

Anterior Cervical Plate Stabilization in One- and Two-Level Degenerative Disease: Overtreatment or Benefit?

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Summary: This consecutive case retrospective chart review of 356 patients compares the reoperation rate of one- and two-level anterior cervical discectomies for degenerative disease with and without anterior cervical plate stabilization (ACPS). A total of 210 patients underwent surgery without ACPS (bone alone) and 146 patients underwent surgery with the addition of ACPS. Follow-up ranged from 1 to 9 years. A total of 22 patients with one- or two-level cervical arthrodesis required a second surgical intervention (19 bone alone, 3 with ACPS). Reoperations were performed in the bone-alone group for pseudarthrosis in 12 cases and for progression of degenerative disease in 7 cases. The reoperations in the ACPS group were performed for pseudarthrosis in one case and settling of the graft with screw fracture before fusion in two cases. The log-rank test, which uses all patients and their total follow-up periods, was statistically significant in favoring ACPS ($p = 0.05$). Furthermore, the reoperation rate after 1 year was also significantly lower when ACPS was utilized compared with bone alone ($p = 0.0308$, Fisher's exact test, two tailed). These data provide evidence that the addition of ACPS in one- and two-level cervical degenerative disease does not constitute overtreatment but rather supplements the internal stabilization initially provided by the bone graft and yields a lower reoperation rate. **Key Words:** Anterior cervical plate stabilization—Anterior cervical discectomy.

The optimal technique of performing stabilization, arthrodesis, and alignment of a cervical segment following discectomy with neural decompression in degenerative disease has yet to be determined. Anterior arthrodesis following discectomy has been reported utilizing no graft (25,32,42,43,53,57,67,69,70), allograft (14,26,28,33,41,58, 59,71), autograft (12,14,21,27,30,31,34,37,38,44,48,56), hydroxylapatite (10,24,50,51,72), and polymethyl methacrylate (9). Anterior cervical arthrodesis has also been reported both with and without (Fig. 1) the addition of an anterior cervical plate stabilization (ACPS).

Graft fracture, dislocation, or resorption can lead to a nonunion and may cause angular deformity (Fig. 2), subluxation, and/or pain. Graft dislocation (Fig. 3) can also lead to dysphagia. These complications not only result in unsatisfactory pain resolution but often require a second surgical intervention to complete a solid fusion of the segment and restore the normal lordotic anatomic alignment. Nonunion occurs in 4–26% of single-level fusions without ACPS (6,68). The pseudarthrosis rate for two- and three-level procedures has been reported to be 17–63 and 50%, respectively, without ACPS (2,9,13,45,55). Instability caused by pseudarthrosis produces long-term or persistent painful neck-shoulder-arm syndromes in 33–60% (2,13,45,47) of the cases and requires a second surgical intervention (19).

The advantages of using anterior trapezoidal plate stabilization with bicortical screws in cases involving trau-

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FIG. 1. Lateral cervical radiograph 5.7 years after a C6-7 arthrodesis with autologous iliac crest bone graft and 2.3 years after a C5-6 arthrodesis with allograft fibula cadaver graft and anterior cervical plate stabilization. Note both levels have a mature fusion and have maintained the lordotic and disc space height correction.

matic instability, strut fusions in tumors, inflammatory processes, multisegmental fusions in degenerative diseases, single- and multilevel myelopathy, and "failed fusion" were first reported in 1981 with a 98% fusion rate (15). These advantages included immediate stability, restoration of the normal lordotic curve, shortened fusion time, enhanced fusion quality, and significant reduction of

pseudarthrosis rates to 2% (15-20). Other authors have also confirmed these initial findings (1,8,11,19,20,23,36,39,40,47,52,60,61,63,65,66,68). Unicortical plating has also been reported to be beneficial.

It was our clinical impression that radiographically mature and clinically pain-free fusions were routinely obtained with the addition of ACPS in cases that failed to mature into a solid fusion or had dislocated the bone graft in a prior arthrodesis without plating (Fig. 3B). It was therefore hypothesized that the addition of the plating step to a one- or two-level anterior cervical decompression and arthrodesis performed for degenerative disease would enhance the fusion rate and decrease the need for a second surgical intervention.

The objectives of this study were first to assess whether the number of patients requiring a second cervical surgical intervention was changed as a result of utilizing ACPS and second to determine the additional risks associated with the hardware implantation and its benefits.

MATERIALS AND METHODS

This study is a consecutive case retrospective chart review of the experience at two neurosurgical spine centers (Chicago Institute of Neurosurgery and Neuroresearch, Chicago, IL, U.S.A., and University of Saarland, Homburg/Saar, Germany) with one- or two-level anterior cervical discectomies and arthrodesis for treatment of degenerative disease performed both without (210 total; 153 Illinois, 57 Germany) and with (146 total; 95 Illinois, 51

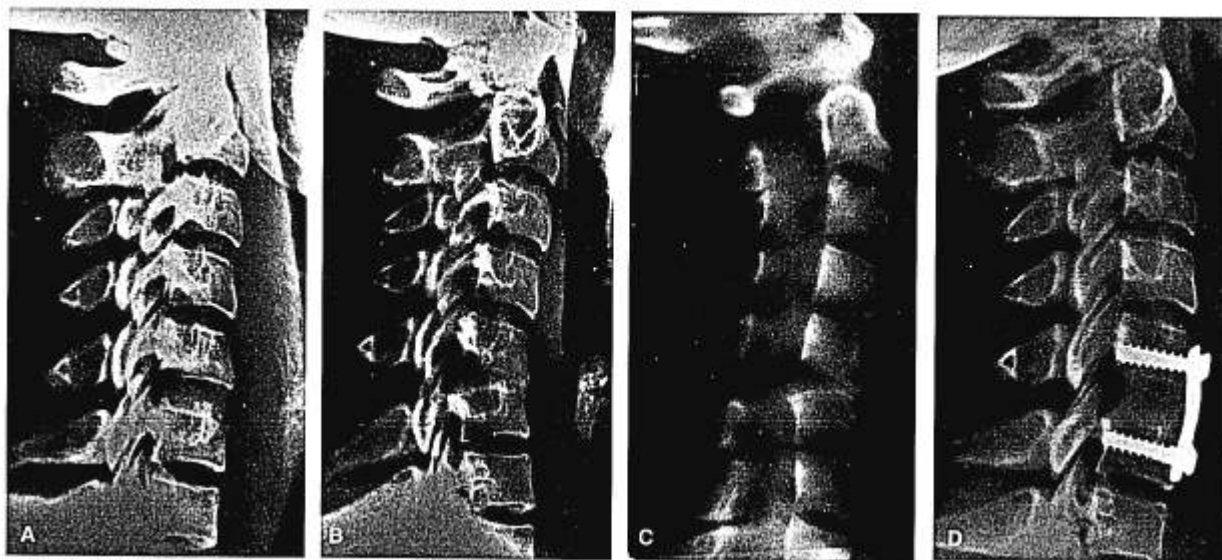


FIG. 2. Initial postoperative lateral radiograph (A) following a C5-6 anterior cervical arthrodesis with iliac crest autograft without anterior cervical plate stabilization (ACPS). Six-month follow-up lateral cervical radiograph (B) and lateral tomogram (C) of same patient, demonstrating a collapse of the bone graft and resulting fusion of C5-6 in a flexion deformity of 18°. One year after the revision surgery at C5-6 for correction of the flexion deformity with ACPS (D).

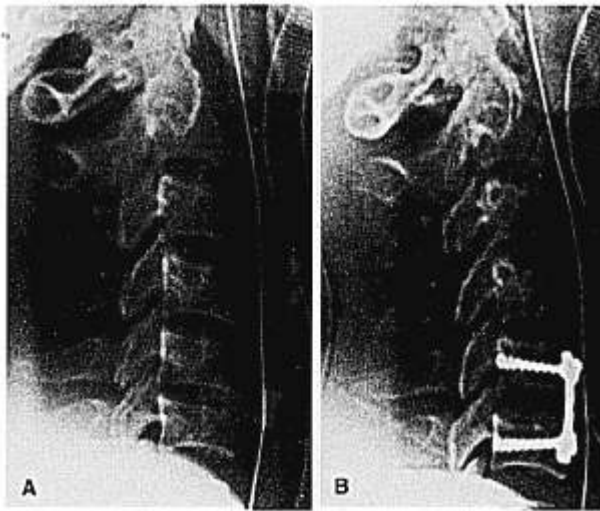


FIG. 3. A: Patient following C5-6 iliac crest autograft arthrodesis with dislocation of the graft, causing mechanical collapse of the segment and dysphagia. B: After revision of the C5-6 arthrodesis with anterior cervical plate stabilization.

Germany) ACPS. The patients all had a diagnosis of cervical radiculopathy, myelopathy, or myeloradiculopathy and a radiological diagnosis of herniated disc, posterior osteophyte, or cervical stenosis causing foraminal narrowing or spinal cord compression. All patients underwent anterior cervical interbody arthrodesis according to Smith and Robinson surgical techniques (4,5) after clinical and radiological examination including plain films and computed tomography/myelogram or magnetic resonance imaging. A hard cervical collar was used in all patients for an average of 6 weeks when autograft was used and 10 weeks when allograft was used. Routine minimum clinical and radiologic follow-up was 6 months with autograft and 1 year for allograft. Delayed complications and potential reoperations were monitored by follow-up clinic visits.

The patients analyzed in this study underwent cervical surgery between September 1985 and May 1995 at the Illinois site and between January 1990 and February 1993 at

the Germany site. The patient population comprised 214 men (60.1%) and 142 women (39.9%). The average age was 45 years, ranging from 22 to 80 years, with the majority of patients in the fourth and fifth decades of life, reproducing an age distribution previously noted for this disease (Fig. 4). The levels involved in the single-level cases were C2-3 in 0.4%, C3-4 in 3.3%, C4-5 in 11.4%, C5-6 in 45.5%, C6-7 in 36.2%, and C7-T1 in 3.3%, as shown in Fig. 5. At the Germany site, all two-level surgeries utilized ACPS; however, at the Illinois site, there was a division of the two-level cases based on surgeon preference. The distribution for two-level surgeries is presented in Fig. 6. All patients were followed for a minimum of 1 year. Our long-term experience of 15 years has shown that stable bony fusion occurs within 2-3 months after plating when autograft is used (2,18,64). The longest follow-up period is greater in the bone-alone group because at the Illinois site the patients with one- and two-level degenerative disease have only had ACPS utilized in the last 4 years, whereas data were available for 9 years in the bone-alone group. Thus, as the patients in this retrospective analysis were followed from the time of their surgery, there is a spectrum of total follow-up times. The patients with ACPS were followed from 1 to 4 years and patients in the bone-alone group were followed from 1 to 9 years. The exact number of patients at each follow-up time is listed in Table 1.

Arthrodesis with ACPS was performed using either an iliac crest bone graft (59 total cases; 8 Illinois, 51 Germany) or a cadaver bone graft (87 total cases; all Illinois). For patients without ACPS, the arthrodesis was performed with iliac crest bone graft (200 total cases; 143 Illinois, 57 Germany) or cadaver bone graft (10 total cases; all Illinois). Three different cervical plating systems were utilized in this patient population. The cervical plating systems consisted of both bicortical (54 total; 3 Illinois, 51 Germany) and unicortical (92 total; all Illinois) screw plate systems. The unicortical screw plate systems locked the screws to the plate. The anterior plating systems utilized in this study were (a) Caspar Bicortical Anterior Cervical

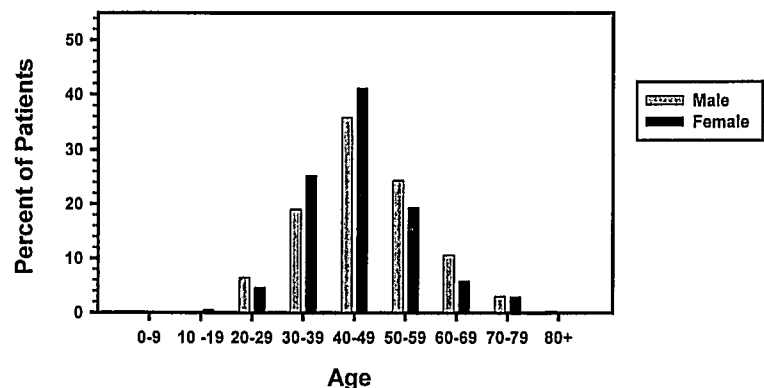


FIG. 4. Age distribution of anterior cervical fusion patients, demonstrating the typical age peak in the 30- to 59-year range.

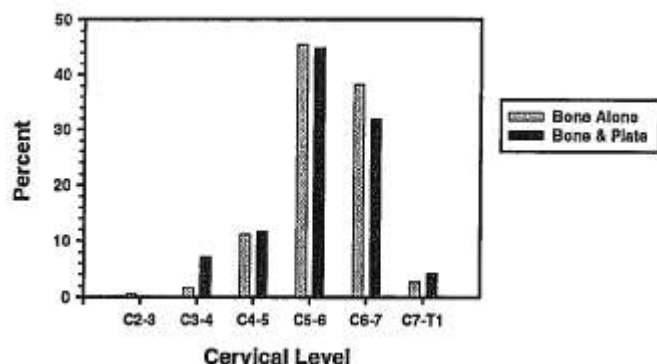


FIG. 5. Distribution of 246 cases of single-level cervical fusions.

Plate (Aesculap AG, Tuttlingen, Germany) (54 total, a bicortical system); (b) Cervical Spine Locking Plates (Synthes Spine, Paoli, PA, U.S.A.) (84 total; 42 single level, 42 two level, a unicortical system); and (c) Orion Anterior Cervical Plating System (Sofamor-Danek U.S.A., Memphis, TN, U.S.A.) (8 total; 2 single level, 6 two level, unicortical system). When allograft was used with a plating system, the cadaver fibula bone graft (Regional Organ Bank of Illinois, Chicago, IL, and Musculoskeletal Transplant Foundation, Holmdel, NJ, U.S.A.) was filled with Grafton DBM Gel (Osteotech, Eatontown, NJ, U.S.A.). A detailed distribution of bone graft use by center, number of levels requiring surgery, use of an ACPS, and bicortical versus unicortical screws is presented in Table 2.

Some patients who underwent surgery with the addition of ACPS included cases of pseudarthrosis and instability that were referred into these centers after a prior anterior cervical arthrodesis surgery (10 total; 6 Illinois, 4 Germany). These reoperations were believed to be more difficult cases in which to obtain an arthrodesis than unoperated patients and were all revised utilizing ACPS. Twelve corpectomies were included in the Illinois cases of two-level disease (10 with ACPS, 2 without ACPS) and also

are believed to represent more difficult cases in which to obtain an arthrodesis. As there were no additional noteworthy differences between the two groups, it is thus deduced that the two groups are relatively evenly matched with a slight imbalance of more difficult cases in the ACPS group. There is no evidence that the bone-alone group comprised more difficult cases.

RESULTS

A second cervical intervention was required in 22 of the 356 patients (6.2%). The reasons for reoperation were classified into one of three groups: (a) pseudarthrosis, which includes graft collapse and extrusion in addition to clinically significant pseudarthrosis (Figs. 7 and 8); (b) hardware-related complications; and (c) progression of the degenerative disease requiring an adjacent cervical level decompression and arthrodesis. Of these 22 patients, a second cervical procedure was required in 13 for pseudarthrosis, in 2 for hardware-related complications, and in 7 for progression of the disease. Of the 13 cases of pseudarthrosis, 12 underwent surgery without ACPS (10 one-level cases and 2 two-level cases) and 1 with ACPS (two-level

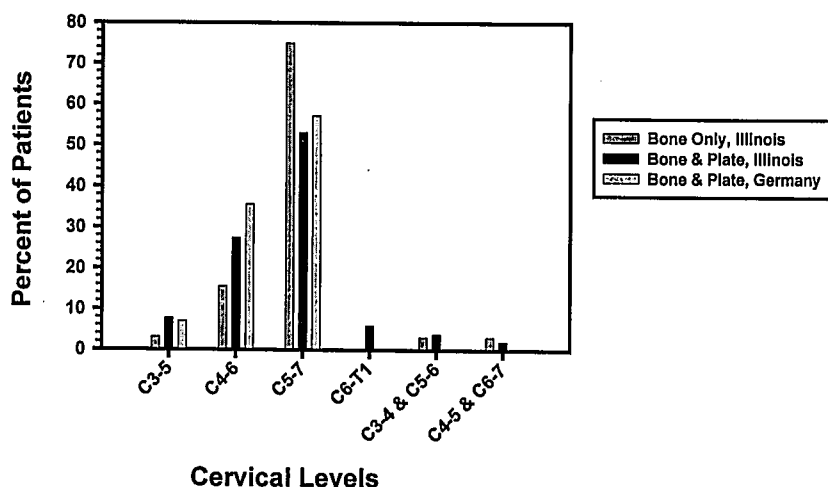


FIG. 6. Distribution of 110 cases of two-level cervical fusions.

TABLE 1. Follow-up time of anterior cervical fusion patients

| | Length of follow-up (yrs) | No. with bone and ACPS | No. with bone alone | Total no. of patients |
|--------------------------------|---------------------------|------------------------|---------------------|-----------------------|
| One-level ACDF | | | | |
| | 1 | 68 | 178 | 246 |
| | 2 | 61 | 158 | 219 |
| | 3 | 45 | 146 | 191 |
| | 4 | 0 | 89 | 89 |
| | 5 | 0 | 57 | 57 |
| | 6 | 0 | 39 | 39 |
| | 7 | 0 | 23 | 23 |
| | 8 | 0 | 9 | 9 |
| | 9 | 0 | 2 | 2 |
| Two-level ACDF | | | | |
| | 1 | 78 | 32 | 110 |
| | 2 | 62 | 25 | 87 |
| | 3 | 43 | 22 | 65 |
| | 4 | 0 | 21 | 21 |
| | 5 | 0 | 16 | 16 |
| | 6 | 0 | 10 | 10 |
| | 7 | 0 | 5 | 5 |
| | 8 | 0 | 4 | 4 |
| | 9 | 0 | 1 | 1 |
| One- and two-level ACDF | | | | |
| | 1 | 146 | 210 | 356 |
| | 2 | 123 | 182 | 305 |
| | 3 | 88 | 167 | 255 |
| | 4 | 0 | 110 | 110 |
| | 5 | 0 | 73 | 73 |
| | 6 | 0 | 49 | 49 |
| | 7 | 0 | 27 | 27 |
| | 8 | 0 | 13 | 13 |
| | 9 | 0 | 3 | 3 |

ACPS, anterior cervical plate stabilization; ACDF, anterior cervical plate discectomy and fusion.

case). The two hardware-related complications were fracture of a C7 screw with settling before fusion, loosened screws with backout and swallowing difficulty (Fig. 9A and B), and fracture of a C5 screw in a patient with a C6 corpectomy after settling of the graft before fusion (Fig.

9C). No noteworthy differences were found with the use of unicortical and bicortical screw systems or with the use of allograft versus autograft (data not shown). No patient in this study obtained a neurologic deficit as a result of the surgical procedure. A complete breakdown of reoperations both with and without ACPS is listed in Tables 3 and 4.

As the number of patients available for analysis is less at progressively longer follow-up periods, the data are presented at 1, 2, and 3 years of follow-up and as a cumulative proportion analysis of patients remaining without additional surgery. The number of patients at risk, the number of reoperations, and the reoperation fractions for patients with and without ACPS after 1, 2, and 3 years of follow-up are listed in Table 5. After 1 year of follow-up, the reoperation rate in one- and two-level surgeries with ACPS was 0.68% (1 of 146) compared with 4.8% (10 of 210) with bone alone, representing a decrease in reoperation rate with ACPS of 4.1%. This difference was calculated based on the data of all 356 patients and is statistically significant ($p = 0.0308$, Fisher's exact test, two tailed) (StatX-act Ver 3.0; Cytel Software Corp., Cambridge, MA, U.S.A., 1993).

The cumulative proportion of one- and two-level anterior cervical arthrodesis patients surviving without additional cervical surgery is presented in Fig. 10. This analysis accounts for the decreasing number of patients available in the longer follow-up periods. These two curves can be compared using a cumulative proportion analysis technique with right censoring the data, which analyzes all 356 patients with their total yet different time periods of follow-up (49,62). The log-rank test stratified on ACPS group or bone-alone group using the Breslow-Gehan method (62) yielded $p = 0.05$, signifying a statistically significant difference between the two groups. Furthermore, visual inspection of Fig. 10 indicates an initial reoperation rate in the bone-alone group of 5.5% within the first year and then a rate of 0.75% per year thereafter, whereas the ACPS group had a reoperation rate of 0.75% per year without an increase in the first year.

TABLE 2. Distribution of bone graft use according to neurosurgical center, no. of levels requiring surgery, use of ACPS, and bicortical versus unicortical screws

| | No. of levels in ACDF arthrodesis | Autograft with ACPS | | Autograft alone | Allograft with ACPS | | Allograft alone |
|----------------------------|-----------------------------------|---------------------|-------------------|-----------------|---------------------|-------------------|-----------------|
| | | Unicortical screws | Bicortical screws | | Unicortical screws | Bicortical screws | |
| Illinois | 1 | 3 | 0 | 117 | 41 | 1 | 4 |
| | 2 | 4 | 1 | 26 | 44 | 1 | 6 |
| Subtotal | — | 7 | 1 | 143 | 85 | 2 | 10 |
| Germany | 1 | 0 | 23 | 57 | 0 | 0 | 0 |
| | 2 | 0 | 28 | 0 | 0 | 0 | 0 |
| Subtotal | — | 0 | 51 | 57 | 0 | 0 | 0 |
| Total Illinois and Germany | — | 7 | 52 | 200 | 85 | 2 | 10 |

ACDF, anterior cervical discectomy and fusion; ACPS, anterior cervical plate stabilization.

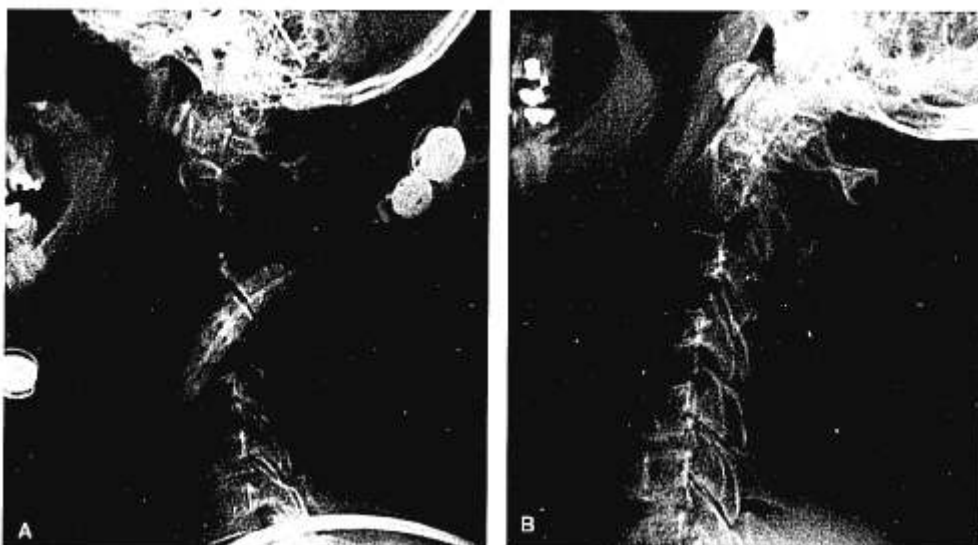


FIG. 7. Patient had a two-level fusion at C5-6 and C6-7 with autologous iliac crest without anterior cervical plate stabilization. **A:** The C6-7 disc space bone graft collapsed in the immediate postoperative period. **B:** The patient went on to have a pseudarthrosis at C6-7 with motion on flexion extension lateral radiographs.

The reoperation rate in one- and two-level surgeries continues to favor ACPS patients after 2 years (1.6% ACPS, 6.0% bone alone) and 3 years (3.4% ACPS, 6.6% bone alone). The number of patients with 2- and 3-year follow-up is <1 year follow-up time with overlapping confidence intervals (Table 5), indicating a lack of statistical significance. The differences in the reoperation rates, however, remained relatively constant in this longer follow-up period, favoring ACPS (4.4% after 2 years, 3.2% after 3 years).

The data were subdivided into one- or two-level disease and further analyzed. At 1-year follow-up, the reoperation rate in cases with single-level ACPS was 0% (0 of 68

patients) compared with 5.1% (9 of 178 patients) with bone alone. The decrease in reoperation rates with ACPS was 5.7% after 2 years and 6.16% after 3 years. After 1 year of follow-up, the reoperation rate in patients with two-level ACPS was 1.3% (1 of 78) compared with 6.3% (2 of 32) with bone alone. The decrease in the reoperation rate is a notable 5.0%. As with one-level procedures, the decrease in the reoperation rate with ACPS was maintained after 2 years (12.8%) and 3 years (11.2%). Table 5 details the analysis of the groups, follow-up periods, confidence intervals, and decrease in reoperation rate with ACPS for each group.

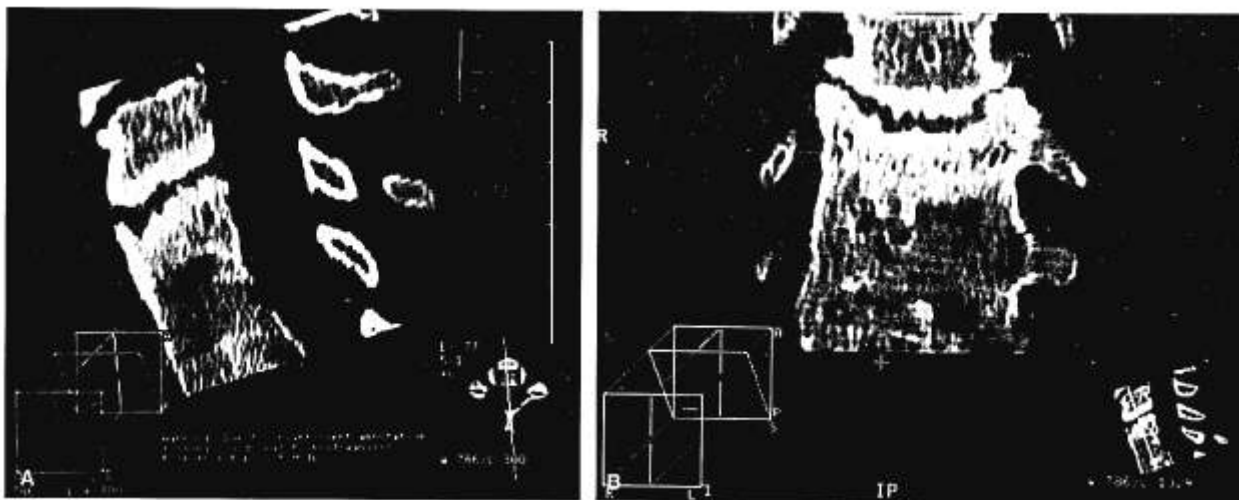


FIG. 8. Sagittal (**A**) and coronal (**B**) computed tomography scan reconstruction of C4-5, demonstrating the pseudarthrosis after arthrodesis with autologous iliac crest bone graft alone.

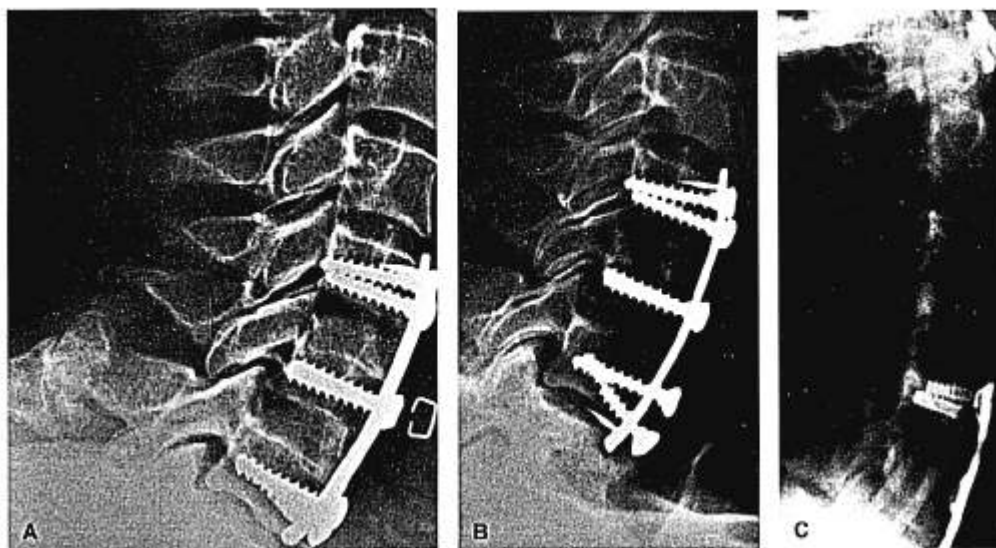


FIG. 9. A second surgical procedure was required for two plate-related complications. **A:** The first patient underwent a two-level cervical arthrodesis with anterior cervical plate stabilization (ACPS) at C5-C6 and C6-C7 with autologous iliac crest graft. **B:** The C6-7 arthrodesis underwent mechanical settling and subsequent fracture through one of the screws at C7, loosened screws with backout, and swallowing difficulty. **C:** A two-level cervical decompression with a C6 corpectomy using fibula allograft and ACPS with a fractured C5 screw and settling of the construct. Surgical inspection at the removal of the hardware disclosed a mature fusion.

DISCUSSION

Since Bailey and Badgley (7) first described anterior cervical interbody arthrodesis using an autologous bone graft and the surgical techniques were advanced by Cloward (22) and Caspar (15-18), this method has become a standard technique for a variety of indications in cervical spine pathology such as degenerative disease (i.e., radiculopathy, myelopathy), tumor, inflammatory process, trauma, and failed fusion (2,3,6,7,15,18-20,22,52,54,64). Although the advantages of anterior plate stabilization (i.e., immediate stability, restoration of normal lordotic curve, shortened fusion time, and enhanced fusion quality) have been reported, plate osteosynthesis after single-level fusion for radiculopathy was not thought to be a major advantage. The main

argument stated that any benefits to the patient as a result of plate stabilization would be lost by plate-related complications such as screw loosening, hardware breakage, or pain caused by the presence of the hardware, requiring its revision or removal. Additional concerns have been voiced regarding potential iatrogenic complications during the surgical application of the cervical plating system.

Stabilization of the arthrodesis segment is accomplished with a combination of internal and external stabilization. The total amount of internal stabilization at the segment is the combination of the stabilization obtained from the bone graft fixing the disc space and the additional stabilization obtained if an anterior screw plate construct is also used. Typically, the bone graft is inserted to form a jammed mechanical system, locking the graft into position with the

FIG. 10. Cumulative proportion of one- and two-level anterior cervical arthrodesis patients surviving without additional cervical surgery. The anterior cervical plate stabilization patients have significantly fewer operations than the bone-alone patients ($p = 0.05$, log-rank test, Breslow-Gelan method).

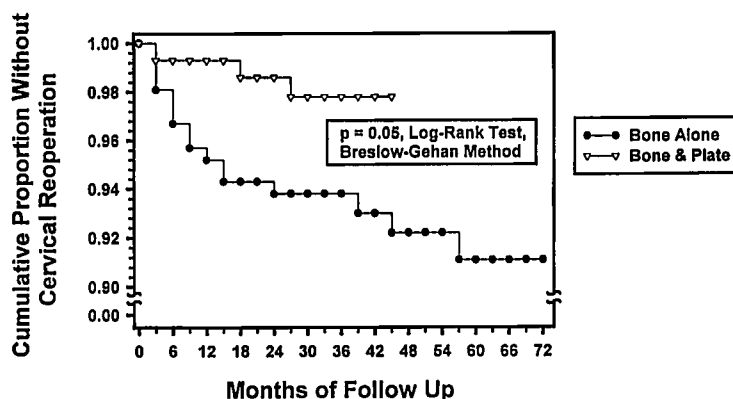


TABLE 3. Anterior cervical fusion patients requiring second cervical intervention

| | No. of levels of ACDF arthrodesis | Mos. to reoperation | Neurosurgery center | Level(s) of surgery | ACPS system used | Arthrodesis bone | Prior operation at same level | Corpectomy performed | Reason for reoperation |
|---------------|-----------------------------------------|------------------------|------------------------|---------------------------|------------------------|---------------------|-------------------------------------|-------------------------|----------------------------------------------------------------------------------------------------|
| Bone and ACPS | 2 | 2.14 | Germany | C5-7 | Caspar | Autograft | No | No | Pseudarthrosis |
| | 2 | 7.34 | Germany | C5-7 | Caspar | Autograft | No | No | Settling of graft, fracture of C7 screw, screw backout and swallowing difficulty |
| | 2 | 17.45 | Illinois | C5-7 | Synthes | Allograft | No | Yes | Settling of graft, fracture of C5 screw |
| Bone alone | 1 | 0.23 | Germany | C5-6 | — | Autograft | No | No | Graft extrusion |
| | 2 | 0.76 | Illinois | C4-6 | — | Autograft | No | No | Graft extrusion |
| | 1 | 1.58 | Germany | C4-5 | — | Autograft | No | No | Graft collapse |
| | 1 | 1.94 | Germany | C5-6 | — | Autograft | No | No | Graft collapse |
| | 1 | 4.11 | Germany | C6-7 | — | Autograft | No | No | Graft collapse |
| | 1 | 4.93 | Germany | C6-7 | — | Autograft | No | No | Graft collapse |
| | 1 | 5.82 | Germany | C5-6 | — | Autograft | No | No | Graft collapse |
| | 1 | 6.74 | Illinois | C4-5 | — | Autograft | No | No | Graft extrusion |
| | 1 | 8.31 | Germany | C5-6 | — | Autograft | No | No | Graft collapse |
| | 1 | 10.58 | Illinois | C4-5 | — | Autograft | No | No | Pseudarthrosis |
| | 2 | 12.12 | Illinois | C4-5, C6-7 | — | Autograft | No | No | Disease progression |
| | 2 | 13.73 | Illinois | C5-7 | — | Autograft | No | No | Pseudarthrosis |
| | 2 | 21.22 | Illinois | C3-4, C5-6 | — | Autograft | No | No | Disease progression |
| | 1 | 38.01 | Illinois | C5-6 | — | Autograft | No | No | Disease progression |
| | 1 | 42.74 | Illinois | C6-7 | — | Autograft | No | No | Disease progression |
| | 1 | 55.07 | Illinois | C6-7 | — | Autograft | Yes | No | Pseudarthrosis |
| | 1 | 72.71 | Illinois | C6-7 | — | Autograft | No | No | Disease progression |
| | 1 | 80.00 | Illinois | C4-5 | — | Autograft | No | No | Disease progression |
| | 1 | 102.61 | Illinois | C5-6 | — | Autograft | No | No | Disease progression |

ACDF, anterior cervical discectomy and fusion; ACPS, anterior cervical plate stabilization.

compressive force maintained by the stretched lateral and remaining anterior cervical segmental ligaments. Anterior, posterior, and lateral displacement of the graft is prevented by placing it within the circumference of the outer cortex of the bodies above and below the segments requiring arthrodesis. Rotation of the disc space is prevented by the surface contact area between the graft and the rostral and caudal bony edges bordering the disc space. The stretch in the ligaments is initially generated by distracting and hyperextending the segments, permitting a bone graft larger than the resting height of the segment to be inserted. Hyperextension of the joint tends to restore normal lordosis, and distraction tends to realign minor subluxations of the segment. Internal fixation achieved with the arthrodesis bone graft can be enhanced with the addition of ACPS. The ultimate

fusion rate in both long bones and the spine is enhanced with the addition of rigid internal stabilization (15-20).

This retrospective analysis includes 356 patients, of whom 146 underwent a plating procedure. Two hardware-related complications occurred: (a) fracture of a C7 screw with settling before fusion, loosened screws with backout, and swallowing difficulty; (b) fracture of a C5 screw caused by settling before fusion. There was only 1 case of pseudarthrosis in one level of a bisegmental plated patient, whereas 12 cases of pseudarthrosis occurred in the one- and two-level arthrodesis group without plating. This study provides evidence that it is safe to utilize a metallic plate for stabilization in an anterior cervical arthrodesis and that the reoperation rate is lower when a plate is used. No noteworthy differences were found with the use of unicortical

TABLE 4. Reasons for reoperation in bone + ACPS and bone-alone anterior cervical fusion patients

| | Neurosurgery center | No. of procedures | No. of pseudarthroses | No. of degenerative disease progressions | No. of hardware-related complications | Sum of nos. of reoperations |
|--------------------|---------------------|-------------------|-----------------------|------------------------------------------|---------------------------------------|-----------------------------|
| Bone + ACPS | | | | | | |
| One-level ACDF | Illinois | 45 | 0 | 0 | 0 | 0 |
| | Germany | 23 | 0 | 0 | 0 | 0 |
| Two-level ACDF | Illinois | 50 | 0 | 0 | 1 | 1 |
| | Germany | 28 | 1 | 0 | 1 | 2 |
| Subtotal | — | 146 | 1 | 0 | 2 | 3 |
| Bone alone | | | | | | |
| One-level ACDF | Illinois | 121 | 3 | 5 | NA | 8 |
| | Germany | 57 | 7 | 0 | NA | 7 |
| Two-level ACDF | Illinois | 32 | 2 | 2 | NA | 4 |
| | Germany | 0 | 0 | 0 | NA | 0 |
| Subtotal | — | 210 | 12 | 7 | — | 19 |
| Total | — | 356 | 13 | 7 | 2 | 22 |

ACPS, anterior cervical plate stabilization; ACDF, anterior cervical discectomy and fusion; NA, not applicable.

and bicortical screw systems or with the use of allograft versus autograft. Obviously, to obtain results similar to those presented here, a low ACPS-related complication rate is required.

These results of high fusion rates with plating are similar to findings from Shapiro (60) [cervical plating with allograft (88 cases) 0% in single and multilevel and pseudarthrosis rate].

This study showed no significant differences in the rate of complications or reoperations between unicortical and bicortical plated patients. It should, however, be emphasized that the bicortical plating systems are considered technically more challenging than unicortical plating systems. The results presented here demonstrate that surgeons with proficiency in bicortical systems can obtain the same results and safety as unicortical systems. These results do

TABLE 5. No. of anterior cervical fusion patients at risk, no. of reoperations, and reoperation fractions for patients with and without ACPS after 1, 2, and 3 yrs of follow-up

| | Type of arthrodesis and internal stabilization | No. of patients at risk | No. of reoperations | Reoperation fraction | 95% confidence interval of reoperation fraction | Decrease in reoperation rate with ACPS % | p value (Fisher's exact, two tailed) |
|--------------------------------|------------------------------------------------|-------------------------|---------------------|----------------------|-------------------------------------------------|------------------------------------------|--------------------------------------|
| One-level ACDF | | | | | | | |
| 1 yr | Bone + ACPS | 68 | 0 | 0.000 | (0.00, 0.05) ^a | — | — |
| | Bone alone | 178 | 9 | 0.0506 | (0.02, 0.09) | 5.06 | — |
| 2 yrs | Bone + ACPS | 61 | 0 | 0.000 | (0.00, 0.06) ^a | — | — |
| | Bone alone | 158 | 9 | 0.0570 | (0.03, 0.11) | 5.70 | — |
| 3 yrs | Bone + ACPS | 45 | 0 | 0.000 | (0.00, 0.08) ^a | — | — |
| | Bone alone | 146 | 9 | 0.0616 | (0.03, 0.11) | 6.16 | — |
| Two-level ACDF | | | | | | | |
| 1 yr | Bone + ACPS | 78 | 1 | 0.0128 | (0.00, 0.07) | — | — |
| | Bone alone | 32 | 2 | 0.0625 | (0.01, 0.21) | 4.97 | — |
| 2 yrs | Bone + ACPS | 62 | 2 | 0.0323 | (0.00, 0.11) | — | — |
| | Bone alone | 25 | 4 | 0.160 | (0.05, 0.36) | 12.77 | — |
| 3 yrs | Bone + ACPS | 43 | 3 | 0.0698 | (0.01, 0.19) | — | — |
| | Bone alone | 22 | 4 | 0.182 | (0.05, 0.40) | 11.22 | — |
| One- and two-level ACDF | | | | | | | |
| 1 yr | Bone + ACPS | 146 | 1 | 0.0068 | (0.00, 0.04) | — | — |
| | Bone alone | 210 | 10 | 0.0476 | (0.02, 0.09) | 4.08 | 0.0308 |
| 2 yrs | Bone + ACPS | 123 | 2 | 0.0163 | (0.00, 0.06) | — | — |
| | Bone alone | 182 | 11 | 0.0604 | (0.03, 0.11) | 4.41 | — |
| 3 yrs | Bone + ACPS | 88 | 3 | 0.0341 | (0.01, 0.10) | — | — |
| | Bone alone | 167 | 11 | 0.0659 | (0.03, 0.11) | 3.18 | — |

ACDF, anterior cervical discectomy and fusion; ACPS, anterior cervical plate stabilization.

^aThis confidence interval is 97.5% because there is uncertainty in only one direction.

not imply that the two systems are equally safe for use by surgeons inexperienced in the procedures.

This study demonstrates that the addition of ACPS to one- and two-level anterior cervical surgery decreases the reoperation rate. To definitively determine whether the addition of ACPS to a single-level anterior cervical arthrodesis in degenerative disease is beneficial and the complications can be maintained at a low level, a large multicenter study involving hundreds of randomized patients will be required. A study of this size and scope will provide the statistical robustness and the experience of multiple surgeons. Sample size estimates for a study of this type can be based on the data in this study. If the initial decrease is 5.5% for the bone-alone group and 0.75% per year thereafter and the ACPS group has 0.75% per year with no increase in the first year, then 500 patients are needed for a 1-year follow-up period, 600 patients are needed for a 2-year follow-up period, 730 patients are needed for a 3-year follow-up period, and 880 patients are needed for a 5-year follow-up period to obtain a two-tailed α of 0.05 and β of 0.20 (GraphPad InStat Ver. 2.04; GraphPad Software, San Diego, CA, U.S.A., 1993).

CONCLUSION

ACPS has been demonstrated to be a safe alternative technique for one- and two-level fusions in degenerative disease. These data confirm that the addition of plating does not constitute an overtreatment but rather appears to supplement the internal stabilization of the bony arthrodesis and yields a higher mature fusion rate and a lower reoperation rate.

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