Technical Report

On

Clinical Research

On

Bridge-link Combined Internal Fixation System

Completed by:

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Bridge-link Combined Internal Fixation System (BCFS) and Clinical Application Research

Abstract: [Objective] to discuss the structural performance of the BCFS system and its clinical efficacy in treatment of long tubular bone fractures. [Method] This system is designed as a locked modular internal fixation system composed of three components: fixing rods, clamps and locking screws. To date, it has been applied clinically in the treatment of a total of 74 cases including of 85 location fractures. Among these cases, there are 24 humeral fracture cases, 18 femoral fracture cases, 26 tibiofibular fracture cases, 4 radial fracture cases, 2 ulnar fracture cases, including 14 near-joint fracture cases, 8 nonunion cases, and 2 radial nerve injury-complicated cases. After operation, X-ray film were taken periodically to compare the injured with the healthy side and measure the angulation, rotation and shortening of the injured limb to conduct integrated assessment. [Result] All the cases were followed up with visits from 6 to 18 months and the fracture healing rate of these cases was 100%. None of wound infection, nonunion, loose or breakage of internal fixation metal or other serious complications occurred. Therapeutic evaluation with Johner-Wruhs method: 55 excellent cases, 15 good cases, and 3 average cases, the total excellent and good rate was 94.6%. [Conclusion] This system has a well-designed structure and good biological and biomechanical features; being in consistent with the modern orthopedic AO and BO principles, it is highly operable and can be applied to a wide range of indications. It can keep the blood circulation of the fracture area to the greatest extent, which helps to heal a fracture as scheduled and to reduce complications. It is an internal fixation system worth researching and popularizing.

Key words: modular internal fixation, long tubular bone, clinical research

The BCFS system is an internal fixation system developed through multidisciplinary cooperation according to the modern internal fixation “AO” and “BO” theories and innovative concepts. It is designed to have a combined integral locked connection structure and it has four specifications. It integrates the locking steel plate, the interlocking intramedullary screw and the external fixator into one in terms of its functionality and utility. It is suitable for fixation and shape-righting of the four limbs, the pelvis and the spinal column and it can substitute nearly 80% of the existing internal fixation products. The clinical efficiency of this system in treatment of 74 long tubular bone fracture cases during June 2007 ~ January 2009 is hereby reported as follows:
1. Structure of the instrument

The BCFS system mainly comprises the fixing rods, the clamps and the locking screws. The fixing rods are round and the system may be classified into four specifications according to the diameter of the fixing rods (Figure 1). The clamps have rod holes and screw holes, through which the locking screws can be screwed in to lock the rod, the screw and the block into a whole tightly. To adapt to the complexity and diversity of fractures, the clamps are diversified into single-rod single-hole, single-rod double-hole, double-rod double-hole, double-rod multiple-hole models and various anatomic models; their screw holes include regular holes and lockup holes adaptable to standard screws and locking screws respectively; internal screw threads of lockup hole and screw threads at the end of locking screw may be engaged and locked up with each other. The locking screw has a double-thread structure. Its front thread is screwed in bone and its rear thread is screwed in the internal thread of the lockup hole of the clamp; when the rear thread is screwed in the clamp, the clamp block will be pressed to clamp the round rod, and at the same time, the tail cap of the screw will clamp and press the rod face to form the rod-block-screw-locked connection. Before lockup with the locking screw, the clamp can rotate and glide freely on the rod. After combined lockup, the entire fixation frame will form a fixed whole. As such, several screws are screwed in to form an integrated locked fixation mechanism (See Figure 2).

2. Methods

As regards operating methods, open direct view fixation, limited incision fixation or closed minimally invasive fixation may be chosen according to the position and type of fracture. The operating method of open direct view fixation is largely the same as steel plate series operations, except that in operation,
open direct view fixation does not need stripping a large area of periosteum and the fixation system may be placed outside periosteum (Figure 3). Different bones may be fixed with screws and rods of suitable specifications, and the clamps of the same specification may be chosen freely according to the position and type of fracture. After being placed, the clamp can glide and rotate freely along the rod to facilitate operation and improve fixation effect. For metaphyseal fractures near a joint, anatomical multi-holed clamps or regular screws may be chosen for lockup or connection. Small incision minimally invasive operation means that a limited small incision is made at the position of fracture and reduction of fracture is conducted under direct view; the fixing rod and clamp are inserted in through this incision. A screw input position is chosen and a 10mm skin incision is made at the position; under the guidance of the locking screw guider, holes are made with an electric drill to input the locking screws (Figure 4). The operation method is like LCP and MISS steel plate. The closed minimally invasive fixation should follow the MIPO technique principle. The fixing rod and clamp are inserted in far from the position of fracture, closed reduction of fracture is conducted under C-arm, and locking screws are input according to the small incision minimally invasive operation method (Figure 5). This system may be used as an external fixation frame for open fractures (Figure 6).
3 Clinical data

3.1 General clinical data

This group included a total of 74 cases covering 85 fractures, of which commuted fractures accounted for 58%. Of cases, there were 24 humeral fracture cases, of which 13 were male and 11 were female, with the age range 21~71, 46.3 on average, including 8 fractures near joint, 4 nonunion cases and 2 cases of fracture complicated with radial nerve injury; there were 18 femoral fracture cases, of which 11 were male and 7 were female, with the age range 17~82, 39 on average, including 7 cases of fracture near joint, 1 case of grade-I open fracture, 2 nonunion cases, and 1 case complicated with sciatic nerve injury; there were 26 tibiofibular fracture cases, of which 28 were male and 7 were female, with the age range 19~68, 37.5 on average, including 4 cases of fracture near joint, 7 cases of grade-I open fracture, 2 nonunion cases, and 19 cases complicated with fibular fracture; and there were 4 radial fracture cases and 2 ulnar fracture cases. Cause of injury: 45 injuries due to traffic accident, 14 injuries due to fall from height, 6 injuries due to crash by heavy object, 7 injuries due to self fall, and 2 injuries due to other causes. Injury of emergency cases was 1 to 10 days from operation, 8 days on average. Nonunion cases lasted 2 years and 3 months at most.

3.2 Efficacy standard

After operation, X-ray film were taken periodically to compare the outer appearance of the injured side with that of the healthy side and measure the angulation, rotation and shortening of the injured limb. Healing of fracture was assessed according to the clinical symptoms and X-ray show: The function of the injured limb was assessed with the Johner—Wruhs method: Excellent: The fracture is healed, the joint moves normally and can withstand force, the gait is normal, no pain, no angulation deformity, the injured limb is shortened by <5 mm and rotated by <5°, no infection, no nerve or blood vessel injuries or other complications; good: the fracture is healed, the joint moves 75% normally, with less withstanding strength, the gait is normal, pain occurs occasionally, angulation deformity is <5°, the injured limb is shortened by 5~10 mm and rotated by 5°~10°, no infection, complicated with mild nerve and blood vessel injury; medium: the fracture is healed, the joint moves 50% normally, with significantly limited withstanding strength, limping gait, moderate pain, bone angulation deformity 10°~20°, the injured limb is shortened by 10~20mm and rotated by 10°~20°, no infection, complicated with moderate nerve and blood vessel injuries; bad: fracture healing delay or nonunion, the joint's activity is below 50% of normal level, the joint can’t withstand force, obviously limping gait, sharp pain, bone angulation deformity >20°, injured limb shortened by >20 mm and rotated by >20°, complicated with injection, and with serious
nerve and blood vessel injuries.

3.3 Result

Of the 74 cases in total, 72 cases were followed up with visits for 6 to 18 months. X-ray film were taken again 2 days, 1 months, 3 months, 6 months and 1 year after operation respectively, the result was: At the time of 3 months, the cases showed obvious porosis and the fracture line was fuzzy; at the time of 6-9 months, the fracture line disappeared and bony union was achieved; of the 8 nonunion cases, 7 cases achieved bony union at the time of 9 months as shown in follow-up visits. The rate of fracture healing was 100%. After operation, there were no serious complications such as wound infection, nonunion, or loosening or breakage of internal fixation metal. According to the assessment standard as above, 55 cases were excellent, 15 cases good, and 3 cases medium. The total excellent and good rate was 94.6%.

4 Discussion

Long tubular bone fractures are the most common fractures in clinics. The conventional operating method includes internal fixation, which includes steel plate series and intramedullary nail series, and external fixation, which includes external fixation frame. The steel plate series, as a way of eccentric fixation, need extensive stripping of periosteum, which leads to great damage to the bone growth environment and the unavoidable problems of stress concentration and stress shielding. This is also the important cause for nonunion and metal breakage. As a way of centric fixation, interlocking intramedullary screws have good biomechanical performance, but they need reaming, which will damage blood supply of intramedullary tissues, and once interlocking is done, the problem of stress shielding will still exist. You often need to change static fixation to dynamic fixation by undoing interlocking three months after operation. Flexible interlocking intramedullary screws have good biomechanical performance but much less fixation strength and stability. In addition, the operating skills and in-operation complications of interlocking intramedullary screws can't be overlooked. The external fixation frame can be used to implement minimally invasive operations, but it renders inferior fixation effect and tends to cause pin tract infection. Therefore, it is often used in early treatment of open fractures. In recent years, with modern biology, biomechanics and internal fixation concept progressing and developing, people have developed new internal fixation instruments, which include LCP and MISS steel plates, by combining the “AO” and “BO” theories \(^2\). They realize less invasive and entirely fixing effect by utilizing the structure of lockup connection between screws and plates. Nonetheless, the problems of stress shielding, stress concentration and post-operation static fixation to dynamic fixation in its biomechanics still remain unsolved. As regards the advantages and problems of the internal and external fixation mentioned as above, a new
internal fixation system has been used clinically, and clinical application has proven the reliability and effectiveness of its internal fixation. This system is named as the Bridge Modular Internal Fixation System due to its structure, performance and usage characteristics and it provides more advantages in terms of structure design, biomechanical features, biological effect, operation and indications.

4.1 Structure design
This system has a entire locked connection structure comprising rods, clamps and screws. The operator can combine and arrange the number of fixing rods and the mode of clamps flexibly according to the specific condition of fracture to realize the internal fixation function of steel plate and intramedullary nail to meet the treatment requirement of most fracture types. For positions with a special anatomical structure, we can choose special anatomical clamps and make the fixing rod into any shape to realize anatomical fixation. Among this group of cases, there were 14 cases of fractures near a joint. We chose double-rod three-hole and double-rod four-hole clamps and spongy bone screws to make all of them achieve good reduction fixation effect.

4.2 Biological effect
The animal test and the clinical research show that, steel plate obviously disturbs the blood supply of dermal bone under it. The close contact between the steel plate and the bone damages blood supply outside bone and that of dermal bone under the plate from the periosteal artery, osteonecrosis will occur and bone reconstruction will be affected, leading to osteoporosis under the plate, thus to negatively affect the healing of fracture. Intramedullary blood circulation will start to resume only weeks after reaming in intramedullary fixation. The bridge modular internal fixation system is like a “built-in external fixation frame”. For open reduction fixation or limited incision or closed minimally invasive fixation, it needs no or slight stripping of periosteum in operation. The internal fixation is placed outside periosteum and does not directly repress the position of fracture, which will effectively avoid the damage to blood supply at the dermal bone under the internal fixation and at the broken end of the fracture, and at the same time, which will reduce the effect of rejection or electrolytic conduction to the end of fracture, so that the effect of the internal fixation operation on the bone growth environment will be minimized.

4.3 Biomechanical characteristics
Conventional steel plates or intramedullary nails are largely troubled by stress shielding at the broken end of fracture. The physiological load can’t pass through the bone mass at the position of fixation with the plate, which reduces the physiological stimulation to the bone mass at this position, leading to local
bone cortex reduction, osteoporosis, reduced bone strength, and stress concentration at both ends of steel plate, as a result, re-fractures after internal fixation operation with steel plate may occur. In addition, the internal fixation operation with rigid steel plate may lead to disordered arrangement and damaged structure of collagenous fiber inside the bone at the fixation section, resulting in reduced bone strength, less withstanding capacity, and easy breakage; another stress concentration problem of rigid steel plate and LCP internal fixation occurs at the position of screw hole of steel plate on the plane of structure. Fatigue breakage of metal is largely due to stress concentration at the weak position of steel plate. This system has realized the following excellent biochemical features through combined collocation and entire locked connection: (1) Similar to LCP, it improves the effectiveness and safety of internal fixation by using the entire lockup structure; (2) single rod series may use multiple screws for fixation purpose to enhance anti-rotation and anti-pulling strength, which is a function only realized by external fixation frame. (3) The modular lockup structure of this system is different from the lockup structure of LCP screw and plate. It may slightly glide axially according to load in the process of healing of fracture, which can not only effectively avoid stress shielding and stress concentration, but also promotes healing of fracture and prevents bone calcium loss. The other meaning of axial glide of the clamp along the rod is to acquire the effect similar to centric fixation, because such glide is realized only if there is no looseness between bone and internal fixation. (4) This system uses rod as the combination structure, which has good stress conduction performance, because rod bridge fixation may avoid to a great extent the problem similar to stress concentration at the screw hole of steel plate; in addition, the flexibility of rod structure may also help callus growth. It's obvious that other internal fixation systems don't have the latter three biomechanical features.

4.4 Operability

Minimal invasion is the developing trend of modern orthopedics. The CRNIF system can apply MIPO (minimally invasive percutaneous osteosynthesis) to realize percutaneous closed internal fixation or limited incision internal fixation to effectively control the injury of multi-section comminuted fractures. In addition, the greatest advantage of this system is the realization of free glide and rotation of clamps by combination and collocation of fixing rods with regular clamps, special clamps, single/double-rod clamps and regular screws or lockup screws. The position and angle of screws can be adjusted freely according to the position and condition of fracture to realize better effect of fixation and improve the operability and flexibility of operation. For example, for comminuted fractures at the position from condylar to supracondylar femur, we can use condylar-anatomical clamp to fix the comminuted condyle, which turns a complicated fracture to a simple one, and then we can use rods and other
clamps to fix the supracondylar comminuted position at near end, and at the same time, we can spread and adjust it with pressure, which can't be realized by all other internal fixation systems, for which please see Figure 7.

![Figure 7. Model of fixed comminuted fracture at condyle of femur](image)

### 4.5 Indications

By combining and collocating rods, clamps and screws freely, the BCFS system can meet the requirement of most fractures at different anatomical positions of long tubular bone fractures, including fractures at positions near a joint, and can substitute anatomical steel plates; in addition, it can substitute interlocking intramedullary nails to treat multi-section or long-section comminuted fractures, and at the same time, it can also be used as external fixation frame. Moreover, better efficacy has been acquired clinically in treatment of pelvic acetabulum and scapulas and other irregularly-shaped bones.

### 4.6 Efficacy analysis and outlook

This group of clinical application included 74 cases covering 85 fractures and achieved 100% healing of fracture and 94.6% excellent and good efficiency, despite the fact that most of the fractures are comminuted fractures. Such a result is very exhilarating, especially when we observe the time, shape and quality of healing of fracture and it also reflects this internal fixation system's advantages in terms of design, operation as well as biological and biomechanical features. At present, in order to prove this system's safety and effectiveness, we have preliminarily completed the comparative animal test and biomechanical test, the result of which is still satisfying.

In theory, the BCFS system is now the most widely used internal fixation system at home and abroad. It has achieved good expected result in treatment of fractures of femur, tibiofibula, humerus, and ulna and radius. We will strive and develop toward the direction of improving and perfecting it, expanding its
application scope to include the fixation and shape righting of the spinal column.

Reference:


Figure 1. Design of BCFS system

Case 1 Comminuted fracture of right tibia
Case 2  Traumatic arthritis and corrective osteotomy of ankle

Case 3 Distal fracture of humerus
Case 4 Distal fracture of tibiofibula

Case 5 Distal comminuted fracture of femur

Case 6 Comminuted fracture of tibia