Improved Ilizarov method for management of deformity and ulceration on foot and ankle of spina bifida

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\textbf{A B S T R A C T}

\textbf{Objective:} To analyze the characteristics of foot and ankle deformity with ulceration in patients with spina bifida, to conclude experiences on management with improved Ilizarov method in one stage.

\textbf{Methods:} 77 cases suffering foot and ankle deformity with ulceration of spina bifida were included from January 2008 to June 2019, in which 30 male and 47 female, aged 6–46 years with an average age of 22.86 years. There were 10 cases on left, 14 on right and 53 on both. The improved Ilizarov method combined soft tissue surgery, bone osteotomy and Ilizarov technique in one stage, by which the ulcer was dressed aseptically and avoid weight bearing preoperatively, no special treatment, no debridement, no flap coverage and no bacterial culture. Antibiotics were given for 3 days routinely, and the dressing was removed 5 days later. If there was exudation, gauze could be used to wrap continually, if there was no swelling and exudation, no need further more caring. General appearance and radiological image of ulcer and deformity were observed during the period of evaluation and treatment, surgical method and complications, foot & ankle function and overall function were evaluated using AOFAS scoring system and special table designed by authors.

\textbf{Results:} 77 cases were followed up for 6–132 months with an average of 50.5 months. Achilles tendon subcutaneous lengthening was performed in 2 cases, posterior tibial tendon and Achilles tendon simultaneous released for 31 cases, subtalar joint arthrodesis 25 cases, calcaneus osteotomy 5 cases, triple osteotomy 28 cases, ankle arthrodesis 19 cases, internal rotation osteotomy of tibia was performed in 1 case and 1 case in external rotation osteotomy. There were 67 cases using Ilizarov fixators and 10 cases using Hybrid fixators for immobilization and correction. Stable feet were obtained and ulcers healed simultaneously when all deformities of foot and ankle had been corrected. The healing time of ulcer was average 26.5 days ranging 7–36 days, and there was no infection or delayed healing occurred in any case. Ankle ankylosis in 25 cases, 3 cases of pin tract infection, 2 wires were broken. The AOFAS score significantly increased from 70.5 ± 4.5 preoperative to 81.6 ± 3.9 postoperative; based special table evaluating, Excellent 28 cases, Good 42 cases, Fair 7 cases.

\textbf{Conclusion:} The patients with foot & ankle deformity and ulceration suffered from spinal bifida can be treated by improved Ilizarov method in one stage, and the results are satisfactory with short treatment period and decreased complications.

\textbf{Translational potential of this article:} The characteristics of foot and ankle deformity with ulceration inpatients with spina bifida have been analyzed and the experiences on management with improved Ilizarov method in one stage have been summarized in this study, which updated treatment concept of neurogenic deformity with ulceration on foot and ankle joint.

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1. Introduction

Foot and ankle deformity with ulceration is common in patients with spina bifida, spinal cord injury or trauma sequelae. Because of sensory abnoramlity and neurotrophic disorder, chronic ulcers always occur on the weight-bearing area of foot & ankle, skin, fascia and bone involved, even osteomyelitis in serious cases. Spina bifida is one of the most common deformity of neural tube development in the central nervous system, although the number of new case has decreased, the disability rate has not improved over time [1,2]. Manifested as lower extremity muscles varying degrees of paralysis and sensory disturbance [3,4] similar to Charcot foot [5], become the main aspect affecting daily life of them. It was called refractory ulcers because of ankle instability, sensory impairment, deformities, chronic ulcers and osteomyelitis [6-8], the results of treatment were always not good in a variety of methods in a number of hospitals, and even some doctors recommend amputation.

In the past, ulcer was considered as primary aspect of treatment of this complex situation above. Many methods were used such as surgical dressing, traditional Chinese medicine, Growth factor, Vacuum Sealing Drainage (VSD) [9] and so on, and even many operations were carried out to remove ulcer and antibiotics were given to eradicate some infections. Although the ulcer could be temporarily healed, it would reoccur once loaded. Some doctors suggested that the ulcer could be cured by correcting the deformity, which often performed with concern for damaged and infected skin and other soft tissues, especially for ulcers that had not healed for a long time [10]. The tibiotaral calcaneus fusion with screws or intramedullary nails was performed to achieve bone stability of ankle joint, however, the operation was complicated and requires high level surgical skills, there were still risks of nonunion, secondary ulcer and infection, and internal fixation failure or being amputated.

Nikolay Mikhailovich Kliushin [11] reported that it was effective in the treatment of this kind of disease with Ilizarov technique, 77 patients were treated by stage procedures: Firstly, low frequency ultrasound debridement (it worked by delivering low frequency ultrasound through a constant flow of saline, sound waves were transmitted to tissue through a treatment applicator) and simple Ilizarov fixator application, intraoperative soft tissues of ulcer and osteomyelitis were taken and sent to the laboratory for pathological examination, bacterial culture, sensitive antibiotic detection, suturing and drainage, lasting for 25–30 days, the general ulcer could be healed; the application of sensitive antibiotics in first 10–20 days. In the second stage, the calcaneus ring was added for distraction osteogenesis. The operation included arthrodesis and osteotomy of calcaneus, talus and midfoot simultaneously. This stage generally lasted for 2–4 weeks, and antibiotics were generally used for 5–7 days. Continuous wearing with frame in third stage, it was allowed to full bearing, the walking plaster below knee was worn after fixator removal, generally lasting for 2–4 months.

According to the principle of aseptic surgery, to reduce the risk of infection, many successful experiences had been accumulated in the treatment of foot and ankle deformity with ulcer by stage procedures in Ilizarov center [12-16]. According to Qinsihe orthopedic database [17], in the 1990s and the early 21st century, we carried out bacterial culture in strict accordance with the principles of infection treatment in same way, but there was no bacteriological law, even in serious cases, the test results showed that there were various bacteria or no bacterial growth at all. Ulcers could healed naturally when the patients were arranged staying in bed for a long time, or the limbs were not loaded with weight bearing, surgical dress changing or traditional Chinese medicine dressing application [18]. However, most of the patients are young, active, and some of them often unable to cooperate with the treatment as the long-term bed rest, and which increases the risk of urinary infection and protracted ulcer.

Based on our previous experience in the treatment of foot and ankle deformity of spina bifida [19-21], the improved Ilizarov method was applied to treat the refractory deformity with ulcer in spina bifida in one stage, and the satisfactory result was obtained, that was, ulcer healed while deformity corrected. Compared with the case of Ilizarov center, the authors investigated the eligible cases and made a retrospective study. The objective is: (1) to summarize the effect of one-stage and staged procedures in the management of foot & ankle deformity and ulcers, and (2) summarize the appropriate treatment methods, indications and clinical pathways for deformity and ulcer in foot and ankle of spina bifida.

2. Materials and methods

77 cases with foot & ankle deformity and ulcer of spina bifida in Qinsihe orthopaedic department were included from January 2008 to June 2019.

Inclusion criteria included:
(1) Foot and ankle deformity with ulcer;
(2) There is no limit to the type and degree of ankle deformity and ulcer;
(3) X-ray of lumbar sacral region indicated incomplete lamina closure;
(4) Age, gender and region are not limited.

Exclusion criteria included:
(1) The case with diabetic foot ulcer;
(2) Patients with cerebral thrombosis, coronary heart disease and other serious chronic diseases;
(3) Patients with incomplete records and data.

There were 30 male and 47 female with an average age of 22.86 years (6–46 years). There were 10 cases on left, 14 on right and 53 on both. In addition to the routine physical examination, detailed specialized
examination was carried out, including deformity and sensation of foot and ankle, degree and position of joint relaxation, location, size and depth of ulcers (Table 1 and Table 2), and the condition of rectal and urinary system.

2.1. Operation

The goal of treatment for foot and ankle deformity with ulcer of spina bifida [21] is to weight bearing on whole foot, ulcer healing and keeping the mobility and elasticity of ankle joint as much as possible. In clinical practice, it is necessary to make decision according to the type of deformity of foot and ankle, the degree of ulcer and joint relaxation, and the general information of the patients such as gender, age, occupation, living environment, economic situation, aesthetic requirements and psychological quality, etc.

The surgeries were performed by the same team in the past more than 10 years. In each process of operation, the patient lay at supine position on the operating table under general anesthesia and disinfected according to the sequence of sterile area and then ulcer area.

1. The ulcer could be dressed aseptically and avoid weight bearing preoperatively. It was protected by cotton ball and skin-protective membrane during surgery. If the ulcer close to the site of osteotomy, it could be resected and osteotomy in same time. No special treatment, no debridement, no excision or flap coverage and no bacterial culture.

2. Triple arthrodesis, subtalar arthrodesis [22] or ankle arthrodesis [23] was performed through lateral approach of foot, which starting from the talonavicular joint crossing the calcaneocuboid joint and 2 cm below the lateral malleolus [24]. To expose three joints, it was necessary to protect the dorsalis pedis artery and the extensor digitorum. The angle and range of osteotomy determined according to the degree and type of foot deformities, joint surfaces of calcaneus, talus, scaphoid and cuboid were removed and aligned once, and the foot was corrected to the neutral position, especially the calcaneus Varus deformity, which must be completely corrected. The foot after osteotomy could be fixed by 2–3 Kirschner wires that diameter 2 mm, and the osteotomy space was implanted by cancellous bone. Generally, subtalar joint osteotomy was selected for those with mild or moderate deformity, triple arthrodesis or ankle arthrodesis was performed for those with serious deformities, or with relaxed joints and arthritic joints.

3. The retractable cavus foot could be managed by posterior transfer of the extensor longus, the first metatarsal osteotomy was performed for bony or stiff cavus foot.

4. For the patients with calcaneal foot, peroneal brevis transfer to Achilles tendon could be done when triceps surae still with three levels of muscle strength. The patients with triceps completely paralized, the Achilles tendon could be replaced by tibialis anterior muscle and peroneus longus. If there were obvious contracture on anterior soft tissue and bony deformity in toes, the tendon of anterior tibialis and extensor digitorum longus could be lengthened or released to make partial dropping angle on foot, and then performing triple arthrodesis for foot backward.

5. The patients with hallux laxity and prolapse could be performed fusion on interphalangeal joint with Kirschner wire or cross pin, and then fixed the extensor digitorum and extensor pollicis tendon in the distal of tibia by drilling holes.

6. Those with obvious leg deformities could be treated at the same time, the proximal tibial osteotomy could be performed in the case of internal or external rotation of tibia.

7. The foot and ankle with mild deformity could be corrected acutely fixing with Hybrid fixator or Ilizarov fixator. For moderate and severe deformities could be corrected partially during operation due to the limitation of medial skin, nerves and blood vessels, the residual deformity could be corrected postoperatively gradually following Ilizarov principle.

2.2. Postoperative management

The affected limb was wrapped with cotton pad and raised 30° to reduce bleeding and swelling postoperatively, antibiotics were given for 3 days routinely, and the dressing was removed 5 days later. If there was exudation, gauze could be used to wrap continually, if there was no swelling and exudation, no need special treatment. The ulcer was exposed without special care. If there was exudation, gauze could be applied to bind and drain, or Chinese Shengji cream for dressing [6]. Unlike conventional methods, did not do bacterial culture postoperatively, and did not disinfect with iodophor, hydrogen peroxide and other disinfectants.

Patients were encouraged to stand and weight bearing intermittently 3–5 days postoperatively, and then began to practice walking with assistance. The goal of foot and ankle deformity correction could be in light equines position, generally 10–20°, the affected foot could be fully loaded on appropriate insole. The external fixator maintained 12–16 weeks and then changed to orthosis when osteotomy site healed postoperatively, and gradually reduced the wearing time until it was replaced with appropriate shoes.

2.3. Evaluation method

General appearance and radiological image of foot and ankle joint could be observed during the process of evaluation and treatment, surgical procedures and complications, foot & ankle function and overall function of limb could be evaluated using following methods.

1. AOFAS(American Orthopaedic Foot & Ankle Society, AOFAS) Ankle and hind foot scoring system, evaluated from subjective pain sensation and objective function examination; Excellent > 90 points, Good 75–89 points, Fair 50–74 points, Poor < 50 points.

2. Special table [35] designed by authors for evaluating of management of deformity and ulceration on foot and ankle of spina bifida was filled in by experienced doctors in one team postoperatively. The table involves different aspects of deformity correction, muscle balance, improvement of movement and walking function, self-evaluation of operation effect, complications and some other problems. The index of evaluation is divided into four levels:3 is Complete, 2 is Major, 1 is Partial,0 is no or recurrence, the final score is the number sum indexes divided by 5, and evaluation level is as follows: Excellent > 2.5, Good > 2, Fair > 1, Poor > 1.

The design and implementation of this study was approved by the ethics committee of Rehabilitation hospital affiliated to National Research Center for Rehabilitation Technical Aids.

3. Results

77 cases were followed up for 6–132 months with an average of 50.5 months. In this series, Achilles tendon subcutaneous lengthening [25] was performed in 2 cases, posterior tibial tendon and Achilles tendon simultaneous released for 31 cases, subtalar joint arthrodesis 25 cases, calcaneus osteotomy 5 cases, triple osteotomy 28 cases, ankle arthrodesis 19 cases, internal rotation osteotomy of tibia was performed in 1 case and 1 case in external rotation osteotomy. There were 67 cases using Ilizarov fixators and 10 cases using Hybrid fixators for immobilization and correction. Stable feet were obtained and ulcers healed simultaneously when all deformities of foot and ankle had been corrected. The healing time of ulcer was average 26.5 days ranging 7–36 days, there was no infection or delayed healing occurred in any case.

Ankle ankylosis in 25 cases, in which 9 cases were completely stiff.
feet had slight recurrence of deformity in 1 year postoperatively, the ulcer was still in original position and did not affect walking function after active intervention with insole (Table 3).

There were 3 cases suffered from pin tract infection. One of them was red, swollen and festering located anterior medial tibia 10 days postoperatively, in consideration of the secondary infection caused by thermal injury when Kirschner wire penetrated bone during operation, the skin healed gradually after pulling out the Kirschner wire. The other 2 pin tract infection improved by decreasing activity and local disinfection.

Two Kirschner wires 2.5 mm in diameter were broken in 2 cases, which occurred in front foot, 1 of which on medial side and 1 wire on lateral side, both occurred around 8 weeks after operation. They were just pulled out until the external fixator removed because of little effect on overall stability.

The results in final follow-up: 3 cases presented normal gait, 67 cases with mild abnormalities, only 7 cases still manifested obvious gait disorders. The AOFAS score significantly increased from 70.5 ± 4.5 preoperative to 81.6 ± 3.9 postoperative, (P = 0.000 < 0.001), which from Paired t-test based on SPSS20.0 (Table 4).

Based special table evaluating of management of deformity and ulceration on foot and ankle of spina bifida above: Excellent 28 cases, good 42 cases, fair 7 cases.

### Table 3
**Complications of patient cohort.**

| Complications           | Frequency |
|-------------------------|-----------|
| Neurovascular injury    | 0         |
| Ulceration relapse      | 3         |
| Deformity recurrence    | 3         |
| Edema of ankle and foot | 12        |
| Marginal necrosis of wound | 0    |
| Pin tract infections    | 3         |
| Pin break               | 2         |

3.1. **Typical case 1**

This was a case of a 19-year-old boy suffered ulcer with equinovarus deformity on left foot. Ulcer healing with correction of ankle deformity achieved as result by improved Ilizarov method in one stage (Fig. 1).

3.2. **Typical case 2 (Figs. 2–7)**

This was a typical case of a 26-year-old male suffered spina bifida with severe talipes equinovarus deformity in left foot for 25 years. The weight-bearing area in the left foot had been ulcerated for 22 years. It had been treated with various methods and remains unhealed, and many

![Figure 1. Equinovarus deformity with ulcer on left foot (Planta view:-A.preoperatively,B.10 days postoperatively).](image)
doctors in different hospitals recommended amputation, even no tumor cells having been found by pathological examination (Fig. 2.ABC (Fig. 3.AB).

The procedures of posterior tibia muscle lengthening, partial ulcer resection, triple osteotomies and Ilizarov fixator application was performed. Dressing was changed at 5 days after the operation (Fig. 4A–D), and the external fixation frame was started to adjust at 7 days. The varus deformity was corrected at 28 days after surgery (Fig. 5. A-C). Residual ulcers naturally healed under push–pull stress stimulation. At 110days after surgery, X-ray showed that the bone of triple arthrodesis had healed, the structure of the foot and ankle joint was restored, so the external fixator was removed. The deformity correction was satisfactory and the ulcer healed. The patient could walk normally. Ankle foot orthosis was worn for 4 weeks. The patient was followed up for 36 months after surgery, deformity and ulcer did not recur (Fig. 6. A,B). He could walk freely in soft-soled shoes. At 11 years follow-up, the patient had no ulcers and could walk for more than 5 km (Fig. 7).

4. Discussion

1. The risk and feasibility of management of foot and ankle deformity and ulcer in spina biﬁda cases in one stage.

In patients with foot & ankle deformity and ulcer of spina biﬁda, the location of the ulcer is related to the position of the load-bearing area, because load area is the area stress concentration. According to the clinical observation, corpus callosum or bursa often form when the patients without sensory nerve disturbance; Otherwise, chronic ulcer form always under the continuous effect of weight-bearing compression, osteomyelitis may occur in severe cases.

Literatures [11,26,27] show that a lot of bacteria are cultured in ulcers, and our initial culture results show that there is also, or no bacterial growth yet. According to statistics, the ulcer cannot be cured completely or long-term by anti-infection medicine. Good effect is often obtained.

Figure 2. Clinical appearance preoperatively. A. One ulcer presented lateral of left foot with severe talipes equinovarus deformity; B. posterior view and anterior view; C. X-ray showed the disordered bones on foot and ankle.

Figure 3. Situation of back. A. This picture showed the surgical scar of neurolysis on lower back. B. X-ray showed incomplete lumbosacral lamina.

Figure 4. Surgical procedures. A. posterior tibia tendon lengthening, B. ulcer resection, triple osteotomies, C. partial deformity was corrected; D. Ilizarov fixator was applied.
Figure 5. Deformity corrected and ulcer healed. A. lateral view; B. medial view and C. anterior view.

Figure 6. 36 months follow-up. A. anterior view; B. lateral view; C. X-ray AP view and lateral view.

Figure 7. Clinical appearance 11 years follow-up. A. anterior view; B. posterior view and C. lateral view.
when the patient weight free or after deformity corrected, which may the fundamental option for treatment of this complex and refractory disease.

The main risk of one-stage treatment for foot and ankle deformity with ulcer of spina bifida is relative infection, which is the original intention of stage treatment also, but a large number of practices have proved that this is not the case. The wounds are open in a long term, multiple bacteria caused by or harmonious symbiosis formed between human and bacteria [26,28].

We have basically cancelled bacterial culture for those cases deformity with ulcer against the principle of "infectious operation" we usually do not clean and close the wound, just carrying out surgeries deformity correction according to pathological condition of the disease. After routine disinfection, gauze and skin protective membrane can be used to protect the wound. Meanwhile, osteotomy, tendon release and other procedures we called improved Ilizarov method are performed. In the ending of surgery, gauze is used to bind up for wires and incision of surgery rather than ulcers. The ulcer healed naturally with deformity correction, new infections and osteomyelitis never be seen at the site of incisions or osteotomies.

This natural phenomenon is that, prof.GA Ilizarov said that bacteria burn in bone regeneration [29,30], which conforms to the significance of Qin Sihe’s idea of Natural Reconstruction [31].

In this group, the healing time of ulcer was 7–36 days, 26.5 days on average, and less recurrence during the period of follow-up. As the reference previously said the first stage was 26.1 days (15–37 days), the second stage was 26.3 days (12–91 days), the third stage was 127.5 days (81–302 days), and the wearing time of external fixation was 179.9 days (128–413 days), and so on. It is obvious that the time of one stage treatment is much shorter than that of staged treatment.

2. Management of foot and ankle deformity and ulceration of spina bifida in Qinshi Orthopedics

According to the overall macro thinking of management for foot and ankle deformity in Qinshi orthopedics, the principle of ulcerative deformity of spina bifida is as follows: deformity correcting, joint stabilization and the application of external fixation, in which the expected goal of treatment as ”plantar, stable and elastic foot”.

With "stress control" as the core of "natural reconstruction [31]", the deformity status should be fully evaluated when the operation plan formulated, and the ulcer can heal naturally in the process of foot and ankle deformity correction. The target of operations including triple arthrodesis, subtalar arthrodesis or and ankle arthrodesis is to correct the bone deformity or stabilize joints [32], tendon release and tendon transfer are used for dynamic balance. The postoperative management followed the principle of "One walk, Two lines and Three balances" [36], the slight plantar foot position instead of 0° position, maximizing the weight-bearing surface so as to disperse the stress, and the ulcer healed naturally with the increase of weight-bearing area of the foot [23].

It is more important to keep elasticity on foot and ankle with deformity and sensory disturbance, that is mean, try not to do or do less joint fusion when correcting bone deformity, especially the ankle joint should be preserved, even mild degeneration. The periarticular osteotomy can be performed to replace arthrodesis surgery. At the same time, the osteotomy should also be done as little as possible to achieve the purpose of deformity correction by bone resection. To some extent, the operation is only to open the osseous connection, and the deformity can be gradually and completely corrected by Ilizarov fixator post operatively.

In this way, the length of foot can be kept and the ischemic injury of soft tissue can be reduced as much as possible postoperatively. The wearing time of fixator on foot and ankle is generally 10–16 weeks depend on the patient in different ages. After fixator removal, due to the possibility of contracture of soft tissue and incision scar, it is generally recommended walking with Ankle Foot Orthosis (AFO)in order to prevent the recurrence of deformities.

Even precise operation and the application of external fixator can reduce the incidence of infection, which cannot be avoided. There is different rate in literatures, which are related to many factors, such as location of wires, skill of wiring, postoperative caring and different doctors so on. The patients in this group were bandaged for 5–7 days after operation, and then the gauze was removed, all pin tract was exposed to the air, no special caring was carried out. In the cases suffering pin tract infection, it could be related to thermal injury, but there was no case coming from ulcers.

Two Kirschner wires locating front foot in two cases were broken, one in medial side and one in lateral side, all the two occurred around 8 weeks postoperatively, which could be related to local stress concentration when excessive load weight bearing, or the relative long-term healing time of osteotomy site. Therefore, we should increase the intensity of fixation and extend the fixation time properly, because little effect on the overall stability when one Kirschner wire broken and be pulled out [33].

Three patients with recurrent ulcer were accompanied by the recurrence of ankle deformity, which in 2 children recurred one-year post operation, may related to insufficient rehabilitation and exercise in growth and developing period. In another case, the recurrence of deformity may be related to delayed healing at osteotomy and premature fixator removal. Biomechanical insoles were used for these three cases to maintain neutral position, no more surgery has been performed until now.

3. Limitations

Marching 77 cases as literature[11], this study tried to be consistent and strive for meaningful results, but it may be biased because the data came from a long term more than 10 years. This study is a retrospective study may have some impact on the overall results due to lack of bacteriological examination, incomplete gait data or finite element analysis [34] and no sample in comparative group. In addition, this study did not collected the data of blood circulation, which needs to strictly design a standard process for diagnosis, treatment and evaluation, especially the multi center cooperative prospective study, which is the focus of future work.

Summary

The fundamental understanding of spina bifida is that foot and ankle deformity accompanied with ulcer, rather than the deformity secondary to ulcer. It can be achieved with satisfactory clinical results, short treatment period, and decreased complications using improved Ilizarov method in one stage. Deformity correction is beneficial to ulcer healing, and the change of biomechanics is the basis of natural reconstruction of deformity and ulceration.

Declaration of competing interest

All authors have none to declare.

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