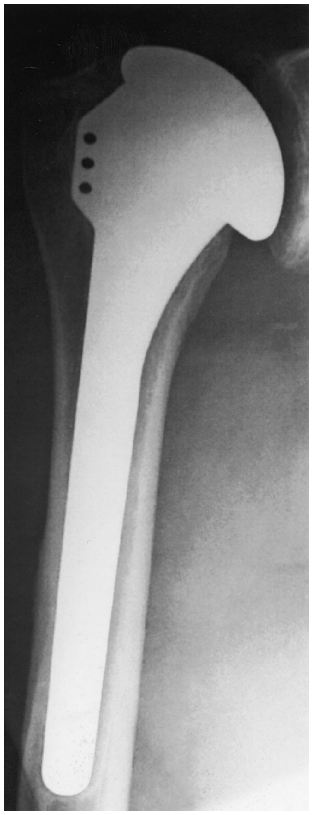

Fig. 3-A

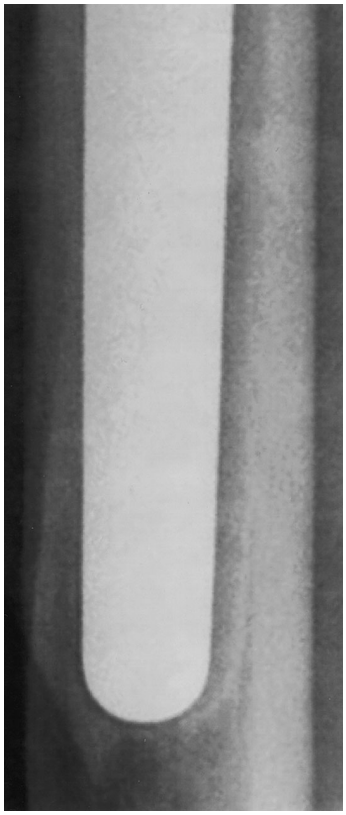

Fig. 3-B

Fig. 3-A Radiograph of a shoulder with a press-fit humeral component, showing a radiolucent line with a width of >2 mm in zone 4 at three years after surgery. **Fig. 3-B** Close-up radiograph showing the radiolucent line in zone 4.

TABLE II Prevalence of Radiolucent Lines Around Varus, Valgus, and Neutral Components

	Orientation of Humeral Component		
	Varus	Valgus	Neutral
No. of shoulders	10	6	111
No. of shoulders with radiolucent lines	9 (90%)	5 (83%)	63 (57%)*

*P = 0.026.

in the canal often could not be achieved, and cement was necessary for secure fixation.

In the past, cylindrical medullary reamers were used in an attempt to convert part of the shape of the medullary canal to a cylinder corresponding with the diameter of a limited number of humeral component stems[8]. While this approach enabled the press-fitting of more stems, a cylindrical stem still had the potential to slide and rotate within a cylindrical canal (Fig. 5). In 1990, Neer pointed out, "When a good fit has been obtained in the humerus, there has rarely been a problem of loosening of the implant. A loose fit with motion may result in further resorption of the bone and further loosening. Unless a firm press fit is obtained, a grouting material, currently acrylic cement should be added."[8]

As predicted by Neer, radiographic evaluations in short and intermediate-term follow-up studies have revealed a small but definite prevalence of implant subsidence or complete radiolucent lines[2-5,12]. Complete radiolucent lines have been reported more frequently around uncemented humeral components[1-7,12,14]. In a series of 113 total shoulder arthroplasties performed with a straight-stemmed (Neer) prosthesis between 1975 and 1981, a shift in position of the humeral component occurred in forty of the eighty-one shoulders with a press-fit stem and in none of the shoulders with a cemented stem[17]. In a more recent update, seventy-two shoulders in which a total shoulder arthroplasty was performed with use of the Neer-II press-fit humeral component were followed radiographically for an average of 4.1 years (range, 2.0 to 7.8 years)[15]. The humeral component was considered to be at risk for clinical loosening when a radiolucent line measuring ≥2 mm in width was present in more than two zones or when tilt or subsidence was identified on sequential radiographs by a majority of the three independent observers. Forty components (55.6%) were judged to be at risk. The group with an at-risk humeral component had no identifiable characteristics other than a longer average duration of follow-up (4.7 years compared with 3.3 years, $p = 0.001$). Humeral components that were at risk were associated with a higher rate of endosteal erosion ($p = 0.04$) and a greater number of zones with sclerosis. Radiographic changes around Neer-II uncemented humeral components are common. None of the humeri in the present study would be considered to be at risk according to the criteria of Sanchez-Sotelo et al.[15].

Press-fitting has the advantages of preserving bone stock and facilitating revision. The results of the present study indicate that press-fitting of a humeral component with a tapered metaphyseal segment can provide fixation that is comparable with that reported for cemented components and superior to that reported for press-fit cylindrical stems.

The results of the present study must be viewed in light of certain limitations. The surgeons were experienced in shoulder arthroplasty and, as such, may not be representative of surgeons in community practice. The surgeons used their

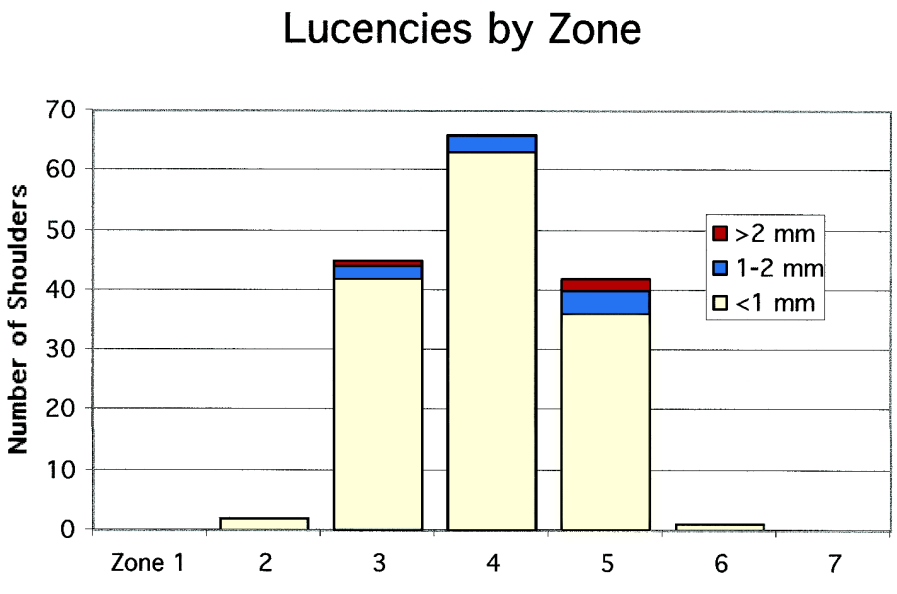

Fig. 4
Graph depicting the size and location of the radiolucent lines in each zone.

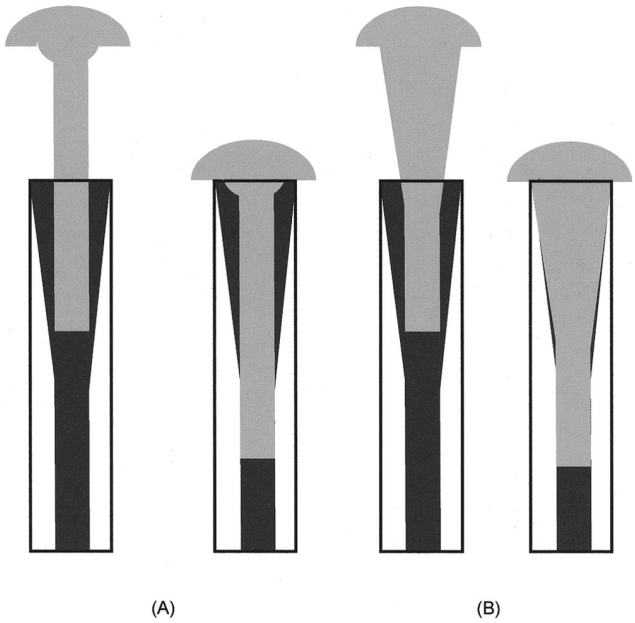

Fig. 5

Illustrations of a prosthesis designed to fit a reamed diaphysis *(A)* and a prosthesis designed to fit a broached metaphysis *(B)*.

own clinical judgment to determine which patients were appropriate for this prosthesis and this technique of fixation. Data on the patients who were excluded from the study by the individual surgeons are not available. In the cases of the 131 patients described here, the surgeons determined that satisfactory fit was achieved at the time of surgery. We do not have data regarding the cases in which the surgeons determined that difficulties were sufficient to preclude the use of this press-fit approach. The duration of follow-up was limited, and longer-term evaluation may reveal a different radiolucency rate. The radiographic results were not correlated with the clinical outcome; thus, the clinical importance of these radiolucent lines was not established in the present study. Finally, the individual variations in technique among surgeons were not documented to determine if they had an effect on the prevalence or magnitude of radiolucent lines. In spite of these limitations, the fact remains that this group of metaphyseal press-fit stems demonstrated no radiographic loosening at five to seven years of follow-up. This type of fixation may be an effective alternative to cementing the humeral stem in individuals with glenohumeral osteoarthritis. ■

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