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Functional and Quality-of-Life Outcomes in Geriatric Patients with Type-II Dens Fracture

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**Background:** Dens fractures are relatively common in the elderly. The treatment of Type-II dens fractures remains controversial. The aim of this multicenter prospective cohort study was to compare outcomes (assessed with use of validated clinical measures) and complications of nonsurgical and surgical treatment of Type-II dens fractures in patients sixty-five years of age or older.

**Methods:** One hundred and fifty-nine patients with a Type-II dens fracture were enrolled in a multicenter prospective study. Subjects were treated either surgically (n = 101) or nonsurgically (n = 58) as determined by the treatment preferences of the treating physicians and the patients. The subjects were followed at six and twelve months with validated outcome measures, including the Neck Disability Index (NDI) and Short Form-36v2 (SF-36v2). Treatment complications were prospectively recorded. Statistical analysis was performed to compare outcome measures before and after adjustment for confounding variables.

**Results:** The two groups were similar with regard to baseline characteristics. The most common surgical treatment was posterior C1-C2 arthrodesis (eighty of 101, or 79%) while the most common nonsurgical treatment was immobilization with use of a hard collar (forty-seven of fifty-eight, or 81%). The overall mortality rate was 18% over the twelve-month follow-up period. At twelve months, the NDI had increased (worsened) by 14.7 points in the nonsurgical cohort (p < 0.0001) compared with a nonsignificant increase (worsening) of 5.7 points in the surgical group (p = 0.0555). The surgical group had significantly better outcomes as measured by the NDI and SF-36v2 Bodily Pain dimension compared with the nonsurgical group, and these differences persisted after adjustment. There was no difference in the overall rate of complications, but the surgical group had a significantly lower rate of nonunion (5% versus 21% in the nonsurgical group; p = 0.0033). Mortality was higher in the nonsurgical group compared with the surgical group (annual mortality rates of 26% and 14%, respectively; p = 0.059).

**Conclusions:** We demonstrated a significant benefit with surgical treatment of dens fractures as measured by the NDI, a disease-specific functional outcome measure. As a result of the nonrandomized nature of the study, the results are vulnerable to the effects of possible residual confounding. We recommend that elderly patients with a Type-II dens fracture who are healthy enough for general anesthesia be considered for surgical stabilization to improve functional outcome as well as the union and fusion rates.

**Level of Evidence:** Therapeutic Level II. See Instructions for Authors for a complete description of levels of evidence.

Type-II dens fracture—i.e., a fracture through the base of the dens just above the C2 vertebral body—is the most common cervical spine fracture in patients sixty-five years of age or older, and these injuries represent the majority of cervical spine fractures in patients over eighty years of age. In contrast to similar injuries in younger patients, dens fractures in the elderly are typically sustained by low-energy mechanisms. Like younger patients, elderly individuals with a dens fracture...
most commonly present without associated spinal cord injury, a finding that has been attributed to the relative capaciousness of the spinal canal at this level. Optimal treatment of geriatric patients with a Type-II dens fracture would permit patients to return to their prior level of function as rapidly as possible while avoiding the morbidity and mortality associated with prolonged inactivity and hospitalization.

The studies of Type-II dens fractures in the elderly that have been published in the literature are relatively small, uncontrolled case series that often preclude direct comparison of treatment modalities to determine the optimal strategy for this injury. The existing literature has, however, established that this population is at a high risk of complications regardless of whether they are treated with a cervical orthosis, a halo vest, or surgical intervention. Few investigators have evaluated outcomes using validated, patient-derived outcome measures such as the Short Form-36 (SF-36) or Neck Disability Index (NDI). Because of the lack of controlled studies and the wide variation in clinical practice among experienced spine surgeons, the treatment of Type-II dens fractures in the elderly is characterized by clinical equipoise between nonsurgical and surgical approaches. Evidence-based treatment algorithms have the potential to optimize outcomes in elderly patients with a Type-II dens fracture.

The aim of this multicenter prospective cohort study was to compare, with the use of validated clinical outcome measures, outcomes and complications of nonsurgical and different types of surgical treatment of Type-II dens fractures in patients sixty-five years of age or older.

Materials and Methods

Subjects

Of 225 patients with a radiographically confirmed Type-II dens fracture, 159 were enrolled in a multicenter prospective study performed at ten sites in the United States and one site in Canada between January 2006 and May 2009. Sites were selected among the members of SpineNET, the clinical research network of AO Spine North America. To be enrolled in the study, patients had to be sixty-five years of age or older, have had a Type-II dens fracture for not longer than ninety days, have had no previous fracture treatment, and no substantial cognitive impairment. Sixty-six of the 225 patients who had been determined to have a Type-II dens fracture on initial screening for the study were excluded because they did not meet one or more inclusion/exclusion criteria or could not provide information about primary outcome variables. Subjects were managed nonsurgically or surgically on the basis of treatment decisions reached by the treating physicians and patients. No protocol-mandated procedure was used to direct the choice of nonsurgical or surgical treatment. Postsurgical rehabilitation was dictated by the treatment protocols at the participating institutions and was not mandated by the investigational protocol.

Outcomes Data

Subjects were followed prospectively with validated outcome measures—the Neck Disability Index (NDI) and the Short Form–36v2 (SF-36v2) as well as for treatment complications at six and twelve months after the initial treatment. The baseline NDI and SF-36v2 scores were based on the subjects’ evaluation of their status prior to sustaining the injury. The NDI is a self-reported questionnaire that evaluates functional outcomes related to neck conditions; the scores range from 0 (best) to 100 (worst). The SF-36v2 is a widely used measure of patient-reported generic health status that describes health status across eight global dimensions of health: Physical Functioning, Role Limitation-Physical, Bodily Pain, General Health, Emotional Well-Being, Role Limitation-Emotional, Social Functioning, and Energy/Fatigue. The eight global dimensions can also be summarized with two composite scores: the SF-36v2 Physical Component Summary (PCS) and Mental Component Summary (MCS) scores. The composite scores were calculated with use of the 1998 U.S. norms and the orthogonal approach to transformation. Complications were prospectively followed with use of a predetermined list of nineteen anticipated complications associated with the treatment of dens fracture, and complications not on the list were also recorded on the standardized forms with use of write-in sections for additional complications. The same list of complications and the same procedure for prospective collection of adverse event data were applied at each institution. Adverse-events data were adjudicated by an adverse-event committee that consisted of a group of physicians participating in the study who were blinded to the patients and participating institutions. Adverse events were categorized as treatment complications and treatment-unrelated events. To ensure accuracy of mortality information, we crosschecked mortality data with the information available at the ancystry.com database. The study was externally monitored to ensure that the data were accurate, reliable, and complete. The SF-36v2 and NDI forms were completed by the subjects themselves. The data from the subjects’ forms and other primary sources of data were transcribed on an ongoing basis with use of a U.S. FDA Good Clinical Practice-compliant web-based electronic data-capture system and were processed at a central Data Management Center.

Analytical Methods

The study end points were the absolute changes between the preinjury and six and twelve-month post-treatment scores for the NDI, the eight SF-36v2 health dimensions, and the two SF-36v2 composite summary (PCS and MCS) scores. A prestudy sample size estimate demonstrated that 150 subjects were needed for an 80% power to detect a difference of 7.5 points in the NDI (a primary study end point) between the surgical and nonsurgical groups, assuming a 70%-30% distribution of surgical versus nonsurgical cases. Missing follow-up scores for subjects who failed to attend their follow-up visit at twelve months were imputed with use of the last value carried forward approach if a six-month score was available. The last value carried forward approach was used for 19.0% of the subjects in the nonsurgical arm and 8.9% of those in the surgical arm. All analyses were performed with use of intention-to-treat principles. Patients who later crossed over to the other treatment group (from nonsurgical to surgical) were kept in their original treatment group for the purpose of comparing group outcomes.

The main analyses of differences in preoperative and operative characteristics between the surgical and nonsurgical management groups were performed by using a Student t test for continuous variables and a chi-square test for categorical variables. Testing of the significance of changes in outcome variables between the baseline data and the six and twelve-month data and of differences in changes between the nonsurgical and surgical arms was performed with repeated-measures analysis of variance (ANOVA). The analysis included factors denoted as ARM (nonsurgical or surgical), TIME (baseline, six months, and twelve months), and TIME*ARM. The factor ARM was used to analyze global differences between the nonsurgical and surgical groups and represents the influence of the treatment arm on the results. The factor TIME was used to analyze changes that occurred from baseline to six and twelve months to describe changes in results based on time since treatment. The interaction TIME*ARM tests the significance of changes between the two groups once overall differences and general trend have been accounted for. From the perspective of the study objective, the most relevant parameter was the TIME*ARM interaction. Significant TIME*ARM interactions would indicate differences in outcomes between the groups. The actual testing was performed with use of SAS PROC GLM (SAS 9.2; SAS, Cary, North Carolina). To adjust for potential confounders, we used the following approach. The selection of baseline characteristics that might confound results and therefore required adjustment was performed in two steps, separately for each of eleven outcomes. First, we screened for potential adjustment variables by calculating the Pearson correlation coefficient between each candidate variable and the target change in
the outcomes score. Variables that were included as candidate predictors were demographic factors, comorbidities, presence of associated injuries, and Injury Severity Score (ISS). Second, candidate predictors with a p value of ≤0.2 were carried into a stepwise forward elimination multiple regression model with a threshold probability to stay in the model of p ≤ 0.1. Variables that remained in the multiple stepwise regression models were used as adjustment variables in the repeated-measures ANOVA models. As in the unadjusted analyses, the factors analyzed in the adjusted analyses were labeled ARM (nonsurgical and surgical), TIME (baseline, six months, and twelve months), and TIME*ARM interaction.

This study was approved by the institutional review boards at all participating sites and the institutional review board overseeing the central data management center. This study is registered with ClinicalTrials.gov (number NCT00266929).

Source of Funding
This study was funded by AOSpine North America. The funding source was not involved in the study design, data collection, data analysis, data interpretation, or writing of the report, nor was it involved in the decision to submit the paper for publication.

Results
O

f the 159 enrolled subjects, 101 were treated surgically and fifty-eight, with a cervical orthosis or halo immobilization. The majority of patients in both groups were treated within one week after injury. There were no differences in the time between the injury and initiation of treatment between groups (p = 0.9969). Twenty-nine subjects (18%; 95% confidence interval [CI], 12.2% to 26.2%) died before reaching the twelve-month follow-up point; fifteen were from the nonsurgical group (annual mortality rate of 26%; 95% CI, 14.5% to 42.7%), and fourteen were from the surgical treatment group (annual mortality rate of 14%; 95% CI, 7.8% to 23.3%) (p = 0.059). Three subjects withdrew from the study prior to twelve months. Of the
remaining 127 subjects, 103 had follow-up information available (follow-up rate, 81%).

The key baseline demographic and clinical parameters of the study groups are summarized in the Appendix. There were no differences in sex, age, race, marital status, presence of associated injuries, ISS, residential status, or comorbid conditions between the two groups.

Of the 101 subjects treated surgically, twelve (12%) were treated with anterior odontoid screw fixation; eighty (79%), with segmental posterior C1-C2 screw-rod fixation; seven (7%), with posterior transarticular screw fixation; one (1%), with Brooks fusion[1]; and one (1%), with occipitocervical fusion. Of the fifty-eight subjects treated nonsurgically, five (9%) had soft-collar immobilization, forty-seven (81%) had hard-collar immobilization, and six (10%) had halo immobilization.

Thirteen subjects (22%) in the nonsurgical arm had unsuccessful nonsurgical treatment and had subsequent surgical treatment. Of the thirteen patients with unsuccessful nonsurgical treatment, eight developed nonunion and the other five had further fracture displacement.

Changes in the outcomes measures from baseline to the six-month and twelve-month follow-up evaluations are

<table>
<thead>
<tr>
<th>TABLE III Treatment Complications by Treatment</th>
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<tbody>
<tr>
<td>Treatment Complication</td>
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<tr>
<td>Acute airway compromise*</td>
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<tr>
<td>Anuria</td>
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<tr>
<td>Arrhythmia</td>
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<tr>
<td>Bradycardia</td>
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<tr>
<td>Closed head injury and concussion</td>
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<tr>
<td>Complications of anesthesia*</td>
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<tr>
<td>Cerebrospinal fluid leak</td>
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<tr>
<td>Delayed extubation</td>
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<tr>
<td>Device failure*</td>
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<tr>
<td>Difficulty breathing</td>
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<tr>
<td>Dysphagia*</td>
</tr>
<tr>
<td>Fall</td>
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<tr>
<td>Fracture displacement</td>
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<tr>
<td>GERD (gastroesophageal reflux disease)</td>
</tr>
<tr>
<td>Hematoma</td>
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<tr>
<td>Hypothermia</td>
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<tr>
<td>Meningitis</td>
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<tr>
<td>Motor evoked potentials dropped</td>
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<tr>
<td>Myocardial infarction</td>
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<tr>
<td>Neurovascular injury</td>
</tr>
<tr>
<td>Nonunion*</td>
</tr>
<tr>
<td>Placement of pacemaker</td>
</tr>
<tr>
<td>Pneumonia*</td>
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<tr>
<td>Posterior decompression at T2-T3</td>
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<tr>
<td>Pulmonary embolism</td>
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<tr>
<td>Respiratory failure</td>
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<tr>
<td>Shortness of breath and fatigue</td>
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<tr>
<td>Stroke</td>
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<tr>
<td>Superficial drainage</td>
</tr>
<tr>
<td>Urinary tract infection</td>
</tr>
<tr>
<td>Wound infection*</td>
</tr>
<tr>
<td>Any complication*</td>
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</table>

*Indicates complication from the predetermined list of nineteen complications †One subject developed nonunion, received surgical treatment, and had nonunion after surgical treatment. Therefore, thirteen nonunion events occurred in twelve subjects.
summarized in Table I. On average, all outcome parameters declined significantly compared with the baseline status as demonstrated by significant TIME factors for all. The NDI outcomes in the surgical group were significantly better than those in the nonsurgical group (TIME×ARM interaction, p = 0.0022). At twelve months after treatment, the NDI increased (worsened) 14.7 points in the nonsurgical cohort (p < 0.0001) compared with a nonsignificant increase (worsening) of 5.7 points in the surgical group (p = 0.0555). The difference in NDI between the surgical and the nonsurgical cohort favoring the surgical cohort was more pronounced at six months than at twelve months (Table I). The nonsurgically treated group also had poorer outcomes in the SF-36v2 dimension Bodily Pain (TIME×ARM interaction, p < 0.0001). The nonsurgical group experienced a decline of 7.0 points (p < 0.001) while the surgical cohort experienced nonsignificant improvement of 1.4 points (p = 0.3334).

Changes in the outcome measures adjusted for baseline confounders are summarized in Table II. After this adjustment was completed, the results still favored the surgically treated cohort. Both the NDI and the SF-36v2 Bodily Pain outcomes remained significantly better in the surgical group compared with those in the nonsurgical group (p = 0.0071 and p = 0.0014, respectively).

An overview of complications is shown in Table III. There were eighty-eight complications reported among the 159 subjects. Although there was a tendency toward a higher proportion of subjects with any complication in the nonsurgically treated cohort, this difference was not significant (36% versus 30% in the surgical group, p = 0.4805). Common complications in the surgical group were dysphagia (eleven cases [11%] compared with three cases [5%] in the nonsurgical group), pneumonia (five cases [5%] compared with four cases [7%] in the nonsurgical group), and acute airway compromise (four cases [4%] compared with one case [2%] in the nonsurgical group). Nonunion occurred in twelve subjects (21%) in the nonsurgical arm compared with five (5%) in the surgical arm (Fisher exact test, p = 0.0033). There were three treatment-related deaths, two (2%) in the surgical cohort (one resulting from sepsis due to a sacral decubitus and the other from respiratory failure) and one (2%) in the nonsurgical group (as a result of choking and subsequent cardiopulmonary failure).

**Discussion**

This study is among the largest prospective investigations of dens fractures performed to date. We demonstrated that surgical treatment of dens fractures provided a significant benefit relative to outcomes measured with the NDI, a disease-specific functional outcome measure for cervical spine pathology. Furthermore, outcomes in the SF-36 Bodily Pain domain were significantly better in the surgical group compared with the nonsurgical group. In contrast, comparison of other SF-36 scores between the nonsurgical and surgical groups did not demonstrate significant differences; this may suggest that other dimensions of this generic health outcome measure are too coarse, or not relevant, to detect the contribution of a dens fracture to an elderly patient’s general well-being.

Our study had limitations. Although it was performed in a prospective manner, the patients were not randomized; instead, treatment decisions were made on a clinical case-by-case treatment-preference basis. In this sense, our study could be subject to selection bias; it is possible that surgeons elected to operate on healthier patients and to leave nonsurgical treatment for sicker individuals or that less healthy patients refused surgical intervention. To mitigate this shortcoming, we adjusted study results using a series of confounding variables, including baseline comorbidity. Surgeon preferences for the type of treatment at many centers were demonstrated by the wide variation in institutional surgical rates. It is possible that selection bias affected our results in a manner that we could not correct through statistical confounder adjustment. Other confounding variables that we did not anticipate and control for, such as differences in post-treatment management and rehabilitation, could explain findings of our study. A second limitation of our study is the relatively short follow-up period of one year. Because of the advanced age of the cohort and previous studies that demonstrated substantial twelve-month mortality rates after dens fracture, one year was thought to represent a clinically important time horizon for the reporting of our results.

Measurement of functional outcomes with the NDI and SF-36v2, which are both validated instruments, showed that elderly patients with a dens fracture do not regain their pre-injury level of function; in fact, the patients had significantly worse scores for almost all outcome measures used in our study. This finding is in contrast to that of Platzer et al., who described no decline in the functional results in a cohort of elderly patients treated with either C1-C2 posterior fusion or odontoid screw fixation. Platzer et al., however, reported results using the Smiley-Webster scale, a four-part classification system described initially for lumbar disc herniation, which may not be sufficiently sensitive to demonstrate more subtle changes in function and has never been validated. We found that the NDI score worsened significantly from baseline in both groups, demonstrating an increase of 14.7 points in the nonsurgical group and an increase of 5.7 points in the surgical group. The change in NDI between the preinjury and one-year follow-up time points in the nonsurgically treated group exceeds the NDI minimum clinically important difference of 7.5 points previously described by Carreon et al., although no studies have established the minimum clinically important difference specific to a cervical trauma cohort. In contrast, while the NDI at one year was worse compared with baseline in the surgical group, this difference falls short of the minimum clinically important difference, suggesting that it may not be clinically relevant. The difference in the change in NDI between the nonsurgical group and surgical group was 9. This difference exceeds the minimum clinically important difference and could suggest that the average patient treated surgically would have a clinically relevant improvement in functional outcome at one year compared with a patient treated nonsurgically.
Survival at one year was relatively high in both groups. Overall, our series had a one-year mortality rate of 18%: 26% of the patients treated nonsurgically and 14% of the patients treated surgically died. This rate is lower than rates in previous clinical series, in which acute in-hospital mortality alone has ranged from 11% to 35%.\textsuperscript{4,5,7,10-12} This difference may be due to the selection of patients in our study. To be enrolled, patients had to be able to provide informed consent and participate in a number of study-related procedures. Nonetheless, our data suggest that most elderly patients with a dens fracture survive the acute postinjury period. Higher survivorship and the relative rarity of devastating neurological injury associated with this injury reinforce the importance of maximizing quality of life and returning patients to their previous level of function.

The decision about whether an elderly patient should undergo surgery for a Type-II dens fracture should not be based on age alone; most elderly patients will survive without substantial neurological deficits.

Much of the discussion about treatment of elderly patients with a Type-II dens fracture has centered on comparisons of the complication rates of nonsurgical and surgical treatment. High complication rates have been described in association with halo vests,\textsuperscript{4,7,11} cervical orthoses,\textsuperscript{10,11} as well as surgical treatment,\textsuperscript{6,12} which reflects the fragile nature of this patient population. We found a higher complication rate in patients treated nonsurgically, although this difference was not significant. Despite the fact that this is the largest prospective study of patients with dens fractures to our knowledge, the number was not sufficient for us to detect significant differences in rates of rare events. We did not analyze the effects of types of surgical care and the quality of surgical reduction and fixation in this study but rather considered surgical care as a single entity. In future subgroup analyses, we hope to investigate whether patients treated surgically and nonsurgically have different outcomes based on type of treatment.

We found that the rate of nonunion after nonsurgical treatment was significantly higher than that after surgical treatment (21% compared with 5%; \(p = 0.0033\)). High nonunion rates after nonsurgical treatment have been previously described.\textsuperscript{6,11,21-23} Lennarson et al.\textsuperscript{24} performed a case-control study that identified age as a significant predictor of nonunion after halo immobilization. This is consistent with the results in a major systematic review\textsuperscript{8}, which favored surgical treatment for displaced dens fractures over nonsurgical treatment on the basis of low-level evidence. The clinical relevance of a dens nonunion in elderly patients is not yet clear. Some authors have advocated that a stable fibrous union can serve as a desirable end point\textsuperscript{1,6,25} because of the paucity of literature describing adverse consequences of fibrous union in this population and the limited activity and lifespan of elderly patients with a dens fracture. In our experience, however, nonunion was frequently not well tolerated; thirteen (22%) of the fifty-eight patients treated nonsurgically crossed over to the surgical group because of symptomatic nonunion or late fracture displacement, suggesting that nonunion is not a desirable end point. Performing primary fusion in patients fit enough for surgery not only may yield superior results but also avoids the need for surgical intervention on a delayed basis and the morbidity and mortality associated with prolonged management.

In conclusion, our study based on prospective data obtained with validated outcome measures may provide useful guidance for surgeons when they are advising geriatric patients and their families about treatment for Type-II dens fractures. Patients who sustain a Type-II dens fracture will have persistent postinjury disability related to their injury. At one year after injury, NDI scores were worse regardless of treatment type, although this decline exceeded the minimum clinically important difference only in the nonsurgical group. Patients and their families should be counseled that treatment might not restore the average patient to his or her preinjury level of function. The relatively lower mortality and improved functional outcome in geriatric patients treated with surgery compared with those who had nonsurgical management favors surgical management. We recommend that elderly patients with a Type-II dens fracture who are healthy enough for general anesthesia be considered for surgical stabilization to improve functional outcome and increase fracture union and the fusion rate.

Appendix

A table showing patient demographics by type of treatment is available with the online version of this article as a data supplement at jbjs.org.
References


