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# Enhancing mechanical strength during early fracture healing via shockwave treatment: an animal study

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**Abstract**

*Objective.* This investigation aims to determine (1) whether shockwave treatment helps fracture healing and (2) whether the effect of shockwave treatment on fracture healing is dose dependent.

*Design.* Shockwave was applied over tibial osteotomy in an animal model to assess its effect on the healing of the fracture.

*Methodology.* Bilateral tibial diaphyseal transverse osteotomy was conducted on 42 rabbits, dividing into experimental and control group, immobilized using an external skeletal fixator, with one leg tested with shockwave therapy and the contralateral leg acting as the control without therapy. Serial radiography and measurement of bone mineral density via dual-energy X-ray absorptiometry were performed to assess the fracture healing. The experimental animals had two or three sessions of shockwave therapy (5000 impulses, 0.32 mJ/mm$^2$, Orthopedic™) over the osteotomy sites on day 7, 21 and 35; while the control group did not receive any treatment. The animals were sacrificed on day 42 or 56. Then, bilateral tibias were harvested and sent for mechanical tests as well as the histological examination. The pertinent statistic methods were applied to analyze the results.

*Background.* Shockwave therapy has become a useful alternative approach in treating various orthopedic conditions, but the mechanism which it works remains unclear. Thus far, shockwave therapy has been found effective in treating long bone pseudoarthrosis, but whether it can benefit fresh fracture healing continues to be debated.

*Results.* Higher union rates occurred during the early but not the late stages in the experimental group, while mechanical strength was higher in the experimental group than in the control group. No significant dose-dependent response occurred between the second and third applications of shockwave treatment. No significant difference in mechanical strength occurred between the experimental groups at 4 weeks and the control group at 6 weeks, or between the experimental groups at 6 and 8 weeks. Furthermore, no significant correlation occurred between the absolute values of maximum torque and bone mineral density.

*Conclusion.* Based on this investigation, shockwave treatment has a positive effect on early fracture healing while its long term effects require further investigation.

**Relevance**

Shockwave therapy can be a useful alternative adjunct modality in the treatment of fresh long bone fracture.

*Keywords:* Shockwave therapy; Dual-energy X-ray absorptiometry; Biomechanical tests

## 1. Introduction

For the past decade, shockwave has been employed for the fragmentation of stone in the kidney and lower urinary tract in the interest of avoiding surgical intervention (Chaussy et al., 1980). In the field of orthopedics, shockwave has been used for the therapy of delayed or non-union of fracture of the long bones (Valchanou and Michailov, 1991). There are three shockwave generator systems: electrohydraulic, piezoelectric and electromagnetic systems. The high energy shock can be produced by a 1-μs spark discharge from a bipolar electrode on a high

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voltage condenser. The electrode is placed in the geometric focus of an ellipsoid reflector. The high voltage discharge in a water medium gives rise to an explosive evaporation of water and generates the shockwaves. These wave reflected from the walls of the ellipsoid and directed to a second focus in the biological tissue (Chaussy, 1968; Eisenberger and Muller, 1987). The shockwaves are not hindered by a water medium, yet the wave acts destructively on bones and calculi in the human body (Haberman, 1987). Although shockwave therapy has become a popular method of treating various orthopedic conditions such as pseudoarthrosis (Plaisier et al., 1994; Rompe et al., 1997), calcifying tendonitis of the shoulder joint (Dahmen et al., 1992; Loew et al., 1995, 1999; Rompe et al., 1995), plantar fasciitis (Rompe et al., 1996a,b; Krischek et al., 1998), lateral epicondylitis of the elbow joint (Maier et al., 2000; Rompe et al., 1996c,d, 1998; Krischek et al., 2000), avascular necrosis of femoral head (Forriol et al., 1994), its effectiveness remains debatable (Plaisier et al., 1994). Previous reports reveal that, besides surgical interventions, shockwave treatment is an attractive alternative approach for treating bony pseudoarthrosis (Valchanou and Michailov, 1991; Rompe et al., 1997). However, the precise mechanism through which bone healing is accelerated with this method remains unclear (Delius et al., 1995). Several investigations demonstrated stimulatory effects at the cellular and molecular levels (Forriol et al., 1994; Kusnierczak et al., 2000). However, whether such effects have any influence on fracture healing is unknown because the fracture healing process involves biological changes as well as mechanical properties. The purposes of this study were to investigate (1) that whether shockwave has a positive effect on the fracture healing, and (2) that the effect of shockwave treatment on fracture healing is dose dependent.

## 2. Methods

### 2.1. Animal experimental design

Forty-two 4-month old male New Zealand rabbits, each weighing 3.5 kg were enrolled in this study. The animals were supplied from the animal laboratory of Chang Gung Memorial Hospital and raised according to the guidelines of the National Science Council, Taiwan. Under sterile condition and general anesthesia with ketamine hydrochloride (Ketalar, Parke-Davies, Taiwan) and Rompun (Bayer, Leverkusen, Germany) intravenous injection, the rabbit was put in the supine position. A 5-cm longitudinal skin incision was made over the anterior aspect of the middle portion of the right leg. Exposed the tibia and four stainless-steel screws were inserted. Then a custom-made external fixator with four screws were applied to immobilize the tibia. The perisoteum was elevated and the tibia was osteotomized transversely using a airtome under saline irrigation. All the animals were intravenously injected with Keflin prophylactic antibiotics. After surgery, the animals were allowed to bear partial or full weight as tolerated. The animals were monitored daily for food and water intake, pin site infection, and ambulation. All studied animals were cared in accordance with regulations of the National Institute of Health of Taiwan under the supervision of a licensed veterinarian

The animals were randomly assigned to the experimental and control groups, labeled groups E and C, respectively. In group IE ($n = 6$), the rabbits received 5000 impulses, and 0.32 mJ/mm$^2$ shockwave treatment (Haupt et al., 1992; Johannes et al., 1994; Seemann et al., 1992) at the osteotomy site using Orthospec™ (therapy zone: 25×95 mm; energy density: up to 0.32 mJ/mm$^2$, pulse rate: 1–2.5 Hz (MEDISPEC Ltd., MD, USA) on Days 7 and 21. Meanwhile, in group IC ($n = 6$), the osteotomy site received no treatment. At the bilateral tibias of each animal, periodical plain radiography and bone mineral density (BMD) measurement using dual-energy X-ray absorptiometry (DEXA) were conducted before surgery and weekly after surgery. On Day 28, the animals were sacrificed by intra-venous injection of over-dosed sedatives, and the bilateral tibias were harvested and sent for torsional testing by a Materials Testing System (MTS) machine. Meanwhile, the rabbits in groups IIE-1 ($n = 6$), IIE-2 ($n = 6$) and IIC ($n = 6$), received radiographic examination and DEXA study before surgery and weekly after surgery. The animals were sacrificed on Day 42. Additionally, the rabbits in group IIE-1 received two sessions of shockwave treatment with the same dose and frequency as in group IE, while the rabbits in group IIE-2 received one additional shockwave treatment on Day 35. The animals in groups IIIE ($n = 6$) and IIIC ($n = 6$), received plain radiographic examination and DEXA study before surgery and weekly after surgery. The animals were sacrificed on Day 56. Besides the two shockwave treatments on Days 7 and 21, group IIIE received one additional shockwave treatment on Day 35, just as in group IIE-2. As with group IC, no treatment was applied onto the osteotomy site of the 12 rabbits in group IIC and IIIC.

BMD measurements were made using a Hologic QDR 2000 dual-energy X-ray absorptiometry (Hologic Inc., Boston, MA, USA). To obtain a reproducible value corrected for individual differences, the preoperative BMD of the middle portion of the tibias was used as the internal control.

### 2.2. The biomechanical test

After sacrifice, the bilateral tibias were harvested by stripping the soft tissues. All specimens were stored at −20 °C until testing. After thawing for 24 h, any soft tissue was removed from each specimen, and the specimens were then fixed by embedding each end of the segment in a rectangular metal frame with acrylic (AcriliMet™) along the longitudinal axis. The length of the non-embedded portion was maintained at a constant 6.2 cm for all specimens. Screws or pincers, which could increase stress levels, were not used to fix the construct. At the stage of embedding, a specially designed external fixator with axial alignment was used to clamp the rectangular metal frames. The application of this external fixator provided two surfaces with right angle, which maintained the alignment of both ends of the rectangular metal frames. The alignment of the harvested tibiae embedded in the acrylic cement was thus ensured. The acrylic–tibia–acrylic assembly was then mounted on a specially designed symmetrical grip with a rectangular holder, which prevented the specimen from sliding during torsional testing. After the specimens were clamped, the torsional test was performed at a constant rotational rate of 1°/s using a MTS machine (Bionix 858, MTS Company, Minneapolis, MN, USA). The relationship between torque value and rotational angle was recorded simultaneously at an increment of 0.2° using MTS Teststar II software. To assess the effect of shockwaves on the healing rate of fracture tibia at various healing periods, the torque magnitude at failure for each individual specimen was selected for comparison by using Student-*t* (two tailed) statistical analysis. A significant difference was reported at $P < 0.05$.

## 3. Results

### 3.1. The radiographic evaluation

Two independent radiologists assessed the fracture healing during the radiographic examinations after surgery.

Three animals were excluded from the study due to the postoperative complications. In the plain radiographic study for assessing the healing of the osteotomy, the rate of complete healing following shockwave treatment was significantly higher in the experimental than the control groups during the early stage (within 28 days, IE vs IC: $P$-value = 0.001) but not in the late stage (after 42 days: IIE-1/IIE-2 vs IIC and IIIE vs IIIC: $P > 0.05$). The alignment of the diaphyseal osteotomy of all the rabbits remained essentially normal (angle of angulation <10°; minimal shortening/lengthening) throughout the course of the experiment.

### 3.2. Measurement of bone mineral density

The BMD assessment looked at the change in the ratio of BMD values between the callus of the osteotomy site of the operated limbs and the middle portion of the non-operated limbs, which were used as the internal control, of the same animal. No significant differences over the BMD changes existed between the experimental and the control groups (IE vs IC groups from Day 0–28; IIE-1, IIE-2 vs IIC groups from Day 0–42; IIIE vs IIIC groups from Day 0–56.

### 3.3. Mechanical strength of fracture healing

Fig. 1 illustrates the typical diagram of torque vs angle curve in the biomechanical testing, showing that the torque magnitude increased linearly with increasing angle before failure. However, torque magnitude declined significantly once maximal torque was reached. Following the failure of the tibia, the fluctuation phenomenon of torque value was observed. It was due to the "damping" effect of the lower segment of the tibia

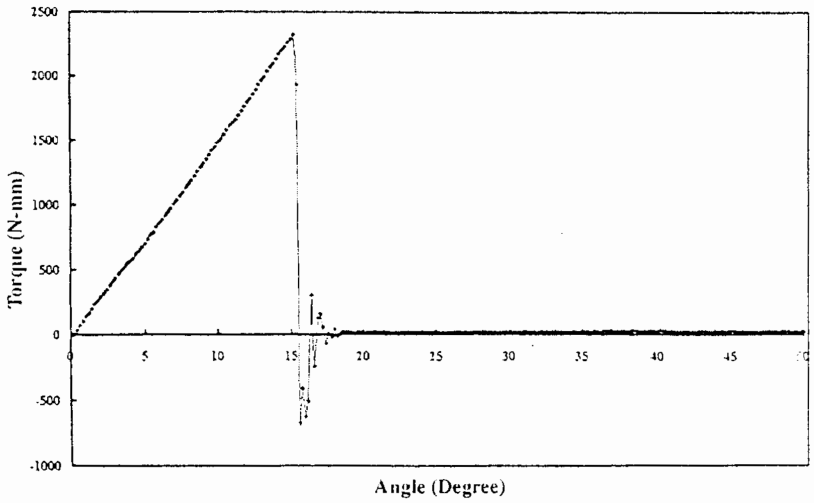

Fig. 1. Typical torque vs angle curve. The magnitude of the torque increased linearly with increasing angle before failure, but declined significantly once maximal torque reached. The peak torque was the failure point of the tibia during torsional testing.

Table 1
Results of biomechanical test at 4 weeks

| Rabbit | | Maximum torque (N mm) | Percentage of maximum torque (right/left) |
|---|---|---|---|
| *IC Group (non-shockwave treatment)* | | | |
| 1 | Right | 256 | 19.5 |
| | Left | 1312 | |
| 2 | Right | 417 | 27.6 |
| | Left | 1514 | |
| 3 | Right | 881 | 48.5 |
| | Left | 1815 | |
| 4 | Right | 781 | 40.0 |
| | Left | 1952 | |
| 5 | Right | 577 | 30.7 |
| | Left | 1882 | |
| 6 | Right | 325 | 20.0 |
| | Left | 1625 | |
| Mean | | | 31.0 |
| SD | | | 11.4 |
| *IE Group (shockwave treatment)* | | | |
| 1 | Right | 1213 | 59.2 |
| | Left | 2048 | |
| 2 | Right | 1716 | 56.7 |
| | Left | 3025 | |
| 3 | Right | 1425 | 56.1 |
| | Left | 2542 | |
| 4 | Right | 1187 | 51.2 |
| | Left | 2319 | |
| 5 | Right | 1131 | 54.0 |
| | Left | 2096 | |
| 6 | Right | 1008 | 58.0 |
| | Left | 1738 | |
| Mean | | | 55.9 |
| SD | | | 3.0 |

Table 2
Result of biomechanical test at 6 weeks

| Rabbit | | Maximum torque (N mm) | Percentage of maximum torque (right/left) |
|---|---|---|---|
| *IIC Group (non-shockwave treatment)* | | | |
| 1 | Right | 734 | 52.5 |
| | Left | 1397 | |
| 2 | Right | 1113 | 49.6 |
| | Left | 2242 | |
| 3 | Right | 965 | 53.9 |
| | Left | 1789 | |
| 4 | Right | 1530 | 54.9 |
| | Left | 2783 | |
| 5 | Right | 1243 | 63.5 |
| | Left | 1958 | |
| Mean | | | 54.9 |
| SD | | | 5.2 |
| *IIE-1 Group (shockwave treatment)* | | | |
| 1 | Right | 1493 | 61.6 |
| | Left | 2423 | |
| 2 | Right | 1516 | 74.1 |
| | Left | 2045 | |
| 3 | Right | 1265 | 76.7 |
| | Left | 1649 | |
| 4 | Right | 1398 | 79.0 |
| | Left | 1770 | |
| 5 | Right | 1839 | 80.2 |
| | Left | 2292 | |
| Mean | | | 72.8 |
| SD | | | 7.5 |
| *IIE-2 Group (shockwave treatment)* | | | |
| 1 | Right | 1993 | 78.2 |
| | Left | 2549 | |
| 2 | Right | 1715 | 71.1 |
| | Left | 2411 | |
| 3 | Right | 1497 | 66.4 |
| | Left | 2256 | |
| 4 | Right | 2157 | 82.1 |
| | Left | 2627 | |
| 5 | Right | 1468 | 73.5 |
| | Left | 1998 | |
| 6 | Right | 1894 | 75.2 |
| | Left | 2518 | |
| Mean | | | 75.6 |
| SD | | | 5.5 |

mounted on the MTS load cell. Tables 1–3 list the maximal torque for each group, emphasizing the ratio of maximal torque between the bilateral tibial diaphysis of the same animal. The ratios of the maximal torques of the experimental groups are significantly higher than the control groups (IE vs IC: $P = 0.0021$; IIE-1 and IIE-2 vs IIC: $P = 0.0001$; IIIE vs IIIC: $P = 0.039$). As shown in Fig. 2, a gradual increase in maximum torques were demonstrated over the experimental and the control groups ($P < 0.01$). A statistical difference thus exists between the two groups at each healing periods. However, no significant dose-dependent response exists between two times and three times shockwave treatment (IIE-1 vs IIE-2: $P = 0.48$). And also no significant differences of the maximal torques were found between the groups of IE (experimental group with shockwave therapy at 4 weeks) vs IIC (6 weeks control group without shockwave therapy); IIE (experimental group at 6 weeks) vs IIIC (control group at 8 weeks). Overall, no significant correlation exists between the absolute values of the maximum torque and BMD (correlation coefficient = 0.56, $P = 0.055$).

### 3.4. The histologic examination

The histology examination was taken from the fracture sites after the torsional test. The specimens of Groups I and II represented the time point at the fourth and sixth week, respectively. In the present study, the osteotomy patterns were identical, and more cartilage portion implied less mineralization. Callus formation in Group IC showed cartilaginous nucleus center with osteochondroid new bone formation on both sides, while callus in Group IE showed similar pattern with a smaller amount of cartilage and more mature bony trabeculaes (Fig. 3). Therefore, the Group IE had better healing status than Group IC. Group IIE with matured bony

Table 3
Results of biomechanical test at 8 weeks

| Rabbit | | Maximum torque (N mm) | Percentage of maximum torque (right/left) |
|---|---|---|---|
| *IIC Group (non-shockwave treatment)* | | | |
| 1 | Right | 1002 | 49.3 |
| | Left | 2034 | |
| 2 | Right | 1923 | 73.6 |
| | Left | 2613 | |
| 3 | Right | 1648 | 66.9 |
| | Left | 2461 | |
| 4 | Right | 2046 | 73.8 |
| | Left | 2771 | |
| 5 | Right | 1015 | 58.0 |
| | Left | 1750 | |
| 6 | Right | 2196 | 78.2 |
| | Left | 2807 | |
| Mean | | | 66.7 |
| SD | | | 11.1 |
| *IIE Group (shockwave treatment)* | | | |
| 1 | Right | 1834 | 77.9 |
| | Left | 2354 | |
| 2 | Right | 1883 | 90.8 |
| | Left | 2075 | |
| 3 | Right | 1285 | 66.7 |
| | Left | 1927 | |
| 4 | Right | 1575 | 87.4 |
| | Left | 1802 | |
| 5 | Right | 2351 | 85.5 |
| | Left | 2751 | |
| Mean | | | 81.7 |
| SD | | | 9.6 |

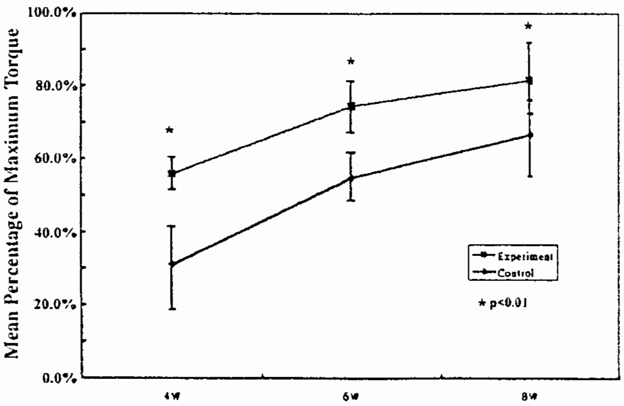

Fig. 2. The mean percentage of the maximum torque vs healing periods. The mean percentage of maximum torque gradually increases with healing periods in both the experimental and control groups.

bridge existed as compared to the soft callus interposition of Group IIC. Callus in Group IIC showed young bone with osteoid matrix and active osteoblast and Group IIE showed new bone with mature bony trabeculaes (Fig. 4). The histological pictures corresponded well with the biomechanical tests.

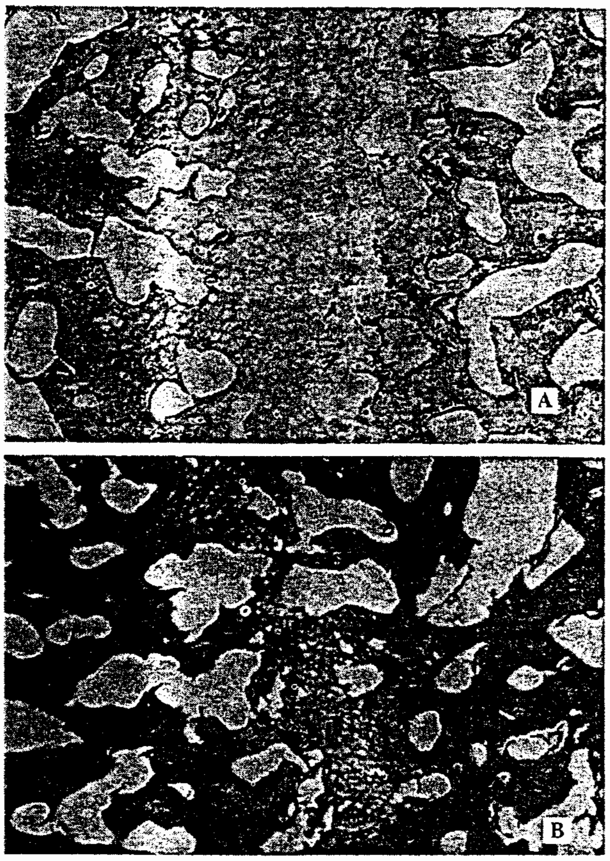

Fig. 3. (A) Histology of Group IC showed callus formation with cartilaginous nucleus center and osteochondroid new bone formation on both sides at 4 weeks (200×, H&E stain). (B) Histology of Group IE showed callus with smaller amount of cartilage and more mature bony trabeculaes, as compared to Group IC at 4 weeks (200×, H&E stain).

## 4. Discussions

In treating pseudoarthrosis of long bone fracture, the high reported success rate makes shockwave treatment an attractive non-operative option for patients (Plaisier et al., 1994; Forriol et al., 1994). However, the precise mechanism of shockwave-induced tissue healing remains uncertain (Delius et al., 1995). The effect of shockwaves on bony structures should be unsophisticated idea that shockwave treatment causes microfractures and subsequent new bone formation.

In the present study, the fracture healing occurred through the indirect healing process due to less rigid external fixation. Proliferation and differentiation of the mesenchymal cell at the fracture site resulted in the formation of the callus, which consisted of fibrous tissue, cartilage and woven bone. Cartilage predominated in the central region with lower oxygen tension. As the vascular invasion with better oxygenation, the endochondral ossification was carried out (Bassett and Herrmann, 1961; Bassett, 1962). Herein, shockwave treatment displays a

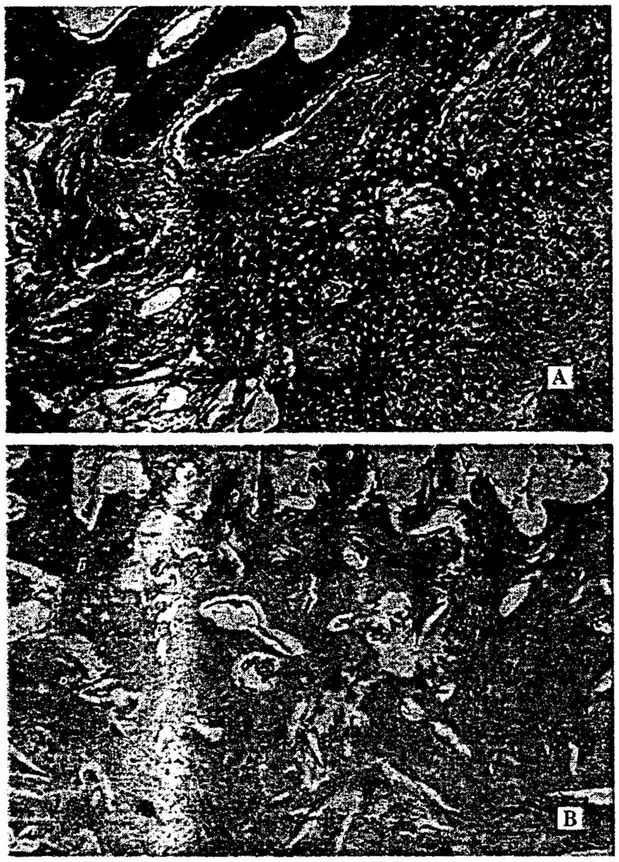

Fig. 4. (A) Histology of Group IIC showed callus with osteoid matrix in young bone and active osteoblast at 6 weeks (200×, H&E stain). (B) Histology of Group IIE showed new bone with mature bony trabeculaes at 6 weeks (200×, H&E stain).

positive effect on early callus formation and mechanical strength. A straightforward radiographic evaluation indicated that initial gap healing following shockwave treatment, especially within 4 weeks of bony union, appears faster than without shockwave treatment, a revelation that agrees with observations of clinical outcomes. In cases of pseudoarthrosis treated with shockwave, accelerated healing occurs both symptomatically and radiographically (Rompe et al., 1997; Forriol et al., 1994). However, the positive influence of shockwaves on gap filling appears to decline after 6 weeks of bony healing. The reasons for and impact of the differential effect on osteotomy healing with time are unknown.

The phenomenon that the maximal torque of the diaphyseal osteotomy in the experimental group is significantly higher than that in the control group is clinically interesting. The mechanical strength of the two groups begins to differ significantly as early as 4 weeks and through 6 weeks and 8 weeks of osteotomy healing. In this animal model, shockwave treatment clearly enhances the mechanical properties of early osteotomy healing, and may also promote early bone healing in clinical practice. If so, then the indication of shockwave treatment can be extended to the cases of fresh fractures.

Mirroring the degree of gap healing with simple radiography, the enhancement of mechanical strength is accompanied by faster gap filling in most of the experimental animals. This phenomenon might imply that shockwave treatment encourages structural organization during callus formation. The results of histological examination clarified, and further strengthened this phenomenon. From the perspective view, the stronger mechanical properties of fracture callus are beneficial for early weight bearing.

This study found little to indicate that dosage influenced the response of shockwave treatment on maximal torque of the healed diaphyseal osteotomy. The healing of the osteotomies was not affected, regardless of whether they were treated with two or three applications of shockwaves for a period of 6 weeks. Shockwaves may affect osteotomy healing earlier, i.e. before 4 weeks. If so, the effect of shockwave treatment on early gap filling before 4 weeks instead of late union after 4 weeks might be explained. However, extensive further study is required to define the optimal treatment dosage for enhancing new bone formation.

One confusing result is the weak correlation between the value of BMD and the mechanical strength of the diaphyseal osteotomy. No significant difference exists between the BMD of the experimental and control groups. BMD was supposed to be relevant to the quantity of bone mass and the degree of mineralization. However, the BMD value may not represent the degree of structural organization, which is essential to the mechanical strength. In fact, the validity and reliability of the DEXA for measuring the actual calcium content of long bones continues to be debated as well as the correlation between BMD and mechanical properties. To our knowledge, no agreement presently exists on the effect of shockwave treatment on BMD.

## 5. Conclusion

Shockwave treatment positively influences the early healing of diaphyseal osteotomy by achieving superior maximal torsion strength and a higher rate of fracture union, but does not influence BMD values. The long-term effect of shockwave treatment on fracture healing deserves further study. Finally, the influence of shockwave treatment on callus structure reorganizations is another issue worth further investigation.

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