Develop and Clinical Application of Clamp and Rod Modular Internal Fixation (CRMIF) System

Abstract

The optimal surgical treatment for limb fractures is still controversial. A new internal fixation system was developed by professor Xiong Ying in China. It consists of a rod connected by several clamps and locking screws, which named clamp and rod modular internal fixation (CRMIF). The advantage of the system is the ability to achieve reduction and fixation with the same instrumentation, and it also can provide flexible internal fixation for almost all types fractures of the limbs. CRMIF has been used in more than 150 patients and proven most adequate for limb fractures. In a prospective trial, 85 operations using this technique were carried out between 2007 and 2009. The rate of union was 100 percent for all the cases. This method of treatment appears to offer significant advantages over conventional technique in the management of limb fractures.

The internal fixation of fractures has evolved in recent decades with a change of emphasis from mechanical to biological priorities. In order to achieve a new balance between stability and biology during the treatment of fractures, CRMIF has been developed. It combines the advantages of point contact fixator and external fixator, which also can provide sliding compression between the fragments. The system can substitute nearly 80% of the existing internal fixation products. We report the structure of system and the results of the clinic application.

PATIENTS AND METHODS

74 patients with 85 fractures of limbs were treated at our institution between January 2007 and January 2009. Among all cases, there were 24 humeral fracture cases, 13 male and 11 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 tibial 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. All the cases were treated with CRMIF, and all operations were performed by the authors. 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. Clinical and radiographic evaluations were performed on admission, during the immediate postoperative period, at discharge, and at 1, 3, 6, 12, 18, 24, and 48 months postoperatively. Age, operation time, blood loss, and admission period were determined by chart review. Patient ability to conduct activities of daily living and to walk were analyzed using the social function score system developed by Jensen1 and the mobility score system devised by Parker and Palmer2. Data were obtained during outpatient
visits or by telephone interview.

**Structure of the Instrument**

CRMIF system mainly consists of fixing rods, 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 clampks 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 (Figure 2).

![Figure 1. Fixation rods, clamps and screws](image1)

![Figure 2. Total locked fixation: Rod-clamp-screw-locked connection](image2)

**Operative Technique**

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).

Figure 3. Fixed outside periosteum

Figure 4. Guided by guider

Figure 5. Limited incision fixation

Figure 6. External fixation application of CRMIFS
RESULTS

3 months after the operation, all 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 complications, 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%.

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. 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.

CRMIF system is like a “built-in external fixation frame”. Which has 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. By combining and collocating rods, clamps and screws freely, the CRMIF system can meet the requirement of most fractures at different anatomical positions of long tubular bone fractures, including fractures near to joint, multi-section or long-section comminuted fractures, pelvic acetabulum and scapulas and other irregularly-shaped bones.

The result of the clinic trial is very exhilarating, especially when we observe the time, shape and quality of healing of fracture. Which indicate CRIMF system has a perfect design and good biomechanical characteristics

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. In theory, the CRMIF 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.

REFERENCES