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## ORIGINAL ARTICLE

# Nine-year outcome after anatomic stemless shoulder prosthesis: clinical and radiologic results

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**Background:** Several stemless shoulder implants are available on the market, but only a few studies have presented results with sufficient mid- to long-term follow-up. The present study evaluated clinical and radiologic outcomes 9 years after anatomic stemless shoulder replacement.

**Methods:** This is a prospective cohort study evaluating the stemless shoulder prosthesis since 2005. Anatomic stemless shoulder replacement using a single prosthesis was performed in 49 shoulders; 17 underwent total shoulder replacement, and 32 underwent hemiarthroplasty. Forty-three patients were clinically and radiologically monitored after a mean of 9 years (range, 90-127 months; follow-up rate, 88%). The indications for shoulder replacement were primary osteoarthritis in 7 shoulders, post-traumatic in 24, instability in 7, cuff tear arthropathy in 2, postinfectious arthritis in 1, and revision arthroplasty in 2.

**Results:** The Constant-Murley Score improved significantly from 52% to 79% ( $P < .0001$ ). The active range of motion also increased significantly for flexion from 101° to 118° ( $P = .022$ ), for abduction from 79° to 105° ( $P = .02$ ), and for external rotation from 21° to 43° ( $P < .0001$ ). Radiologic evaluation revealed incomplete radiolucency in 1 patient without clinical significance or further intervention. No revision caused by loosening or countersinking of the humeral implant was observed.

**Conclusions:** The 9-year outcome after stemless shoulder replacement is comparable to that of third- and fourth-generation standard shoulder arthroplasty.

**Level of evidence:** Level IV; Case Series; Treatment Study

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**Keywords:** Stemless shoulder arthroplasty; primary osteoarthritis; post-traumatic osteoarthritis; shoulder; total shoulder arthroplasty; hemiarthroplasty; canal-sparing shoulder arthroplasty

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The surgical treatment option for severe glenohumeral arthritis is shoulder arthroplasty, resulting in loss of pain and improvement of shoulder function.<sup>5,10,31</sup> As a result of complications caused by the stemmed implant design, such as bone stock loss, intraoperative and postoperative periprosthetic fractures, malpositioning of the humeral implant, especially in

post-traumatic cases with malalignment, and an altered center of rotation, the development of new concepts has been necessary.<sup>7,24</sup>

To provide the advantages of 3-dimensional reconstruction of the humeral head and avoid stem-related complications, Biomet, Inc. (Warsaw IN, USA) introduced a stemless prosthesis, the Total Evolutive Shoulder System (TESS), in 2004.<sup>20</sup> The second stemless design available was the Eclipse shoulder prosthesis (Arthrex, Inc., Naples, FL, USA) and first introduced in 2005. In contrast to other implants, the Eclipse prosthesis offers epiphyseal and metaphyseal anchoring and is inserted over a compression screw for primary stability of the implant. A number of different stemless implants are currently available on the market. However, all types of prostheses aim to reconstruct the humeral center of rotation independent from the shaft axis and to avoid additional osteotomy of greater tuberosity in post-traumatic cases.

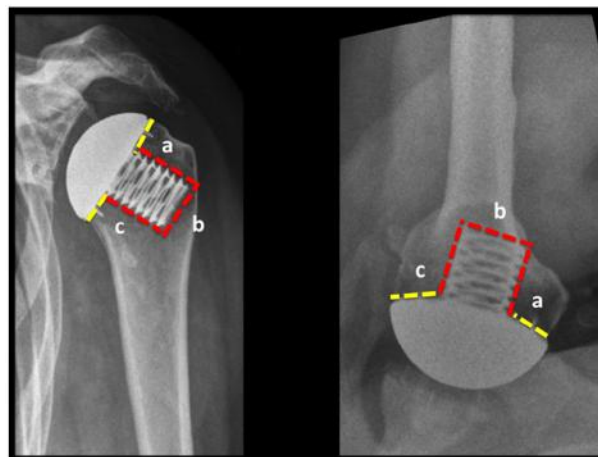
Short- and midterm outcomes available in the literature offer very promising clinical and radiologic results.<sup>4,5,9,22,25,29,33,39,41</sup> Nevertheless, studies with longer follow-up are needed to definitively prove the benefits of this kind of implant. Here, we present clinical and radiologic results obtained 9 years after implanting the Eclipse stemless anatomic shoulder prosthesis. In 2015 we published our results after stemless shoulder arthroplasty with a follow-up of 72 months.<sup>22</sup> The analyzed data and presented results of the current study may involve the same patient cohort, but all patients were evaluated at a different follow-up time.

## Materials and methods

This is a prospective cohort study evaluating the stemless shoulder prosthesis. The stemless shoulder prosthesis has been evaluated prospectively by the senior author (P.H.) since 2005. Included are 49 humeral arthroplasties (27 women and 22 men), with a mean follow-up of 9 years (range, 90-127 months). The patients were a mean age of 56 years (range, 21-81 years). The study excluded patients with rheumatoid arthritis, osteoporosis, and large subchondral cysts. All patients were seen at our hospital 6 weeks, 3 months, 6 months, and 1 year after surgery, and then annually for clinical and radiologic follow-up. Six patients were lost to follow-up, resulting in a follow-up rate of 88% (n = 43).

The age- and sex-related Constant-Murley Score was used to assess the clinical results.<sup>16,17</sup> The ISOBEX dynamometer (MDS Medical Device Solutions AG, Oberburg, Switzerland) was used to measure abduction strength. Radiologic follow-up was performed by examination in 3 planes: true anteroposterior, axillary, and scapular Y views. These planes were used to assess humeral- and glenoid-sided radiolucency, to evaluate changes in mineral bone density, to analyze secondary glenoid wear in cases of hemiarthroplasty, and to observe possible superior migration of the humeral head over time (gothic arc). We used a previously described zone classification in the anteroposterior (AP) and the axillary views by dividing the surrounding humeral and glenoidal bony area in 3 zones (zone A, B, and C; Fig. 1).<sup>22</sup>

Superior migration of the humeral head was defined as progressive discontinuation of the gothic arc compared with the postoperative AP radiographs 6 weeks after surgery. Rotator cuff deficiency was



**Figure 1** We used a previously described zone classification system in the anteroposterior and the axillary views by dividing the surrounding humeral bony area in three different zones (zone a, b, and c).

defined as migration of the humeral head in addition to a loss of active range of motion.

A total of 32 patients were treated with hemiarthroplasty and 17 with total shoulder arthroplasty using a metal-backed glenoid (n = 13) component or a cemented all-polyethylene-keeled glenoid (n = 4) component. Fig. 2 shows a 78-year-old woman 10 years after the hemiarthroplasty procedure. All data were collected as part of the standardized clinical investigation through experienced orthopedic surgeons (P.H., P.M., S.L., M.T.), and all patients provided written consent for the use of their anonymized data.

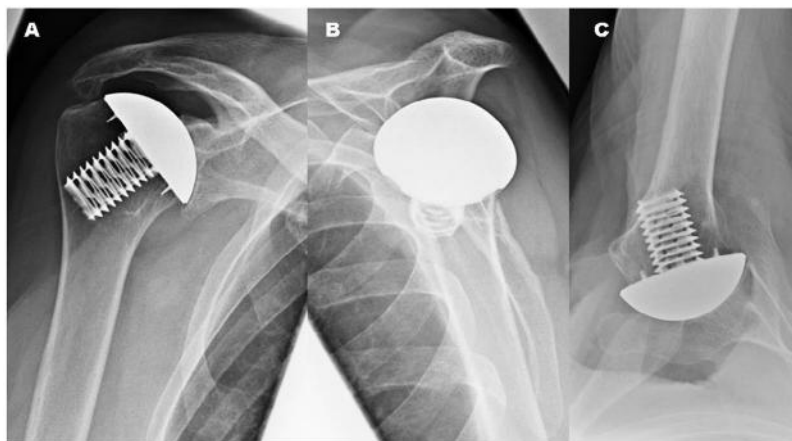
## Surgical technique

The procedure was performed in all patients by the senior author. The patient was placed in a beach chair position after general anesthesia and interscalene brachial plexus block. A deltopectoral approach was used, and arthrotomy was performed by subscapularis tenotomy. The humeral head was resected at the level of the anatomic neck, the trunnion size was determined using a drill template, and the length of the cage screw was determined using a special cage screw sizer.

After the glenoid arthroplasty, if needed, was completed, the definite trunnion was seated onto the cortical rim of the anatomic neck without overlap, and the definite cage screw was inserted into the cancellous metaphyseal bone near, but not perforating, the lateral cortex. Thus, trunnion compression is achieved resulting in primary stable head fixation. A trial humeral head was used to determine the definite head size. After the humeral head was placed onto the trunnion, reattachment of the subscapularis tendon and wound closure were performed in standard fashion.

## Postoperative rehabilitation

After surgery, the shoulder was immobilized by an abduction brace for 3 weeks. Rehabilitation began on the first postoperative day, restricted to passive motion (45° flexion, 30° abduction, 45° internal rotation, 10° external rotation). The range of motion was



**Figure 2** Radiographs in (A) anteroposterior, (B) outlet, and (C) axillary views are shown for a 78-year-old woman with a 10-year follow-up after hemiarthroplasty.

**Table I** Overall functional results

| Variable              | Preoperative Mean (SD) | Postoperative Mean (SD) | <i>P</i> value (pre-op vs. post-op) |
|-----------------------|------------------------|-------------------------|-------------------------------------|
| Constant-Murley Score |                        |                         |                                     |
| Relative, %           | 52 (20)                | 79 (21)                 | <.0001                              |
| Absolute, points      | 42 (16)                | 62 (17)                 | <.0001                              |
| Pain, points          | 8 (4)                  | 12 (3)                  | <.0001                              |
| ADL, points           | 9 (4)                  | 13 (5)                  | .008                                |
| ROM, points           | 17 (9)                 | 24 (8)                  | .001                                |
| Strength, points      | 7 (3)                  | 8 (7)                   | .674                                |
| Active                |                        |                         |                                     |
| Flexion, °            | 101 (47)               | 118 (43)                | .022                                |
| Abduction, °          | 79 (50)                | 105 (43)                | .020                                |
| External rotation, °  | 21 (27)                | 43 (19)                 | <.0001                              |

ADL, activities of daily living; ROM, range of motion; SD, standard deviation.

advanced after the fourth week (90° flexion, 70° abduction, 70° internal rotation, and 20° external rotation), and active and passive range of motion was possible without limitation after week 6.

## Statistical analysis

Statistical analyses were performed using SPSS 19.0 software (IBM Corp., Ehningen, Germany). The level of significance was set at  $P < .05$ . Differences in preoperative and postoperative nonparametric data were analyzed using the Wilcoxon signed rank test. Analyses between groups of patients were performed using the Mann-Whitney  $U$  test.

## Results

Of the 43 patients included in the analysis, the indications for shoulder replacement were primary osteoarthritis in 7, post-traumatic in 24, instability in 7, cuff tear arthropathy in 2, postinfectious arthritis in 1, and revision arthroplasty in 2. Our total results revealed a significant improvement in the overall Constant-Murley Score ( $P < .0001$ ), pain ( $P < .0001$ ),

activity of daily living ( $P = .008$ ), and range of motion ( $P = .001$ ). A certain improvement was noted in abduction strength without yielding statistical significance ( $P = .674$ ; Table I). Active flexion improved from  $101^\circ \pm 47^\circ$  to  $118^\circ \pm 43^\circ$  ( $P = .022$ ), active abduction improved from  $79^\circ \pm 50^\circ$  to  $105^\circ \pm 43^\circ$  ( $P = .02$ ), and active external rotation improved from  $21^\circ \pm 27^\circ$  to  $43^\circ \pm 19^\circ$  ( $P < .0001$ ).

We found no differences in the Constant-Murley Score and subcategories between the patients who underwent hemiarthroplasty and those who underwent total shoulder arthroplasty (Table II). Improvement in the Constant-Murley Score was from 48% to 79% in the hemiarthroplasty group ( $P < .0001$ ) and from 61% to 79% in the total shoulder arthroplasty group ( $P = .046$ ). In addition, the active range of motion did not differ between these groups, with 24 Constant-Murley Score points in the hemiarthroplasty group and 23 points in the total shoulder arthroplasty group. The Constant-Murley pain score (points) in the hemiarthroplasty group was 7 before arthroplasty and 12 after ( $P = .001$ ) and in the total shoulder arthroplasty was 9 before and 13 points after ( $P = .138$ ; Table II).

**Table II** Functional results of hemiarthroplasty and total shoulder arthroplasty in all patients

| Variable                     | HSA<br>preoperative<br>Mean (SD) | HSA<br>postoperative<br>Mean (SD) | HSA<br><i>P</i> value<br>(pre-op vs. post-op) | TSA<br>preoperative<br>Mean (SD) | TSA<br>postoperative<br>Mean (SD) | TSA<br><i>P</i> value<br>(pre-op vs. post-op) |
|------------------------------|----------------------------------|-----------------------------------|---|----------------------------------|-----------------------------------|---|
| <b>Constant-Murley Score</b> |                                  |                                   |   |                                  |                                   |   |
| Relative, %                  | 48 (20)                          | 79 (23)                           | <.0001  | 61 (18)                          | 79 (15)                           | .046  |
| Absolute, points             | 39 (16)                          | 62 (19)                           | <.0001  | 47 (15)                          | 63 (8)                            | .046  |
| Pain, points                 | 7 (3)                            | 12 (3)                            | .001  | 9 (5)                            | 13 (2)                            | .138  |
| ADL, points                  | 8 (4)                            | 12 (5)                            | .025  | 11 (4)                           | 15 (3)                            | .125  |
| ROM, points                  | 17 (10)                          | 24 (9)                            | .005  | 19 (8)                           | 23 (8)                            | .034  |
| Strength, points             | 6 (3)                            | 10 (8)                            | .345  | 8 (3)                            | 6 (3)                             | 1   |
| <b>Active</b>                |                                  |                                   |   |                                  |                                   |   |
| Flexion, °                   | 102 (51)                         | 118 (47)                          | .124  | 101 (38)                         | 119 (33)                          | .060  |
| Abduction, °                 | 82 (51)                          | 106 (45)                          | .055  | 72 (47)                          | 103 (41)                          | .192  |
| External rotation, °         | 24 (23)                          | 80 (18)                           | .003  | 14 (36)                          | 42 (21)                           | .012  |

ADL, activities of daily living; HSA, hemishoulder arthroplasty; ROM, range of motion; SD, standard deviation; TSA, total shoulder arthroplasty.

**Table III** Functional results in post-traumatic arthritis

| Variable                     | Preoperative<br>Mean (SD) | Postoperative<br>Mean (SD) | <i>P</i> value<br>(pre-op. vs post-op) |
|------------------------------|---------------------------|----------------------------|--|
| <b>Constant-Murley Score</b> |                           |                            |  |
| Relative, %                  | 48 (19)                   | 77 (23)                    | .001                                   |
| Absolute, points             | 38 (16)                   | 60 (17)                    | .001                                   |
| Pain, points                 | 8 (4)                     | 12 (3)                     | .002                                   |
| ADL, points                  | 8 (4)                     | 12 (5)                     | .054                                   |
| ROM, points                  | 16 (9)                    | 21 (9)                     | .014                                   |
| Strength, points             | 7 (3)                     | 8 (4)                      | 1                                      |
| <b>Active</b>                |                           |                            |  |
| Flexion, °                   | 89 (45)                   | 106 (46)                   | .031                                   |
| Abduction, °                 | 66 (39)                   | 92 (40)                    | .013                                   |
| External rotation, °         | 8 (23)                    | 35 (16)                    | <.0001                                 |

ADL, activities of daily living; ROM, range of motion; SD, standard deviation.

Arthroplasty was performed in 24 patients (14 women and 10 men) because of post-traumatic avascular necrosis. The mean age in this group was 57 years (range, 37-81 years). The mean follow-up in this subgroup was 108 months (range, 90-127 months). Hemiarthroplasty was performed in 19 of these patients and total shoulder arthroplasty in 5. We found significant preoperative to postoperative improvement from 48% to 77% in the overall Constant-Murley Score ( $P = .001$ ; Table III).

### Radiologic assessment

Upward migration of the humeral head occurred in 14.7% of patients. Incomplete radiolucency  $\leq 1$  mm was observed in 2.3% of patients. Our cohort did not present with loosening of the humeral implant. One post-traumatic patient experienced post-traumatic resorption of the greater tuberosity without influence on the stability of the implant and without further intervention. Lowering of bone mineral density in zone A was observed on the AP radiographs of the humerus in

29.4% of patients. This radiologic phenomenon was not observed in all of these patients on their axillary radiographs. In addition, it was not influenced by age or follow-up time and did not affect the Constant-Murley Score or active range of motion.

On the glenoid side, 1 hemiarthroplasty developed secondary glenoid wear and was revised to total shoulder arthroplasty. In 27.3% of total shoulder arthroplasties, an incomplete radiolucent line was observed at the glenoid side without loosening (cemented all-polyethylene glenoid components, 4 total; cementless metal-backed glenoid component, 13 total). Radiolucency in cemented all-polyethylene glenoid components was noted in 2 patients in zone A and in zone B on the AP radiographs. Radiolucency in cementless metal-backed glenoid components was noted in 1 patient in zone A and zone C on the AP radiographs, in 1 patient in zone A and zone C on the axillary radiographs, and in 1 patient in zone C on the AP radiograph. The zone classification system is illustrated in Fig. 1.<sup>22</sup>

## Complications

An infection in 1 patient (2.3%) led to explantation 7 months after the initial surgery, and an anatomic stemmed prosthesis was implanted as the second stage. A rotator cuff deficiency in 6 patients (13.8%) resulted in a pectoralis major transfer 6 months after surgery in 1 patient and a reverse shoulder prosthesis implanted 74 months after the initial surgery in 1 patient. These cases included the 2 patients with cuff tear arthropathy, as described before. No surgical intervention was performed in the other 4 patients with rotator cuff deficiency. Resorption of a greater tuberosity was observed in 1 patient (2.3%) without revision. A proximal humeral fracture occurred in 1 patient (2.3%) at the surgical neck after a fall at 7 postoperative weeks and was treated conservatively. No humeral implant-related complication was observed. The overall humeral-side complication rate in our cohort was 9.3%. The humeral implant-related complication rate was 0%.

## Discussion

Even if rare, humeral stem-related complications in shoulder arthroplasty present a challenge for surgeons. Complications, such as intraoperative or postoperative periprosthetic fractures, changes in bone constitution with loosening and osteolysis around the stem, and removal of the fixed implant in revision or conversion cases with subsequent bone loss, limit and challenge the surgical options in revision procedures.<sup>2,6,8,11,12,14,15,18,19,27,30,35,36,38,40,42-47</sup>

Especially in post-traumatic or deformity changes of the shoulder joint, or both, restoring the glenohumeral center of rotation could present a challenge. By using a stemless or so-called canal-sparing implant, restoration is possible independent from the humeral shaft.<sup>28</sup> The benefits of a stemless or canal-sparing implant are summarized by Athwal<sup>1</sup> with a theoretically decreased surgical time, less blood loss, bone preservation, and lower risk of intraoperative and, potentially, postoperative periprosthetic fractures. In addition, explantation, if needed, is easier because a standard stem and the stemless or canal-sparing implant could be replaced by a standard-length primary implant. Exactly 1 patient like this is described in our cohort.

Stemless metaphyseal anchored, or canal-sparing, implants, were introduced in 2004. In 2010, Hugué et al<sup>25</sup> first published the results of stemless shoulder arthroplasty using the Total Evolutive Shoulder System (TESS; Biomet, Inc., Warsaw, IN, USA) in 63 patients after a minimum follow-up of 3 years. They reported significant clinical improvement and inconspicuous radiologic follow-up. Ten additional reports on stemless shoulder prostheses (different manufacturers) were then published.<sup>4,5,9,13,22,25,29,33,39,41</sup> A literature review revealed a mean follow-up of 6 to 72 months in these studies.<sup>23</sup> Only 7 reports had a follow-up of at least 24 months, and only 2 studies had a follow-up longer than 3 years (ie, 45 and 72 months). All of the studies concluded that to assess this kind of new implant, studies with longer follow-ups are needed.

Among the various investigated stemless prostheses, the main difference in design is that the Eclipse is additionally inserted over a screw, and the other prostheses are inserted only using an impaction technique. Through implantation through a screw and a trunnion, primary stability of the humeral implant is immediately ensured, not only after bony healing process.

The Eclipse shoulder prosthesis was developed by the senior author (P.H.) and first implanted in 2005. Short- and midterm results (23 and 72 months, respectively) have been published, showing significant improvement without humeral-related complications.<sup>9,22,41</sup> To the best of our knowledge, this study is the first to present a longer follow-up of 9 years for the clinical and radiologic results after stemless shoulder replacement, regardless of the type of implant.

Our overall results revealed significant clinical improvement. This is in accordance with the current literature describing the stemless shoulder arthroplasty as a successful treatment option. Nevertheless, only short- to midterm results have been published until now, which must be taken into consideration. In addition, a certain bias is possible because some of these studies are presented by the designer or codeveloper of the implants.<sup>23</sup>

Comparing the results after hemiarthroplasty and total shoulder arthroplasty, we did not observe differences in the Constant-Murley Score (79% both; **Table II**). Notably, hemiarthroplasty was performed only in patients with a glenoid type A2 according to the Walch classification. Also, the subgroup analysis of the post-traumatic patients revealed statistical significant improvement in the Constant-Murley Score (**Table III**). That primary osteoarthritis is a different entity than post-traumatic osteoarthritis must be taken into account. In the former, there is an osteoarthritic process ongoing on the humeral and the glenoidal side. In post-traumatic osteoarthritis, however, patients mostly do not suffer an ongoing osteoarthritic process in the glenoid.

The radiologic analysis showed an incomplete radiolucency in zone A in 29.4% in the AP radiographs without loosening of the implant or clinical symptoms. For assessment of humeral bone density conventional radiographs do not present an adequate measurement tool.<sup>37</sup> In a previous published study, we hypothesized these changes in the area of the greater tuberosity without changes in the cortical bone thickness were an indication for focal internal remodeling or an age-related osteopenia.<sup>3,26,35</sup> Unlike other types of implants, the Eclipse prosthesis is additionally inserted over a screw. This could reveal changes in transmission forces of the proximal humerus and could explain the radiologic changes in terms of stress shielding. A finite element analysis could show that compressive joint forces are transmitted from the articular surface of the prosthesis to the medial calcar.<sup>32</sup> Contrary to other stemless prostheses, where no radiologic changes are described, the Eclipse prosthesis does not fill out respectively or cover the area of the greater tuberosity. Nevertheless, even a subgroup analysis could not reveal any clinical influences of these radiologic changes in the long-term follow-up of 9 years.

The prevalence of substantial changes in the rotator cuff with increasing age also in patients without intervention is a known phenomenon.<sup>48</sup> Melis et al<sup>34</sup> retrospectively evaluated failures after anatomic shoulder arthroplasty revised by reverse shoulder arthroplasty. They included 37 patients with failure after anatomic shoulder arthroplasty, with a mean interval of 75.3 months between the primary intervention and revision. The reason for revision in 24 patients was a rotator cuff tear. Young et al<sup>49</sup> described a humeral head migration using a third-generation implant in 46.5% of patients after a mean follow-up of 10 years. Our study revealed an upward migration in the radiologic examination in 14.7% of patients. These results are in accordance with literature and do not present as a failure of the implant.

In accordance with the studies presenting results after stemless shoulder arthroplasty, our patients did not experience any complications related to the humeral component. The clinical results after stemless shoulder arthroplasty are comparable to third- and fourth-generation stemmed implants for primary osteoarthritis and post-traumatic arthritis as presented, for example, by Gonzales et al,<sup>21</sup> Young et al,<sup>49</sup> and Raiss et al.<sup>38</sup>

Nevertheless, this study has some weaknesses. Shoulder arthroplasty was performed for different indications, presenting the largest group with post-traumatic cases. We did not include a control group for comparison purposes. In addition, follow-up measures were performed by the surgeon or by qualified medical personnel not blinded to the patient's surgery or prosthesis.

## Conclusions

Our study indicates that good results are obtained up to 9 years by using a stemless humeral implant. Follow-up revealed no loosening of the humeral implant. The clinical results were comparable to third- and fourth-generation stemmed implants.

## Disclaimer

Peter Habermeyer receives patent fees for the Eclipse Prosthesis from Arthrex, Inc. Peter Habermeyer, Mark Tauber, and Sven Lichtenberg are consultants for Arthrex, Inc. None of the other authors, their immediate families, and any research foundations with which they are affiliated have received any financial payments or other benefits from any commercial entity related to the subject of this article.

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