

LETTERS TO THE EDITOR

Necrotizing Fasciitis: Clinical Presentation, Microbiology, and Determinants of Mortality

To The Editor:

My colleagues and I reviewed ninety-nine cases of necrotizing fasciitis that were treated at our institution between July 1989 and June 1995 and noted a 219% increased prevalence during that six-year period. The mortality rate was 18% overall (11% during the final three years of the study).

Unlike Wong et al. in their study entitled "Necrotizing Fasciitis: Clinical Presentation, Microbiology, and Determinants of Mortality" (2003;85:1454-60), my colleagues and I did not find increased mortality in diabetic patients or in patients who were intravenous drug abusers. We did, however, find two factors that were significantly related to mortality: patient age and the presence of a positive blood culture.

In our group, there was one death among the thirty-six patients who were younger than forty years old and there were seventeen deaths among the sixty-three patients who were more than forty years old. Not noted in the study by Wong et al., but seen in our cohort, was a significant relationship between a positive blood culture and mortality. In our study, seventy-one patients had a blood culture on admission. Eight of the nineteen patients with a positive blood culture died, whereas only seven of the fifty-two patients with a negative blood culture died ($p = 0.02$).

My colleagues and I agree that early recognition and aggressive débridement are the cornerstones of care for this devastating disease. We suggest that blood cultures also be performed at the time of admission because, in our experience, a positive culture has been shown to be a predictor of a more fulminant problem.

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ity. No commercial entity paid or directed, or agreed to pay or direct, any benefits to any research fund, foundation, educational institution, or other charitable or nonprofit organization with which the author is affiliated or associated.

C.-H. Wong replies:

We thank Dr. Schnall for sharing his institution's extensive experience with ninety-nine patients who had necrotizing fasciitis. In that series, the most significant predictors of adverse outcome were patient age and the presence of sepsis as indicated by a positive blood culture.

We would like to clarify the findings of our study. Of the twelve factors that were previously reported to adversely affect survival, three factors (patient age, the presence of two or more associated comorbidities, and a delay of operative débridement beyond twenty-four hours) were noted to be associated with patient mortality on univariate analysis. Because of the potential of interdependence between these factors, a more suitable test of significance would reside in multivariate analysis of the factors that were significant in the univariate model. We performed this analysis and found that the only factor that was independently associated with mortality was delayed operative débridement of beyond twenty-four hours after admission.

Delayed débridement was also the strongest predictive factor noted by McHenry et al.¹. The association of intravenous drug abuse complicated by necrotizing fasciitis and mortality was not analyzed as only one such patient presented in this manner. The presence of diabetes in itself was not a predictor of mortality in our study.

Dr. Schnall noted that adverse predictors of outcome in his series included patient age and a positive blood culture at the time of admission. While we did not analyze the association between positive blood cultures and mortality in patients with necrotizing fasciitis, this finding is of interest and deserves further discussion. The angiothrombotic liquefactive necrosis of the fascia

that characterizes necrotizing fasciitis suggests that delivery of antibiotics to the infected fascia will be compromised. Progression of infection despite intravenous antimicrobials is therefore the rule in necrotizing fasciitis, underscoring the need for aggressive surgical débridement. However, antimicrobial therapy reduces the bacterial load in the circulation and may decrease the rate of organ failure.

The mortality rate in our series was 21.3%. This rate was somewhat lower than those in many series reported in the literature¹. We postulate that this finding may be due to the increasing use of broad-spectrum antibiotics in the prehospital setting by primary care physicians; in our study, 70.8% of the patients were given antibiotics empirically before admission. Patients who delay seeking medical attention and are admitted with severe sepsis without antimicrobial therapy are more likely to have a positive blood culture. One could speculate that patients with bacteremia may have more severe sepsis and multiple-organ involvement and therefore a higher mortality. This is consistent with Dr. Schnall's finding of an association between bacteremia and mortality. Blood cultures performed at the time of admission are not only helpful for the prediction of a more fulminant course but also are an indispensable guide for appropriate antimicrobial selection.

We reiterate that early recognition and débridement are the cornerstones of management and should be the focus of the approach to this dreaded disease. However, as we have shown, necrotizing fasciitis is often clinically indistinguishable from other, more benign soft-tissue infections such as cellulitis. While modalities such as frozen-section biopsy and magnetic resonance imaging of the affected part have been shown to be capable of detecting early cases of necrotizing fasciitis, these investigations are not readily available on an emergent basis at

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many centers^{2,3}. They are also costly if performed for all suspicious cases of soft-tissue infection. We therefore developed a diagnostic scoring system based on laboratory tests (including determination of the complete blood count, the level of electrolytes, and the level of C-reactive protein) that are routinely performed for all soft-tissue infections and that are readily available at the time of admission⁴. We think that this diagnostic scoring system, the LRINEC (laboratory risk indicator for necrotizing fasciitis) score, is capable of distinguishing even early cases of necrotizing fasciitis from other soft-tissue infections. With a focused approach in the evaluation of soft-tissue infections, we hope that necrotizing fasciitis can be detected even early in its evolution and that patient survival can be improved.

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These letters originally appeared, in slightly different form, on jbjs.org. They are still available on the web site in conjunction with the article to which they refer.

Effect of Achilles Tendon Lengthening on Neuropathic Plantar Ulcers

To The Editor:

In their article "Effect of Achilles Tendon Lengthening on Neuropathic Plantar Ulcers. A Randomized Clinical Trial" (2003;85:1436-45), Mueller et al. present the provocative hypothesis that, even though the surgical group had a nonsignificant trend toward longer healing times (57.5 days compared with 40.8 days in the nonsurgical group, or 41% longer), a larger number of

ulcers healed in the surgical group (thirty of thirty compared with twenty-nine of thirty-three in the nonsurgical group) and the recurrence rate was lower in the surgical group (four of twenty-seven ulcers recurred compared with sixteen of twenty-seven in the non-surgical group) after seven months of follow-up.

My first question pertains to the role of protected weight-bearing while the ulcers healed after randomization. In the Materials and Methods section, it is noted that the cast group was allowed to bear full weight immediately, whereas the surgical group had protected weight-bearing for a week, after which they were gradually allowed to bear weight but were advised to limit their activity. The authors' introductory review suggests that ulcers are directly related to high plantar pressures and, as such, weight-bearing becomes a confounding variable because the two groups differed substantially in their allowed-weight-bearing status. The nonsurgical group did not receive a trial of non-weight-bearing.

Secondly, patients with a neuropathic foot ulcer would clearly be at risk for wound complications with ankle surgery, which is not an insignificant risk even in healthy patients undergoing Achilles tendon repair. Although the tenotomy-style procedure likely limited this risk, there was one deep infection requiring surgical débridement as well as four heel ulcers that developed only in the surgical group, suggesting that the benefits may be more modest than proposed (for example, perhaps the heel ulcers should be counted as "plantar ulcers" and not excluded as separate complications). Hence, rather than a risk ratio of 4.0 (16/27, or 59%, for the nonsurgical group, compared with 4/27, or 15%, for the surgical group, with a reported 95% confidence interval of 1.8 to 8.9) for the recurrence of "forefoot" ulcers, the true ratio may be closer to 1.8 (16/27, or 59%, compared with 9/27, or 33%). Also, if the surgically managed patient who died during treatment is considered a perioperative mortality, then the risk-to-benefit ratio is again higher.

While this is a very interesting and extensive piece of research, the full data in the article lead one to become concerned over wound-healing; the differences in weight-bearing-status allowed in the two groups; and the paper's inclusion of heel ulcers, deep infection, and possible perioperative mortality

as surgical issues, which were kept separate from the apparent recurrence rate.

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M.J. Mueller, D.R. Sinacore, M.K. Hastings,
M.J. Strube, and J.E. Johnson reply:

Dr. Kaspar points out that the patients in our total-contact cast group were allowed to bear weight immediately whereas those in the Achilles tendon lengthening group were instructed to remain partially weight-bearing for one week. Although it was not clearly described in the Materials and Methods section of our article, both groups were advised to limit activities as much as possible. We agree that this difference in weight-bearing instructions is a potential (although, in our view, probably minimal) confounding variable affecting the interpretation of the results.

A greater confounding variable is the use of a walking boot by the Achilles tendon lengthening group as they transitioned from a cast to shoes. This boot was needed because of the instability that some subjects showed during walking, and this variable was discussed in the paper.

Dr. Kaspar's second question relates to the actual risk of the procedure. We agree that one could consider the appearance of heel ulcers as either a recurrence or a complication. Prior to the start of the study, we defined ulcer recurrence as being limited to the forefoot. We did not change this definition when heel ulcers developed.

Infection is always a potential complication of a surgical procedure, although only one infection developed in what is now a series of several hundred Achilles tendon lengthening procedures.

We do not believe that there was a meaningful difference in primary wound-healing. It was excellent in both groups. We think that the results of the study suggest that an Achilles tendon lengthening should be considered as an adjunct to treatment with a total-contact cast to reduce the rate of ulcer recurrence in patients with a recurrent

neuropathic forefoot ulcer and limited ankle dorsiflexion. The serious risks associated with ulcer recurrence are wound infection and lower-extremity amputation.

We encourage readers to consider all benefits and risks of this procedure and to discuss them with each prospective patient. Additional research is needed to help determine optimal methods to prevent ulcer recurrence without the risks of a surgical procedure.

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Venous Thrombosis After Hallux Valgus Surgery

To The Editor:

Early in our academic career, we had the fortunate experience of being authors of one of the earliest prospective, randomized clinical studies in orthopaedic surgery. The study was designed to determine whether the use of a thigh tourniquet influences the incidence of deep venous thrombosis¹. The results in a cohort of 117 patients who underwent elective forefoot surgery showed that no patient had a venous thrombosis. A recent study entitled "Venous Thrombosis After Hallux Valgus Surgery" (2003;85:1204-8), by Radl et al., also showed a very low rate of venous thrombosis; only four (4%) of 100 patients had calf-vein thrombosis. This recent paper did not reference our article.

Although the study design, the method of detection of the thrombosis, and the purpose of the two studies were different, the inclusion and exclusion criteria, study population, number of patients, type of surgical procedure, use of a thigh tourniquet, and outcomes were similar. However, despite their data and ours, Radl et al. conclude that "patients who have undergone hallux valgus surgery are at a certain risk for venous thrombosis and patients over sixty

years of age especially may benefit from medical prophylaxis against thrombosis."

No preoperative or baseline contrast studies were performed in the study by Radl et al. The four patients who had positive studies were significantly older ($p = 0.034$); this is a small difference when considering that just four patients had a positive study. All of the positive contrast studies were only abnormal in the calf, a condition that is unlikely to lead to a pulmonary embolus.

Therefore, we strongly disagree with the suggestion of Radl et al. that prophylactic anticoagulation is indicated for routine elective hallux valgus surgery, or any forefoot surgery.

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R. Radl and R. Windhager reply:

We thank Drs. Simon and Mass for their interesting comments regarding our article on venous thrombosis following bunion surgery. In the diagnosis of deep-vein thrombosis, three methods have been shown to be accurate in the investigation of symptomatic patients: venography, ultrasonography, and impedance plethysmography². However, in the detection of asymptomatic thrombosis in the calf veins, Doppler ultrasonography, phleboreography, and other noninvasive techniques were found to be unreliable as routine surveillance tools^{3,4}.

Ascending venography remains the most reliable screening modality and therefore is said to be the gold standard in the detection of venous thrombosis, but it is invasive³. Hence, on the basis of our findings, we suggest that thrombosis screening with use of venography instead of ultrasonography and phleboreography, as in the study by Simon et al., might have led to a higher prevalence of detected postoperative thrombosis¹.

Preoperative contrast studies were not performed in our series. We wanted to avoid causing a postphlebographic venous thrombosis and to minimize the risk of other phlebography-related complications

by performing only one invasive investigation, as the risk of deep-vein thrombosis following minor surgery is known to be very low. Venography was performed at four weeks postoperatively to include detection of late deep-vein thrombosis. Also, preoperative screening for nonsymptomatic deep-vein thrombosis possibly would have resulted in the selection of a cohort that was not representative.

Although it has been stated that about half of calf thromboses resolve spontaneously within seventy-two hours, about one-sixth extend to the proximal veins and thus increase the risk of pulmonary embolism⁵. Therefore, we do not agree with the assumption of Drs. Simon and Mass that calf-vein thrombosis is unlikely to lead to a pulmonary embolus. Finally, the main message of our study was that there is a possible risk of deep-vein thrombosis following bunion surgery. We believe that patients with obvious risk factors for deep-vein thrombosis should receive medical prophylaxis against deep-vein thrombosis.

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To The Editor:

I read the article on "Venous Thrombosis After Hallux Valgus Surgery" (2003;85:1204-8), by Radl et al., with interest. The authors have conducted a well-planned study. It is reassuring to note the low rate of venous thrombosis at four weeks after hallux valgus surgery.

I believe that this single investigation performed four weeks after surgery may not have accurately quantified the true rate of venous thrombosis. In their discussion, the authors clearly state that most thrombi form in the first postoperative week and support this statement with a reference¹. Perhaps a noninvasive investigation in the first week after surgery might have diagnosed more cases of venous thrombi.

The study suggests that there is a significant association between venous thrombosis and the age of the patient. On the basis of the inclusion and exclusion criteria, a relatively risk-free population was selected for the study. Can the authors explain the reason for the significant age-dependent increase in the rate of venous thrombosis that was noted in their study?

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R. Radl and R. Windhager reply:

We thank Mr. Thalava for his commentary on our article. The intention of our study was to evaluate the potential risk of venous thrombosis following hallux valgus surgery. Venography was performed only once, to minimize the possibility of postvenographic thrombosis². In our study, venography was performed four weeks after the operative procedure, with the intention of also discovering late deep-vein thrombosis³⁻⁵. We agree that the risk of postoperative thrombosis might be highest within the first postoperative week. The performance of an additional noninvasive investigation, such as ultrasonography, one week after the surgical procedure probably would have detected more cases of throm-

bosis; however, this method is known to be unreliable as routine surveillance for the detection of asymptomatic venous thrombi in the calf⁶. In the present study, no symptoms indicating a venous thrombosis were detected during the first postoperative week. Additionally, we want to emphasize that venous thrombi that degenerate in this short time-period and that cannot be detected four weeks after the operation might not be of serious clinical relevance. Since the routine use of low-molecular-weight heparin as anti-thrombotic prophylaxis following hallux valgus surgery is very common in our country, the local ethics committee insisted on rigorous exclusion criteria. The findings of our study suggest that patients who have had operative correction of hallux valgus are at a certain risk of venous thrombosis. Therefore, we believe that patients with obvious risk factors for venous thrombosis need medical prophylaxis against thrombosis. The inclusion of patients with risk factors might have increased the number of cases of venous thrombosis.

Advanced age is a well-known clinical risk factor for the development of first-time venous thrombosis⁷. The prevalence of thrombosis following total hip replacement or major trauma rises significantly with increasing age^{1,8}. On the basis of these findings, it is easy to speculate that the activity level might be a reason for the significant age difference between patients with and without postoperative venous thrombosis. Unfortunately, in our patients, the exact postoperative activity level was not measured and therefore we can only speculate, but this issue should be a concern in future prospective studies.

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Angulatory Stresses After High Tibial Osteotomy: Are They Relevant Enough to Warrant Additional Fixation?

To The Editor:

In the article "Tibial Osteotomy for the Treatment of Varus Gonarthrosis. Survival and Failure Analysis to Twenty-two Years" (2003;85:469-74), Sprenger and Doerzbacher compiled an interesting statistical retrospective analysis of osteotomy for the treatment of tibial gonarthrosis. However, there seem to be certain flaws in the logic behind the technique described. The authors did not provide conclusive biomechanical evidence of the utility of this construct in preventing nonunion or malalignment due to axial or angular stresses and torsional loads^{1,2}. In addition, application of a tension-band wire on the medial side would entail further periosteal stripping, which is undesirable these days as there is a trend toward the use of minimal implants, and the application of hardware on both surfaces is not desirable³. Moreover, the exposure for applying tension-band wiring after osteotomy requires a separate incision to be made very near the site of plate applica-

tion, hence decreasing the vascularity of the intervening skin. Even if a single skin incision were used, it would require a long exposure of the bone. The final clinical outcome with regard to union of the osteotomy and pain relief did not vary significantly from the outcomes reported in other series in which single-sided fixation constructs had been used. This casts doubt on the usefulness of the medial tension-band wiring^{3,4}. The authors also seem to have changed the technique described in the original article, by Sprenger et al.⁵, in which the osteotomy was made proximal to the level of the tibial tuberosity and two proximal screws and three distal screws were used; in the current study, three proximal and four distal screws were used and the osteotomy was distal to the tibial tuberosity, as shown in Figures 1-B and 1-C.

Furthermore, the authors performed a lateral closing-wedge osteotomy in all patients irrespective of collateral ligament laxity. If collateral ligament laxity is present, it should be regarded as an indication for an opening-wedge osteotomy⁶.

With regard to the safe zone described for fibular osteotomy, the extensor hallucis longus is also innervated by two to three thin branches, arising from the deep branch of the peroneal nerve; however, in 25% of the specimens, only one large branch was found. This branch is placed under tension by manipulating the distal aspect of the tibia forward. Thus, it may be damaged by the Hohmann retractor during distal screw fixation, tensioned by hyperextension, or directly injured during mid-shaft fibular osteotomy⁷.

The message of the article is that high tibial osteotomy is appropriate for patients who are less than sixty years old; however, the results should have been compared with those in the literature (specifically, the studies of Ranawat and Boachie-Adjei⁸, Rand and Ilstrup⁹, and Scuderi et al.¹⁰ as noted in the article) to firmly authenticate the relative advantage of high tibial osteotomy in such patients.

The authors addressed the issue of achieving the required angle of correction in high tibial osteotomy very well, but they did not touch on limb-length discrepancy¹¹, patellar height alteration¹², or differences in the quality of life after a high tibial osteotomy compared with that after total knee replacement. They also did not discuss the difficulties faced by a surgeon who per-

forms an arthroplasty after a failed high tibial osteotomy.

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*T.R. Sprenger and
J.F. Doerzbacher reply:*

We thank Dr. Aggarwal, Professor Sangwan, Dr. Yadav, and Dr. Singh for their inquiry and their interest in tibial osteotomy. The primary purpose of our presentation was to study alignment in relation to length of survival. Since our presentation was not a review article, other techniques were not discussed.

The technique that we described was developed in the late 1960s. Medial tension-band wiring is not needed today because techniques are now available that stop short of violating the medial cortex, thus producing a construct that is superior in preventing nonunion or malalignment due to axial or angular stresses and torsional loads^{4,13}. Eliminating the necessity for medial wiring permits the use of a shorter incision. The senior one of us (T.R.S.) has no experience with opening-wedge osteotomies.

All osteotomies were accomplished as shown in Figures 1-A and 1-B of the original article and were proximal to the tibial tubercle⁵. The screw that was placed through the proximal hole in the long arm of the T-plate, as shown in the second report, was applied to serve as a lag screw after it crossed the osteotomy site. The angle of this screw may have created the impression that the technique had been changed.

Maquet¹⁴ reported that it was not necessary to augment tibial osteotomies with ligament procedures because ligament balance is reestablished as a result of the realignment procedure. Problems with ligamentous instability were not recognized in our study.

Considerable differences of opinion

persist as to whether the results of total knee arthroplasty after a failed osteotomy are as good as those after primary arthroplasty. We believe that total knee arthroplasties are more difficult to perform in knees with a marked varus or valgus deformity and that substantial axial malalignment from an osteotomy is an important factor in the failure to achieve an ideal result. Further difficulty may be encountered if patella infera has resulted from cast immobilization.

We believe that the information provided in your letter about the Hohmann retractor possibly injuring the peroneal nerve is important. In our procedure, the distal aspect of the tibia was not moved forward as in a Maquet procedure combined with a tibial osteotomy.

By the late 1980s, when studies of patellar height alterations following tibial osteotomies first appeared, all but one of the osteotomies in our series had been done. Since standardized lateral radiographs of the patella were not done, we have no data on patellar height.

For patients with a high-demand, high-impact lifestyle who are less than sixty years old, we believe that the tibial osteotomy is the better alternative, leaving the arthroplasty as the procedure of choice for patients with a low-impact, low-demand lifestyle.

Complaints about limb-length discrepancy were not recognized in our study. Hernigou et al.¹² presented some interesting observations in that regard.

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Corticosteroid Compared with Hyaluronic Acid Injections for the Treatment of Osteoarthritis of the Knee

To The Editor:

I read with interest the article "Corticosteroid Compared with Hyaluronic Acid Injections for the Treatment of Osteoarthritis of the Knee. A Prospective, Randomized Trial" (2003;85:1197-203), by Leopold et al. I am writing regarding the methodology of this study.

The aim of the study was to compare Hylan with steroid injections. However, the group that received Hylan also underwent aspiration of effusions whereas the group that had steroid injections did not. Aspiration of effusions alone may influence symptoms¹. It is thus possible that part of the response attributed to Hylan was due to aspiration of the effusion.

In the article, no justification was given for not performing aspirations in the steroid group.

—Charalambos P. Charalambous,
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S.S. Leopold, B.B. Redd, W.J. Warme, P.A. Wehrle, P.D. Pettis, and S. Shott reply: Dr. Charalambous is correct in noting that, in our Hylan G-F 20 (Synvisc) group, we aspirate any detectable effusions prior to injecting the product, whereas, in the corticosteroid group, aspirations were not performed prior to injection. As pointed out and as the indicated reference suggests¹, the aspiration of joint effusions may produce some relief of symptoms, and this may indeed have had some impact on our results.

Our goal was to perform each study intervention as it is commonly carried out in practice and as the manufacturer of the drug or device directs. The manufacturer's directions on the package insert for Synvisc call for joint aspiration prior to injection, and we thought that it was important to follow this direction carefully. The package insert for the corticosteroid used in the study does not mandate joint aspiration, and there is inconsistent performance of joint aspiration before injection of corticosteroids reported in the literature, including the article referenced¹. Those who conducted that study apparently aspirated only very large effusions (ones in which the "bulge sign" or positive patellar tap was present)¹.

In any case, we used corticosteroid injection as the "control," against which the newer, more expensive product was tested. No consequential differences in efficacy between corticosteroid and Synvisc injections were observed in our study. Since this appears to be the case, despite what may be, perhaps correctly, perceived to be a bias favoring the Synvisc group, it would tend to support our conclusion that "we do not consider Hylan G-F 20 a first-line treatment for patients with osteoarthritis who are considering intra-articular knee injections for palliation of symptoms."

—Seth S. Leopold, MD
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These letters originally appeared, in slightly different form, on jbjs.org. They are still available on the web site in conjunction with the article to which they refer.

To The Editor:

I am writing to comment on the article entitled "Corticosteroid Compared with Hyaluronic Acid Injections for the Treatment of Osteoarthritis of the Knee. A Prospective, Randomized Trial" (2003;85:1197-203), by Leopold et al.

I am a physician who has used hyaluronic acid injections for the past five years. Although I have had similar early results with various products, overall I believe that hyaluronic acid lasts much longer than does corticosteroid treatment. Therefore, I question the results of this study on the basis of my own clinical experience. More importantly, I have found that a combination of glucosamine and hyaluronic acid injections seems to prolong and to improve the rapid onset of benefits. In many patients, the pain-free interval has been extended from six months to one year. I have become so comfortable with and supportive of this combination treatment that I am extending the indications to younger and younger individuals with early chondromalacia of various aspects of the knee.

Therefore, I believe that this article does this treatment option a disservice by comparing it with corticosteroids.

—David A. Brys, MD
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S.S. Leopold, B.B. Redd, W.J. Warme,

P.A. Wehrle, P.D. Pettis, and S. Shott reply:

The kinds of observations made by Dr. Brys are similar to those that we make on a daily basis: at some level, we all must decide what seems to work in our hands and in our own patient populations.

That said, there are shortcomings to this approach, including recall bias on the part of the surgeon and loss to follow-up (so-called transfer bias) with respect to which patients return to the office, among others. Before performing our study, we would have said that our impressions were much the same as those of Dr. Brys. We thought that Hylan GF-20 (Synvisc) provided a longer period of relief than did corticosteroid injections. However, because we were concerned about our own abilities to detect these two types of bias as well as about what we noted to be a subpopulation of patients who did not seem to have much of a response at all to Hylan GF-20, we decided to perform a randomized, controlled trial. The results of this study—as is so often the case—were not what we expected. We found, in our independently funded and amply powered study, that both intra-articular corticosteroids and Hylan GF-20

improved outcome scores modestly from baseline but that there were no significant differences between the two treatment groups after three or six months of follow-up. We also found some unexpected gender-related differences in the response to treatment, which bear further investigation.

It is absolutely reasonable for a practitioner who reads a clinical trial to question why the published results are at odds with his or her own outcomes. Such discrepancies occur all the time and are worth exploring in some detail. That exploration usually goes in one or more of three directions: (1) Is the study methodologically flawed or critically biased (that is, does the study have internal validity)? (2) Does the study involve patients who are substantially different in some important way from the practitioner's own patients (that is, does the study have external validity)? (3) Does the self-assessment of the practitioner's own results reflect actual outcomes, or is that assessment hampered by one or more sources of bias? Answering these questions is at the heart of the evidence-based medicine paradigm, and asking them is the critical exercise that we all perform when we read peer-reviewed journal articles.

We are not able to comment on the use of glucosamine in combination with hyaluronic acid injections because our study did not specifically address this practice. Likewise, extending the indications of hyaluronic acid products to off-label uses

as Dr. Brys describes was beyond the scope of our report, and we do not support this practice. Treating younger patient populations in this manner is likely to result in such patients receiving repeated courses of treatment; we would be reluctant to move in that direction on the basis of the results of our previous work demonstrating increased frequency of acute local reactions in patients treated more than once with Hylan GF-20¹.

We thank Dr. Brys for sharing his perspective on this topic with us and for his interest in our work.

—*Seth S. Leopold, MD*

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Reference

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