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Shock Wave Therapy Compared with Intramedullary Screw Fixation for Nonunion of Proximal Fifth Metatarsal Metaphyseal-Diaphyseal Fractures

By John P. Furia, MD, Paul J. Juliano, MD, Allison M. Wade, MD, Wolfgang Schaden, MD, and Rainer Mittermayr, MD

Investigation performed at the Evangelical Community Hospital, Milton S. Hershey Medical Center, Hershey, Pennsylvania, and the AUVA Trauma Center, Vienna, Austria

Background: The current “gold standard” for treatment of chronic fracture nonunion in the metaphyseal-diaphyseal region of the fifth metatarsal is intramedullary screw fixation. Complications with this procedure, however, are not uncommon. Shock wave therapy can be an effective treatment for fracture nonunions. The purpose of this study was to evaluate the safety and efficacy of shock wave therapy as a treatment of these nonunions.

Methods: Twenty-three patients with a fracture nonunion in the metaphyseal-diaphyseal region of the fifth metatarsal received high-energy shock wave therapy (2000 to 4000 shocks; energy flux density per pulse, 0.35 mJ/mm²), and twenty other patients with the same type of fracture nonunion were treated with intramedullary screw fixation. The numbers of fractures that were healed at three and six months after treatment in each group were determined, and treatment complications were recorded.

Results: Twenty of the twenty-three nonunions in the shock wave group and eighteen of the twenty nonunions in the screw fixation group were healed at three months after treatment. One of the three nonunions that had not healed by three months in the shock wave group was healed by six months. There was one complication in the shock wave group (post-treatment petechiae) and eleven complications in the screw-fixation group (one refracture, one case of cellulitis, and nine cases of symptomatic hardware).

Conclusions: Both intramedullary screw fixation and shock wave therapy are effective treatments for fracture nonunion in the metaphyseal-diaphyseal region of the fifth metatarsal. Screw fixation is more often associated with complications that frequently result in additional surgery.

Level of Evidence: Therapeutic Level III. See Instructions to Authors for a complete description of levels of evidence.

There are three distinct fracture types in the proximal part of the fifth metatarsal: tuberosity avulsion fracture, fracture of the metaphyseal-diaphyseal junction (Jones fracture), and diaphyseal stress fracture¹. Tuberosity fractures heal well, Jones fractures heal less well, and diaphyseal stress fractures heal poorly.

The prevalence of delayed union and nonunion of an acute closed fracture involving the metaphyseal-diaphyseal region of the fifth metatarsal has been reported to range from 7% to 44%¹⁻⁵. Management can be challenging.

There have been reports of successful nonoperative treatment of acute fractures and fracture nonunions of the proximal part of the fifth metatarsal with a weight-bearing or

non-weight-bearing cast². However, compliance with this form of treatment, particularly non-weight-bearing, is often difficult. Other potential problems include continued pain despite radiographic evidence of healing, substantial muscle atrophy, disuse osteoporosis, increased susceptibility to reinjury, and, perhaps most importantly, persistent fracture nonunion^{1,3-8}.

For these reasons, most clinicians recommend a surgical approach^{2-4,8-10}. Options include tension band wiring¹¹, corticocancellous inlay bone-grafting with or without intramedullary screw fixation², dorsomedial bone-grafting¹², and intramedullary screw fixation alone^{3,9,10,13,14}. Reports of the results of these surgical treatments have generally been favorable^{2,5,10,12}.

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Unfortunately, complications with surgical intervention, particularly intramedullary screw fixation, are not uncommon^{1,3,7,14}. Intramedullary screw fixation offers little resistance to rotation of the proximal and distal fragments relative to one another¹⁵. This is one reason why, even with ideal screw placement, intramedullary screw fixation may not result in fracture-healing. Fracture of the screw, a breach of the medullary cortex, chronic pain at the insertion site, and impingement of the screw head on the cuboid are all risks with this technique^{3,5}. The prevalence of refracture on screw removal is also disturbingly high^{1,7}.

With the advent of better technology and the desire for a less invasive approach, shock wave therapy has emerged as an alternative treatment for fracture nonunions¹⁶⁻²¹. Although its exact mechanism of action remains unknown, basic-research studies have shown that shock wave therapy has an osteogenic effect on bone, enhances neovascularity in tissues, and stimulates growth-factor release²²⁻²⁵. Studies of shock wave therapy as a method of augmenting fracture-healing in animals have shown favorable results, and several clinical trials of humans have supported the use of shock wave therapy as a method of treating fracture nonunion^{16-18,22,24-28}.

The primary advantages of shock wave therapy are its efficacy, its high safety profile, and its noninvasive nature. The primary disadvantages are the variability in the treatment protocols and the scarcity of treatment centers in the United States.

Because of the unpredictable response, incomplete relief, and frequent recurrences associated with nonoperative treatment as well as the risks associated with intramedullary screw fixation and the favorable results in prior studies of shock wave therapy as a treatment for fracture nonunion, the aim of this study was to determine whether shock wave therapy is a safe and effective technique for the treatment of fracture nonunions of the proximal part of the fifth metatarsal. The hypothesis was that shock wave therapy would be as effective as, and yield fewer complications than, intramedullary screw fixation.

Materials and Methods

Institutional review board approval was obtained for this retrospective comparative study. From August 1, 1999, to May 1, 2007, all patients in whom an established nonunion of an acute fracture of the proximal part of the fifth metatarsal had been treated at a tertiary referral center where shock wave therapy is typically performed were considered for inclusion in the study. Some of the patients were initially treated by an orthopaedic surgeon on staff, whereas others were referred to the center by an orthopaedic surgeon from outside the community. Patients were specifically referred to be considered for shock wave therapy. The shock wave therapy procedures were performed by one of fourteen staff physicians.

During the same time period, a similar group of patients in whom an established nonunion of an acute fracture of the proximal part of the fifth metatarsal had been treated with intramedullary screw fixation at one of two different centers were considered for enrollment in the study. After a review of

the cases of all patients who had undergone intramedullary screw fixation of an acute metatarsal fracture during the collection period, we identified twenty-five patients who had had intramedullary screw fixation of a fracture nonunion of the fifth metatarsal. The only parameter used to select these twenty-five patients was the existence of an established nonunion of the proximal part of the fifth metatarsal. These patients were enrolled from the clinical practices of two fellowship-trained orthopaedic surgeons (one trained in foot and ankle surgery and the other, in sports medicine) and represented all patients treated for this condition by these two surgeons during the collection period. Thirteen patients were treated by one surgeon (P.J.J.) and twelve were treated by the other surgeon (J.P.F.) with the technique favored by each physician.

For the purposes of this study, a nonunion was defined as a fracture that had failed to demonstrate cortical continuity radiographically for six months despite operative or nonoperative intervention or that had shown no radiographic evidence of healing for three months and was associated with pain and/or tenderness on palpation.

The inclusion criterion was an established nonunion of an acute, isolated, closed, proximal metaphyseal-diaphyseal fracture of the fifth metatarsal in a skeletally mature patient who had been treated with either shock wave therapy or intramedullary screw fixation. No patient had prodromal symptoms prior to the fracture. All patients were evaluated on the basis of the history, physical examination, and a set of anteroposterior, lateral, and oblique radiographs. Other imaging studies were performed on a case-by-case basis.

Exclusion criteria included local infection, skeletal immaturity, open fracture, pregnancy, tumor, a previous fracture of the fifth metatarsal shaft or tuberosity, a previous stress fracture, and the presence of a cardiac pacemaker.

Demographics

Shock Wave Group

Electrohydraulic shock wave therapy was administered with use of either the OssaTron device (HMT [High Medical Technologies], Lengwil, Switzerland) (sixteen patients) or the Orthowave-280 device (MTS, Konstanz, Germany) (eight patients). There was incomplete follow-up data on one patient, and this patient was excluded from the study. Thus, twenty-three patients with a total of twenty-three fracture nonunions of the fifth metatarsal were available for analysis. These patients made up the shock wave group.

There were ten female and thirteen male patients in the shock wave group, with a mean age (and standard deviation) of 42.7 ± 18.0 years (range, seventeen to seventy-eight years). Two of the patients were smokers, and one had diabetes. The average time between the injury and treatment was 10.4 ± 7.0 months (range, six to thirty-nine months) (see Appendix).

Fixation Group

Twenty-five patients had intramedullary screw fixation during the study period. Three of the patients had a stress fracture, one had multiple fractures, and one had an open fracture, and

those five patients were excluded from the study. Twenty patients with a total of twenty fracture nonunions of the proximal part of the fifth metatarsal met the inclusion criteria and were available for analysis.

Ten patients were treated with a 6.5-mm cancellous screw (Synthes, West Chester, Pennsylvania), nine were treated with a 4.5-mm cannulated screw (Synthes), and one was treated with a 4.5-mm noncannulated screw (Synthes).

There were twelve women and eight men in the fixation group, with a mean age of 40.8 ± 18.6 years (range, nineteen to seventy-eight years). Two of the patients were smokers, and one had type-II diabetes. The average time between the injury and the treatment was 6.2 ± 2.3 months (range, four to thirteen months) (see Appendix).

Shock Wave Therapy Technique

All patients provided signed informed consent. The details and potential risks of the procedure were discussed fully before treatment. High-energy shock wave therapy was administered with use of either the OssaTron device (sixteen patients) or the Orthowave-280 device (seven patients) as technical support for the OssaTron device was lost during the latter part of the collection period. The two devices are very similar; both are high-energy devices and utilize electrohydraulic methods to generate the shock waves. Eleven of the procedures performed with the OssaTron device were done with the patient under general anesthesia, four were performed with the use of regional anesthesia, and one was performed with use of local anesthesia only. Four of the procedures performed with the

Orthowave-280 device were done with the patient under general anesthesia, two were performed with the use of regional anesthesia, and one was carried out with the use of local anesthesia only.

The procedure was performed in the same manner with either device. The patient was positioned in a supine position and received treatment on a standard fracture table (Fig. 1). The nonunion site was localized with an image intensifier. Ultrasound gel was then applied to the skin overlying the site of the nonunion. The center of the shock wave targeting device (the focal point) was positioned in such a way that the administered shock waves were directed at the fracture site. The targeting device was then docked to the skin overlying the nonunion site. Shock waves were applied to the fracture nonunion and the adjacent cortical structures in an anterior-to-posterior direction. The average size of the area of treatment was approximately 2 cm in width and 2 cm in length. The procedure was guided with use of the image intensifier.

Each fracture was treated with 2000 to 4000 pulses with a voltage of 26 kV, corresponding to an energy flux density per pulse of 0.35 mJ/mm^2 . The total number of impulses was divided equally along the proximal and distal margins of the nonunion. Treatments lasted approximately ten to twenty minutes. The patient's vital signs were monitored throughout the procedure by an anesthetist.

Procedure Following Shock Wave Therapy

After completion of the procedure, the foot was assessed for swelling, hematoma, and ecchymosis. A well-padded weight-

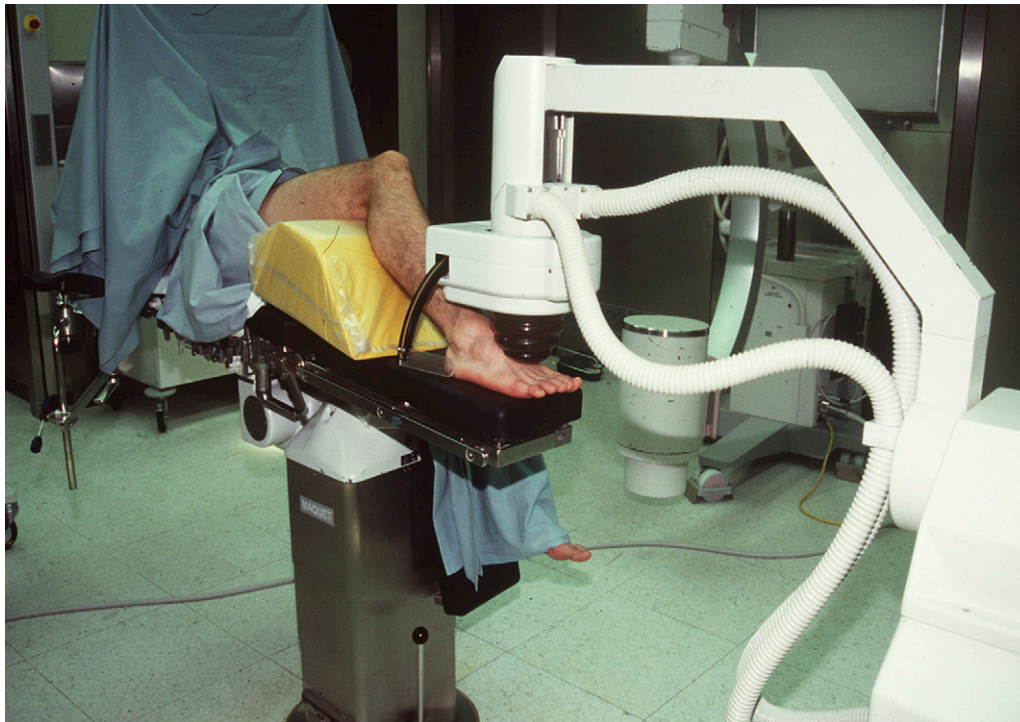


Fig. 1
The OssaTron shock wave generator.

bearing short leg plaster cast was then applied. The patients were monitored in the same-day-surgery recovery area and then discharged later the following day. As a result of the logistics of the referral center, patients scheduled to receive shock wave therapy are assigned a lower priority than are patients with an acute traumatic injury. As a result, the shock wave therapy was usually administered very late in the day or even at night. Therefore, all patients who had shock wave therapy stayed overnight in the hospital.

Immobilization in a weight-bearing cast was continued for a period of four to six weeks. All patients were subsequently monitored in the clinic at four to six-week intervals. Standardized anteroposterior, lateral, and oblique radiographs were made at four-week intervals, with use of the same machine, the same exposure setting, and comparable positioning of the leg at each follow-up visit. Patients were transitioned from a cast to normal shoes as healing progressed, but no sooner than four to six weeks after treatment.

Surgical Technique

All operations were performed with use of fluoroscopic guidance on an outpatient basis by one of two authors (J.P.F. or P.J.J.). All patients provided signed informed consent. The details of the procedure and potential risks were discussed fully before treatment.

A 1.5-cm incision was made just posterior to the proximal tip of the fifth metatarsal and was extended proximally in line with the metatarsal. Careful blunt and sharp dissection was used to expose the peroneus brevis insertion. The fracture site was exposed.

For fractures treated with the 6.5-mm cancellous or 4.5-mm noncannulated screw, either a 4.5-mm drill-bit (for the fractures treated with the 6.5-mm screw) or a 3.5-mm drill-bit (for those treated with the 4.5-mm screw) was placed into the proximal tuberosity, across the fracture site, and down the medullary canal. The insertion was observed in both the oblique and the lateral plane with use of the fluoroscope. Next, a standard tap and countersink device were utilized to prepare the canal and the proximal cortex, respectively. A partially threaded 6.5 or 4.5-mm cancellous screw was then inserted under direct imaging.

For fractures treated with the cannulated screw, a standard guide pin (Synthes) was introduced into the proximal tuberosity and inserted across the fracture site and down the medullary canal. The insertion was observed in both the oblique and the lateral plane with use of the fluoroscope. A 3.5-mm cannulated drill-bit was then passed over the guide pin to create a hole for the screw. Next, a standard tap and a countersink device were utilized to prepare the canal and proximal cortex, respectively. A partially threaded 4.5-mm cannulated screw was then inserted over the guide pin.

In each case, special attention was paid to ensuring that all screw threads were distal to the fracture site. An attempt was made to use the longest screw possible without violating the distal diaphyseal cortex. The head of the screw was countersunk to minimize the chance of subsequent impingement of

the screw head on the cuboid. Wounds were closed in a routine fashion. A sterile compressive dressing and a well-padded posterior fiberglass splint were applied.

Postoperative Treatment

Postoperatively, the patients wore a posterior splint and were restricted from bearing weight for two weeks. The patients were seen in the clinic two weeks following the surgery. At that time, use of the splint was discontinued, the skin staples or sutures were removed, and a hard-sole shoe or a prefabricated walking boot was applied. The patients were then allowed to walk with toe-touch weight-bearing using crutches and were advanced to weight-bearing as tolerated over a period of four to six weeks. Nonimpact activities such as stationary cycling were often initiated at the first return visit. At approximately four weeks following the surgery, the patients were transitioned from the hard-sole shoe to athletic shoes with a stiff sole. Orthotic devices were utilized only if the patient had used them preoperatively. Stair-stepping and elliptical training exercises were begun after the patient was comfortable wearing standard athletic shoes. Easy jogging was begun approximately eight to ten weeks postoperatively as long as the patient continued to be pain-free. The patients were allowed to return to competitive sports on a case-by-case basis.

The patients were followed in the clinic at approximately four to six-week intervals. They were evaluated with a physical examination as well as direct questioning regarding residual symptoms such as pain with walking. Radiographs were routinely made at four-week intervals and assessed for fracture-healing.

Assessment of Healing

All radiographs in both groups were assessed by an independent physician who was not one of the authors (the shock wave group) or by the treating physician (the fixation group) and an independent radiologist. A fracture was defined as being clinically healed when the patient could bear full weight on the affected limb, there was no pain or tenderness at the fracture site on compression, and there was radiographic evidence of healing. The patient was considered to have radiographic evidence of healing when four cortices (two seen on the anteroposterior radiograph and two seen on the lateral radiograph) were bridged or when no fracture gap could be detected on the radiographs. Both the radiographic and the clinical criteria had to be met for union to be established. The time to healing was assessed from the date of the procedure to the date of documented fracture-healing.

Sports Activities and Occupation

Three of the patients in the shock wave group and four of the patients in the fixation group said that they participated in some type of regular recreational sports activity. All of the athletes in the shock wave group were soccer players. In the fixation group, one of the athletes played college soccer, one played recreational soccer, one played recreational basketball, and one was a jogger. Four of the patients in the shock wave



Fig. 2-A



Fig. 2-B

Fig. 2-A Anteroposterior, oblique, and lateral radiographs of a twenty-three-year-old male recreational soccer player with a thirteen-month history of a metaphyseal-diaphyseal nonunion of the fifth metatarsal. **Fig. 2-B** Anteroposterior and oblique radiographs, made four months after treatment with high-energy shock wave therapy and cast immobilization, demonstrate healing of the nonunion.

group and five of the patients in the fixation group worked as laborers or in an occupation that required extensive physical activity, such as carpentry and industrial factory work.

Outcome Measures

The primary outcome measure was the number of fractures that had healed at three months after treatment. The secondary outcome measures were the number of fractures that had healed at six months after treatment and the rate of complications.

Source of Funding

There was no external funding source for this study.

Results

The mean duration of follow-up was 64.7 ± 29.6 months (range, six to 111 months) in the shock wave group and 18.7 ± 10.6 months (range, six to fifty-six months) in the fixation group, and the median durations of follow-up were sixty-one and eighteen months, respectively.

Twenty of the twenty-three fractures in the shock wave group (Figs. 2-A and 2-B) and eighteen of the twenty fractures in the fixation group had healed by three months after treatment. Two of the three patients with a persistent nonunion in the shock wave group had been treated with the OssaTron device, and one had been treated with the Orthowave-280 device. One of the two fractures treated with the OssaTron device was healed at six months after treatment, and the other was not. The fracture treated with the Orthowave-280 device was not healed at six months. Thus, at six months after treatment, twenty-one of the twenty-three fractures in the shock wave group were healed.

The patient who had a persistent nonunion after treatment with the Orthowave-280 device elected to undergo shock wave therapy again six months after the initial treatment. The fracture was healed one month after the second session of shock wave therapy (that is, seven months after the initial session). The one patient with the persistent nonunion after treatment with the OssaTron device declined additional treatment.

Neither of the patients in the fixation group who had a persistent nonunion at three months after treatment had healing at six months. Thus, six months after treatment, eighteen of the twenty fractures in the fixation group were healed. One of the patients with a persistent nonunion had been treated with a 6.5-mm cancellous screw, and the other had been treated with a 4.5-mm cannulated screw. The patient treated with the 4.5-mm cannulated screw underwent screw removal secondary to pain at the screw insertion site and was treated with five additional weeks of immobilization in a walking boot. The fracture was healed two months later. Superficial cellulitis developed in the patient treated originally with the 6.5-mm cancellous screw and resolved without a course of oral antibiotics. This patient also experienced pain from a prominent screw head and underwent screw removal. The patient was treated with four weeks of full weight-bearing in a hard-sole shoe; however, the fracture did not heal. The patient was offered a revision

surgical procedure that was to include bone-grafting but declined additional treatment.

All three of the athletes in the shock wave group were able to return to playing soccer approximately three months after treatment. In the fixation group, the college soccer player was a senior and returned to playing soccer, on a recreational level, approximately six months after surgery. The recreational soccer player returned to playing recreational soccer approximately six months after surgery, and both the jogger and the basketball player returned to their respective sport approximately four months after the intramedullary screw fixation.

All four patients in the shock wave group and all five patients in the fixation group whose job had required extensive physical activity were able to return to their preinjury work status.

One patient in the shock wave group had a minor complication: some mild, transient petechiae developed but then resolved within twenty-four hours without treatment. In contrast, nine patients in the fixation group had a total of eleven complications. Both of the patients with a persistent nonunion also had symptoms related to a prominent screw head and underwent hardware removal. As mentioned above, superficial cellulitis also developed in one of these two patients. Seven other patients had impingement of the screw head against the cuboid and ultimately underwent screw removal. Of these seven patients, four had been treated with a 6.5-mm cancellous screw and three had been treated with a 4.5-mm cannulated screw. One of these seven patients also sustained a refracture of the fifth metatarsal approximately one year after the index procedure. The refracture was treated with five weeks of immobilization in a walking boot and it ultimately healed.

Discussion

There is little published information regarding the management of proximal fracture nonunions of the fifth metatarsal^{1-4,8-14,29,30}. Most reports have been of small uncontrolled case series^{9-14,30}, and there is no consensus regarding optimal treatment^{9,13,14,30}.

Treatment with a non-weight-bearing cast may be a reasonable approach for less active individuals. Torg et al. reported their experience with a variety of treatment methods for forty-six Jones fractures². Of ten patients with a delayed union or an established nonunion treated with a non-weight-bearing cast, seven had healing in a mean of fifteen months and three ultimately required a bone-graft procedure². Although others have also reported success with non-weight-bearing cast immobilization, in each series the duration of the immobilization was lengthy, ranging from a mean of nine weeks in one trial²⁹ to a minimum of twelve weeks in another⁸.

In contrast, the patients in the shock wave group in our series were treated with immobilization for as little as four weeks and for as long as six weeks. The patients in the shock wave group were also permitted unrestricted weight-bearing after the immobilization period. As we have gained experience and confidence with the technique, the duration of immobilization has continued to decrease.

Others have had less success with nonoperative treatment. Kavanaugh et al. reported on twenty-two patients with a total of twenty-three Jones fractures³. Twelve of eighteen patients who were initially treated nonoperatively had a delayed union or nonunion. Thirteen fractures that underwent fixation with a noncannulated intramedullary screw were clinically healed in six weeks and had radiographic evidence of healing in three months³. Raikin et al. reported that twelve (57%) of twenty-one Jones fractures that had been initially managed nonoperatively with a non-weight-bearing cast or boot for two to eight months (mean, 4.2 months) went on to delayed union or nonunion⁹.

Presently, most clinicians treat proximal nonunions of the fifth metatarsal surgically. Autogenous bone-grafting procedures may be efficacious, but they have some substantial drawbacks, including the potential to further disrupt the already tenuous metaphyseal-diaphyseal blood supply^{1,12,13}. Tension band wiring with use of pins and wires is another alternative, but this technique usually results in symptomatic hardware, which often must be removed with a second surgical procedure¹¹.

Intramedullary screw fixation, a procedure originally recommended for athletes, has become a preferred treatment method^{3,4,6,7,9,31}. Reese et al. reported on nine acute fractures and six chronic fractures treated with cannulated intramedullary screw fixation³⁰. All fractures healed, at a mean of 7.9 weeks (range, four to twenty-five weeks) postoperatively. In the series reported by Raikin et al., all of the twelve chronic fractures that were eventually treated with intramedullary screw fixation had radiographic evidence of healing nine weeks postoperatively and clinical evidence of healing 12.4 weeks (range, eight to eighteen weeks) postoperatively⁹.

Unfortunately, complications, particularly refracture, are not rare following intramedullary screw fixation. In the series reported by Kavanaugh et al., five patients had a complication (screw breakage during insertion in three patients and a screw that missed the medullary canal in the other two)³. Glasgow et al. reported six complications, including three refractures and three delayed unions, in six patients treated with intramedullary screw fixation¹³.

More recently, Wright et al. reported on six patients who sustained a refracture after demonstrating clinical and radiographic evidence of healing of a Jones fracture that had been treated with intramedullary screw fixation⁷. Four of the patients were professional football players, one was a college basketball player, and one was a recreational athlete⁷. Three of the football players sustained the refracture within one day after returning to full activity, and the other athletes sustained the refracture 2.5, four, and 4.5 months after returning to full activity⁷. Others have also reported a disturbingly high rate of refracture following intramedullary screw fixation¹⁴. It is noteworthy that none of the twenty-three patients in the shock wave group in the present series sustained a refracture after a median duration of follow-up of sixty-one months.

In light of the prolonged healing time and rate of persistent nonunion associated with traditional nonoperative man-

agement as well as the potential complications and morbidity associated with surgical intervention, we believe that alternative treatment methods should be pursued.

Holmes successfully treated five delayed unions and four nonunions of the proximal part of the fifth metatarsal with pulsed electromagnetic fields. The patients were treated with an external coil device that provided pulsed electromagnetic fields for eight to ten hours per day³². All fractures ultimately healed (at a mean of four months; range, two to eight months). All patients returned to their preinjury level of activity, and no case required additional intervention. Unfortunately, this technique required prolonged daily treatment sessions and, to the best of our knowledge, the results have not been duplicated in similar trials by other investigators.

Shock wave therapy has emerged as another safe and noninvasive method of treatment of fracture nonunions. Basic-science studies have shown that shock wave therapy can have an anabolic effect on bone^{22-27,33,34}. Selective destruction of osteocytes, microfractures of trabeculae, and minor bleeding in the medullary space were observed in rabbits treated with shock wave therapy^{33,34}. Approximately three weeks after treatment, histological and biochemical analyses revealed thickening of the cortex, an increase in the number of osseous trabeculae, and a substantial increase in the number and activity of treated osteoblasts^{33,34}.

Uncontrolled clinical trials of the use of shock wave therapy to treat a variety of fracture nonunions have shown promising results¹⁶⁻¹⁸. Overall reported success rates have ranged from 72% to 80%¹⁶⁻¹⁸. Unfortunately, the inclusion criteria in each of these trials were very broad, with none of the studies limited to the investigation of a specific bone. Furthermore, the location of the nonunion site in a particular bone, such as the proximal part, diaphyseal region, or distal part of the tibia, varied among the patients in each of these trials. In contrast, strict inclusion criteria were utilized in the present study, which was limited to patients with a nonunion located in the proximal metaphyseal-diaphyseal region of the fifth metatarsal that had not responded to nonoperative management. The outcomes in this population were evaluated and compared with those in a group of similar patients treated with intramedullary screw fixation.

The nonunion healing rates were similar in the two treatment groups. The shock wave therapy was well tolerated and yielded only one complication. In contrast, screw fixation resulted in eleven complications, including nine cases of symptomatic hardware that required a second surgical procedure and one refracture that required an additional period of immobilization.

All but two shock-wave-therapy procedures were performed in the operating room with the patient under general or regional anesthesia. Prior studies involving patients with chronic plantar fasciitis, Achilles tendinopathy, or lateral epicondylitis have demonstrated that application of a local anesthetic to the area of shock wave delivery compromises the effects of the treatment^{35,36}. It has been hypothesized that local anesthesia might interfere with clinical focusing of the shock

waves or, more likely, alter the neurogenic inflammatory response and antinociceptive effects associated with shock wave therapy^{35,36}. That said, both patients treated with local anesthesia in this study had a healed fracture at three months after treatment and neither had a post-treatment complication.

On the basis of our experiences with the use of shock wave therapy as treatment for fracture nonunions, we still believe that a period of immobilization is an important adjunct to our post-treatment protocol. We believe that the biological effects of shock wave therapy, involving osteogenesis, angiogenesis, and increased growth factor proliferation, are enhanced by a period of immobilization. For this reason, patients who cannot comply with this temporary restriction are not optimal candidates for this procedure.


This study was a retrospective cohort study and, as such, has some inherent limitations. There was no randomization. Also, the study sample was relatively small, but that reflects the very strict inclusion criteria. The mean and median durations of follow-up were 64.7 and sixty-one months in the shock wave group compared with 18.7 months and eighteen months in the fixation group. However, for the vast majority of the patients, a positive treatment effect—that is, fracture-healing—was evident by just three months after treatment.

Two different shock-wave generators were used in this trial. However, the devices were very similar. Each was a high-energy device that utilized electrohydraulic energy to generate the shock waves. Other limitations include the potential for surgeon bias as patients were treated by different physicians using different techniques. Also, the post-shock-wave-therapy and postoperative protocols were slightly different. Finally, advanced imaging was not performed for each patient. However, the findings used to define a proximal metaphyseal-diaphyseal fracture nonunion of the fifth metatarsal (moderate-to-severe pain located over the fracture site, pain with weight-bearing

activities, and radiographic evidence of an incompletely healed fracture) are generally accepted as being appropriate diagnostic descriptors of this condition.

Acknowledging these weaknesses, we believe that this series contributes valuable information. It suggests that both shock wave therapy and intramedullary screw fixation can be effective treatments for a proximal fracture nonunion in the metaphyseal-diaphyseal region of the fifth metatarsal. Shock wave therapy is safe; is well tolerated; and, unlike intramedullary screw fixation, yields few complications. Additional prospective trials are needed to substantiate these conclusions.

Appendix

 Tables presenting details on all study subjects are available with the electronic version of this article on our web site at jbjs.org (go to the article citation and click on “Supporting Data”). ■

John P. Furia, MD
SUN Orthopaedics and Sports Medicine, 900 Buffalo Road,
Lewisburg, PA 17837. E-mail address: jfuria@ptd.net

Paul J. Julianio, MD
Allison M. Wade, MD
Department of Orthopaedics and Rehabilitation, Penn State Milton S.
Hershey Medical Center, 30 Hope Drive, EC089, Hershey, PA 17033

Wolfgang Schaden, MD
AUA Trauma Center Meidling, Kundratstrasse 37, 1120 Vienna, Austria

Rainer Mittermayr, MD
Ludwig Boltzmann Institute for Experimental and Clinical
Traumatology, Donaueschingenstrasse 13, 1200 Vienna, Austria

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