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Effect of Shock Wave Therapy on Acute Fractures of the Tibia

A Study in a Dog Model

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The effect of shock wave therapy on acute fractures of the tibia was studied in eight adult dogs. A fracture with a 3-mm gap was created in both tibias and the fractures were fixed internally with a small metallic plate and screws. Each of the right limbs received 2000 impulses of shock waves at 14 kV whereas the left limbs were used as controls. The evaluations included the callus formations based on serial radiographic examinations at 1, 4, 8, and 12 weeks and histologic examinations at 12 weeks for tissue distribution including bone tissues. Based on radiographic findings, there was no statistically significant difference in the amount of callus formation between the treated and the control groups at 8 weeks or less. However, the radiographic findings at 12 weeks statistically showed more callus formations in the treated group. In histologic examinations, there was significantly more cortical bone formation in the treated group at 12 weeks and the bone tissues were thicker, denser, and heavier. Shock wave therapy enhanced callus formation and induced cortical bone formation in acute fractures in dogs at 12 weeks. The effect of shock wave therapy seemed to be time-dependent at 3 months.

Shock wave therapy has been shown to be effective in the treatment of chronic nonunions of long bone fractures. The success rate of achieving bony union ranged from 50% to 85% in reported series.[1,4–6,8–10,12] Shock wave therapy is a relatively simple procedure that does not have a surgical risk or postoperative pain and is cost-effective. Therefore, shock wave therapy is an attractive alternative in the treatment of fracture nonunions. The exact mechanism of a shock wave remains unknown. It is thought that shock wave application produces microtrauma or microfracture and hematoma formation at the nonunion site, which induces neovascularization, and subsequently increases osteoblast or fibroblast activity that enhances fracture repair and eventual bony union.[2,4,7]

Acute fractures of long bones caused by high-energy trauma that compromises local

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circulation often result in delayed unions or nonunions. Traditionally, the treatment of choice for nonunions includes a bone grafting procedure.[12,13] However, surgical treatments potentially may have certain risks including infection.[14] In addition, patients may suffer from pain and functional disability after surgery, which incurs substantial healthcare costs. The clinical results of shock wave treatment in chronic nonunions of long bone fractures are equal to or better than the surgical results because there are no surgical risks and because it is more cost-effective. [1,4,8–11] However, the indication of shock wave therapy for an acute fracture is not yet established and the effects are unknown. The purpose of the current study was to investigate the effects of shock wave application on acute fracture of the tibia in dogs.

MATERIALS AND METHODS

Ten adult dogs with body weight ranging from 7 to 15 kg were used in the current study. The study was approved by the Institutional Review Board and was performed under the guidelines and care of animal research of the authors' institution. [3,7]

The dogs were anesthetized with intramuscular ketamine (25 mg/kg) and intravenous phenobarbital (30 mg/kg). The right lower limb was treated whereas the left lower limb was used as the control. Both lower limbs were scrubbed and draped in a surgical sterile manner. A fracture was created by osteotomy at the middle ⅓ in each tibia and a 3-mm gap was made with an osteotome at the osteotomy site. The fracture was stabilized with a six-hole small metallic plate and screws. The wound was closed in a routine fashion after irrigation with normal saline solution. Shortly after the fracture was created, the right lower limb was given 2000 impulses of shock wave treatment at 14 kV (0.18 mJ/mm^2 energy flux density). The left limb did not receive shock waves. The source of the shock wave was from the OssaTron orthopaedic lithotriptor (High Medical Technology, Kreuzlingen, Switzerland). The depth and location of the shock wave application were confirmed with the control guide and a surgical lubricate was placed on the skin in contact with the tube. The right lower limbs then were inspected for redness, swelling, and hematoma. Radiographs of both lower limbs were obtained to confirm the fracture and the fixation devices. The lower limbs were immobilized with bulky dressing and bandages. The dogs then were returned to the individual cages and were cared for by a veterinarian. The wounds were inspected and the activities of the dogs were monitored daily. Prophylactic ampicillin (50 mg/kg) was given intramuscularly every 12 hours for 5 days postoperatively.

Anteroposterior (AP) and lateral radiographs of both lower limbs were obtained at 1, 4, 8, and 12 weeks. The dogs were sedated with intramuscular ketamine (25 mg/kg) when the radiographs were obtained. The radiographs of the lower limbs were evaluated for fracture alignment, fracture gap, and callus formation. The amount of callus formation was determined by the measurement of visible callus against the width of the adjacent tibial bone on the radiographs. The radiographs of the right limb were compared with the radiographs of the control left limb.

A biopsy of the bone, including the fracture site, was obtained 12 to 14 weeks postoperative regardless of whether there was radiographic evidence of bony union. The dogs were anesthetized and both lower limbs were scrubbed and prepared in a sterile manner. The tibia was exposed through the previous scar. The bone tissues were removed with a micro-oscillating saw. The biopsy specimens consisted of a 2-cm long bone tissue crossing the fracture site, and the width was less than ¼ of the circumference of the tibia. This did not induce fracture and might not affect new callus formation. The bone specimens were decalcified, sectioned, and stained with hematoxylin and eosin. The microscopic examinations were performed by a bone pathologist (HYH), and the fibrous tissue, cartilaginous tissue, fibrocartilage, woven bone, and cortical bone were evaluated. Each type of tissue was quantitated by the average percent of each type of tissue present in three representative low power fields (× 40) under microscopic examination.

RESULTS

Two dogs were excluded because of postoperative deep wound infection. The results of the remaining eight dogs were included in the analysis. The values between the treated and the control limbs were compared statistically using the Mann-Whitney test with a statistical significance at $p < 0.05$.

Radiographic Examinations

The details of the radiographic examinations are summarized in Table 1. At 1 week after shock wave application, none of the radiographs showed evidence of callus formation. The fracture gaps remained unchanged and the fracture alignments were well maintained.

At 4 weeks, the average callus formations were 50% for the treated group and 27.5% for the control group. There was more callus formation in the treated group but the difference between the treated group and the control group was not statistically significant (p = 0.056). The difference in the amount of callus formation was very obvious only in two dogs and no discernible difference was seen in six dogs. One dog in the treated group had almost complete bony union and one dog in the control group had a large amount of callus formation.

At 8 weeks, the average callus formation was 61.3% for the treated group and 45% for the control group, and the difference was not statistically significant (p = 0.260). The difference in the amount of callus formation was obvious in three dogs, and not obvious in five dogs. Two dogs in the treated group and one dog in the control group had almost complete bony union. The fracture fixations in the remaining dogs were intact and there were no hardware failures.

The average callus formation was 84.4% for the treated group and 59.4% for the control group, respectively, at 12 weeks and the difference was statistically significant (p = 0.024). Four dogs in the treated group had almost complete bony union. In the control group, one dog had almost complete bony union and two dogs had many increased callus formation. It seemed that shock wave application enhanced the callus formation in acute fractures of the tibia in dogs and the effects of the shock wave treatment were time-dependent at 12 weeks. The radiographic findings of the shock wave treated and untreated fracture healing from a representative case are shown in Figure 1.

Histologic Examinations

The detailed features of the microscopic findings are summarized in Table 2. The average distributions of fibrous tissue at 12 weeks were 22.5% for the treated group and 38.8% for the control group (p = 0.224). The average cartilaginous tissues were 13.1% for the treated group and 18.1% for the control group (p = 0.555). The average fibrocartilages were 35.6% for the treated group and 56.9% for the control (p = 0.065). The microscopic appearance and the vascularity of fibrous tissue, cartilaginous tissue, and fibrocartilage were similar for the treated group and the control group.

TABLE 1. Callus Formations After Shock Waves by Radiographic Examinations

	1 Week		4 Weeks		8 Weeks		12 Weeks	
Dog	*Treatment*	*Control*	*Treatment*	*Control*	*Treatment*	*Control*	*Treatment*	*Control*
1	0	0	25%	20%	45%	40%	100%	75%
2	0	0	25%	0	50%	25%	75%	50%
3	0	0	75%	25%	100%	50%	100%	75%
4	0	0	25%	25%	40%	50%	50%	50%
5	0	0	100%	80%	100%	100%	100%	100%
6	0	0	50%	25%	50%	100%	100%	25%
7	0	0	75%	25%	80%	50%	75%	50%
8	0	0	25%	20%	25%	20%	75%	50%
Average	0	0	50%	27.5%	61.3%	45.0%	84.4%	59.4%
p value*			0.056		0.260		0.024	

*Mann-Whitney test.

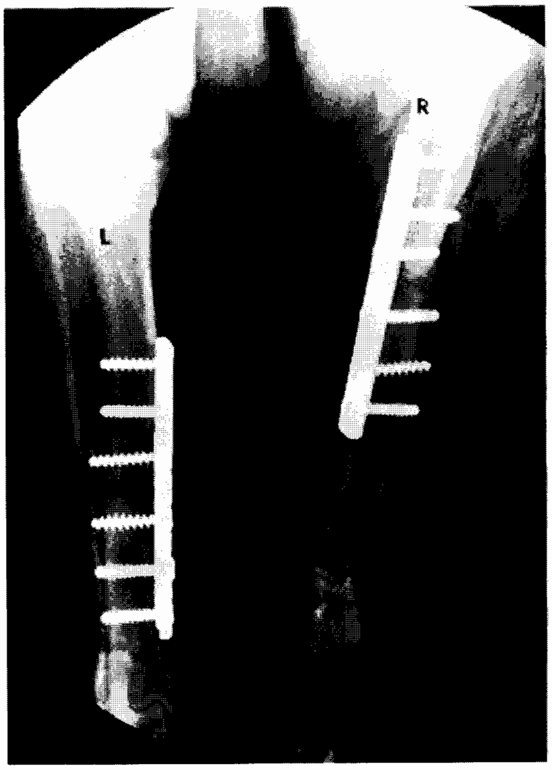

Fig 1. Radiographs of both lower limbs taken 12 weeks postoperatively showing complete healing with excellent callus formation (arrow) in the treated limb (right limb), and incomplete fracture healing with less amount of callus formation (arrow) in the control limb (left limb). L = left; R = right.

The percentage of woven bone was 23.8% for the treated group and 26.9% for the control (p = 0.428), and the average percentage of cortical bone was 40.6% for the treated group and 16.3% for the control group (p = 0.018). There was a statistically significant increase in the amount of cortical bone formation for the treated group at 12 weeks. The total amount of bone tissue was 64.4% for the treated group and 43.8% for the control group, but the difference was not satistically significant (p = 0.065). The cortical bones in the treated group were thicker and heavier with normal appearance in bone architecture and osteoblasts. Similarly, the woven bones in the treated group were heavier and denser with preservation of normal cancellous bone structure. The microscopic findings of a representative case are shown in Figure 2.

TABLE 2. Histologic Findings at the Fracture Sites After Shock Wave Treatment (Percent Per Low Power Field × 40)

Animal	Fibrous Tissue		Cartilaginous Tissue		Fibrocartilage		Woven Bone		Cortical Bone		Total Bone	
	Treatment	*Control*	*Treatment*	*Control*	*Treatment*	*Control*	*Treatment*	*Control*	*Treatment*	*Control*	*Treatment*	*Control*
1	35	55	0	25	35	80	30	20	35	0	65	25
2	10	10	35	35	45	45	5	40	50	15	55	55
3	50	50	5	25	55	75	5	15	40	10	45	25
4	0	0	0	0	0	0	20	25	80	75	100	100
5	30	65	0	0	30	65	15	35	55	0	70	35
6	5	10	20	25	25	35	60	40	15	25	75	65
7	20	35	35	30	55	65	25	30	20	5	45	35
8	30	85	10	5	40	90	30	10	30	0	60	10
Average	22.5	38.8	13.1	18.1	35.6	56.9	23.8	26.9	40.6	16.3	64.4	43.8
p value*	0.224		0.555		0.065		0.428		0.018		0.065	

*Mann-Whitney test.

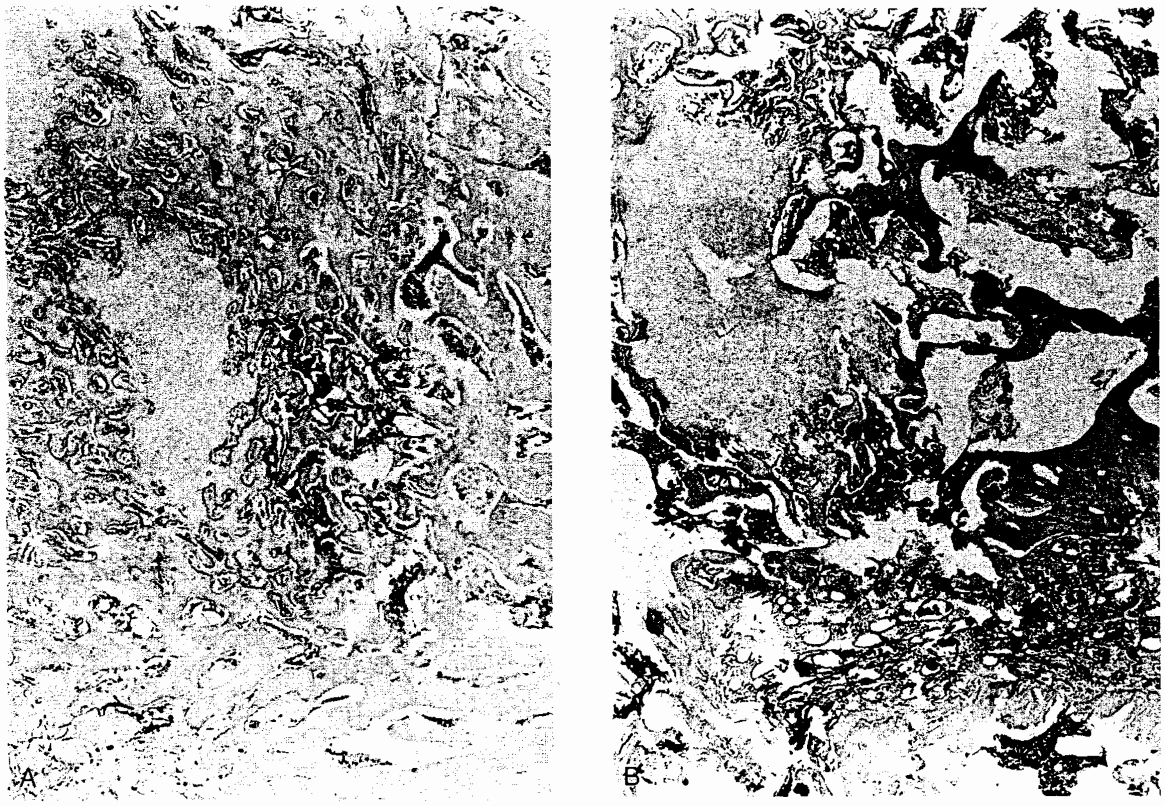

Fig 2A–B. (A) Photomicrograph of the right limb (treated) showing intense cortical bone formation with thicker and heavier bone tissues 12 weeks after shock wave application (Stain, hematoxylin and eosin; magnification, × 40). (B) Photomicrograph of the left limb (control) showing less cortical bone formation. (Stain, hematoxylin and eosin; magnification, × 40).

DISCUSSION

In acute fractures, the bony repair process begins with hematoma formation at the fracture site which in turn forms the soft callus, which consists of fibrocartilage and fibrous tissues at 2 to 4 weeks, and the hard callus formation, which consists of osteoblasts and bone matrix that bridge the fracture gap and eventual fracture healing at 4 to 6 weeks. The rate of fracture repair is influenced by many factors including the type and severity of fracture and the neurovascular status at the fracture site. In general, more serious fractures, such as open fracture or communited fractures caused by high-energy trauma, have a higher risk of poor fracture healing and frequently result in delayed union or nonunion.

Numerous clinical studies have shown a positive effect of shock waves for treating nonunions of long bone fractures with a success rate varying from 50% to 85%.[1,5,6,8–11] However, there are conflicting results on the effect of shock wave therapy on bone healing in different animal models. Several studies showed a positive effect of shock wave therapy on fracture healing,[6,7] whereas another study showed negative results in animals.[3] The possible reasons for the discrepancy included the type of animals used in different studies and the different shock wave influx energy applied. Haupt et al,[6] in an experimental model in rats, confirmed a positive effect of shock wave treatment of fracture healing. Johannes et al[7] showed the promotion of bony union with shock wave therapy in hypertrophic nonunions in dogs. However, Forriol et al,[3] reached an alternative conclusion and thought that shock wave treatment might delay bone healing and did not recommend its use in clinical orthopaedics. The current authors chose adult dogs for the study because of the bone size and applied 2000 impulses of shock wave at 14 kV (0.18 mJ/mm^2 energy flux density), which generated shock wave energy on bones of this size close to what was used clinically in humans. The results of the current study showed that the difference in the amount of callus formation based on radiographic findings at 1, 4, and 8 weeks between the treated group and the control group was not statistically significant. However, the difference in callus formation became statistically significant at 12 weeks favoring the treated group. It was observed that shock wave enhancement of bone healing in acute fracture in dogs would take 12 weeks or more.

The number of limbs showing almost complete bony union was higher in the treated group and increased with time after shock wave application. In either group, no limb had bony union at 1 week after shock wave treatment. Bony unions were observed in only one dog at 4 weeks, two dogs at 8 weeks, and four dogs at 12 weeks in the treated group. In contrast, only one bony union was observed in the control group during the same period although two dogs had considerably more callus formation at 12 weeks. It seemed that the effect of shock wave treatment was time-dependent at 3 months or more.

Delius et al,[2] using a rabbit model, showed that shock wave treatment could produce intense formation of new cortical bone and minor trabecular remodeling. The results of the current study showed that there was a considerably higher percentage of cortical bone formation in the treated group at 12 weeks and the difference in cortical bone formation was statistically significant ($p = 0.018$) favoring the treated group. In addition, the microscopic appearance of the cortical bone in the treated group was much thicker, denser, and heavier than in the control group. The current results were similar to the results of Delius et al[2] who reported that shock wave therapy produced more intense cortical bone formation that would benefit the healing process of long bone fractures.

Currently, shock wave therapy only is recommended in chronic nonunions of long bone fractures. The authors' data support the fact that shock wave treatment enhanced cortical bone formation and increased callus formation in acute fractures in dogs as evaluated histologically and radiographically, respectively. The results of the current study suggest that shock wave therapy may be used clinically as an adjunct treatment in certain acute fractures, especially those fractures with a higher risk of having nonunions such as open and communited fractures caused by high-energy trauma and those fractures with surgically compromised local circulation.

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