Application of Target muscle reinnervation (TMR) and Muscle redistribution technique (MRT) in ULP

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Abstract:

How to control the movement of bionic prosthesis with consciousness has been a hot spot in the research of bionic prosthesis. The realization of this function is mainly based on Electromyographic signal (EMG) signal and biological capacitive signal(C-SENs). How to improve the signal quality and promote the better operation of bionic prosthesis according to consciousness is very important. As important surgical methods to realize the above goals, Target muscle reinnervation (TMR) and muscle redistribution technique (MRT) improve the signal quality and the function of intentional movement of biological prosthesis respectively by increasing signal origin and increasing muscle deformation. In this paper, TMR and MRT are introduced focus on upper limb prosthesis (ULP) in detail through surgical case analysis, and their advantages and disadvantages are analyzed. We also propose the characteristics of the ideal bionic prosthesis.

Key word: TMR, MRT, Bionic prosthesis

With the development of electronic technology and information processing technology, Bionic machinery has entered every aspect of life. As an important type of disability, upper limb amputation seriously affects the daily life of patients and brings many inconveniences. The emergence of bionic prosthesis brings a great dawn to the solution of this type of disability problem. As a different type of prosthesis from traditional prosthesis, bionic prosthesis can partially replace or completely replace the function of patients' original limbs through mechanical activities. Therefore, to meet this requirement an intelligent bionic prosthetic controller should be able to accurately decode and recognize the movements intention of the human body, which is the first step to complete the specified movements.

However, as we all know, the function of human upper limb is so complexity that can finish lots of motion of hand and movements of arm as we intention.

It should be able to converse of physiological signals into signals that can be processed mechanically by a computer.

In this paper, we will introduce some technology and our own-perspective which will mainly focus on Application of Target muscle reinnervation (TMR) and Muscle

Redistribution technology (MRT) in ULP.

Comparation between conscious based control and manual based control

Here we'd like to introduce two tests to compare the performance of the with the example of EMG-controlled prosthetic and manual control with the example of conscious control i-pad-controlled Prosthetics.

First came the box and blocks test, which asked subjects to move an inch of blocks from one box, over a short wall, and into another box. This assessment is considered a standardized test by experts. The goal of the experiment was to see how many blocks subjects could move in two minutes.

The result is EMG controlled prosthetics moved more blocks than i-pad group. (table. 1) Kuiken and his team also designed a clothing pin test that required subjects to use a terminal device, an elbow and wrist rotation device.They should pick up the clothing pins on a horizontal bar, rotate the pins, and then place them on a higher vertical bar (Kuiken et al., 2004).The purpose of these experiments was to see how long it took the subjects to move three clothes clips.

As a result, patients using the myoelectronically controlled prosthesis were able to remove the clothe clip faster than the I-PAD prosthesis (Kuiken et al., 2004) (Table 2). The advantages of conscious control are illustrated by the examples of electromyographic control and prosthesis.

Traditional EMG based control strategies

When it comes to traditional control strategies, each function of the prosthesis is operated sequentially using the amplitude of the EMG signal from the remaining muscle.

At that time, actually, some external electronic equipment such as iPad or cell phones would be used to control the prosthesis (Kurosaka et al., 2016). From the results, the iPhone and iPad technique could achieve acceptable performance, and the authors have used the OrthoPilot finished the navigation system which got high accuracy and reliability of this system (Xu et al., 2014). However, using these smart phones is not enough, since one would physically incapable of giving out WIFI or mobile internet signals from his own body. Therefore, control strategies cannot just depend on electronic equipment. Moreover, an individual with trans humeral amputation must trigger a 'mode switch (trigger to switch the controlled Prosthesis part like elbow, wrist, and hand) to sequentially select which of these devices is to be actuated. Apparently, it is so inconvenience that we considered it not bionic at all. Therefore, an amplified and corrected measure is supposed to design.

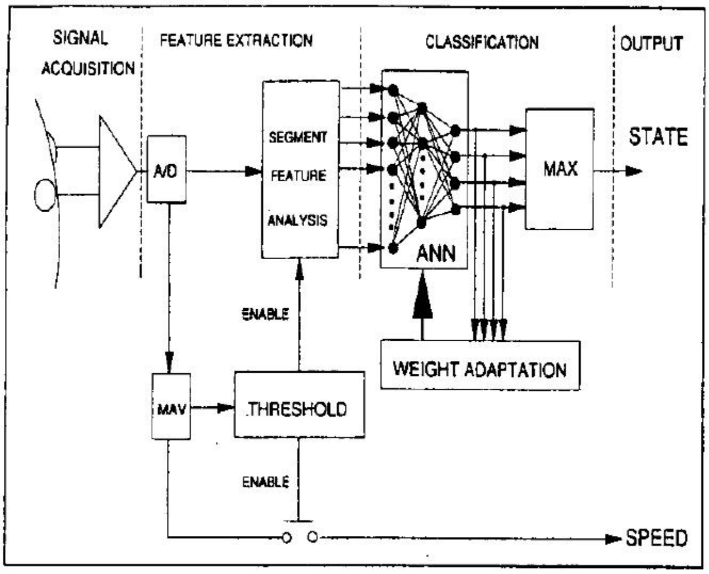

Fig.1 Flow chart for signal recognition (Kuikenet et al., 2009)

An amplified and corrected measure

Considering the pros and cons of traditional strategies, a bionic control method is designed now. Before illustrating this design, some processes are supposed to demonstrated. As shown in the figure, the EMG signal is acquired from the surface electrodes, at that time, the signal may be noisy. Therefore, before recording it into computers, these EMG signals would be transmitted into a pre-amplifier and some filters circuit consisting of capacitance and inductance coils. Then, some basic signal processing may be used such as amplifier, band pass filter or rejector to separate the signal and noise.

The Analog to Digital conversion is used subsequently, aims to completing the next step, calculating the feature values. By analyzing the characteristics of these signals, we do some feature extraction using some feature values of time domain or frequency domain (such as continuous wavelet coefficients) and combine them to the feature vectors. And finally, construct the classifier to distinguish them (Rafiee et al., 2011).

In the flow chart, an ANN algorithm would be used and the final results would output and instruct prosthesis to finish different kinds of motions. If so, the patients would just think about what they want to do, by acquiring EMG signals, prosthesis would auto-activate and follow the instruction.

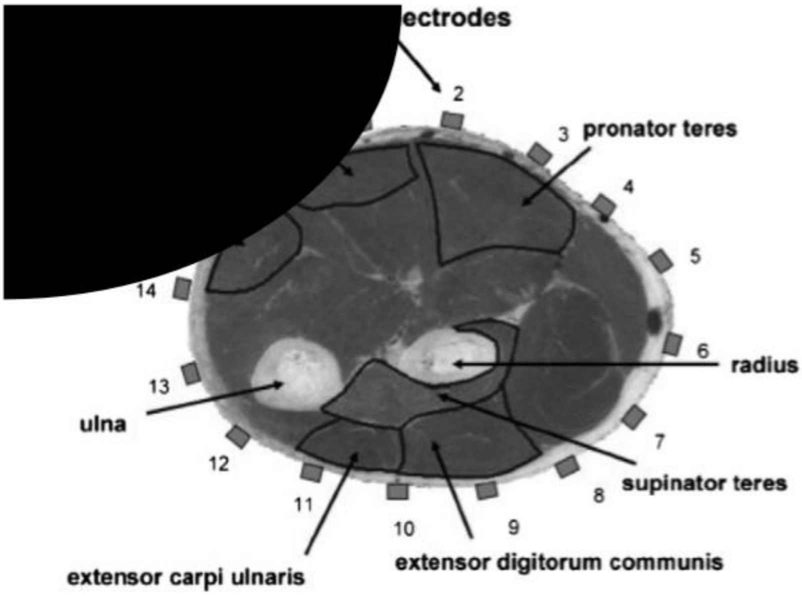

Fig.2 A cross section of the upper forearm to illustrate the locations of 16 surface electrodes and six needle electrodes (Kuikenet et al., 2009)

Theoretically, it seems like a perfect design. However, always, Bio-physiological signals are so weak or not so excellent for guiding the bionic prosthetic moving correctly especially EMG signals, can easily be confused with ECG signals or interference by non-targeted muscle, which lead to a lot of discomforts and inconvenience even misleading.

For example, the biceps and triceps are used by a humerus amputee to control the elbow, wrist, and hand. Because the identification is not so precise and needs to be activated, the user, as mentioned earlier, must trigger a "mode switch" to choose which of these devices is activated. This type of operation is not intuitive because the remaining muscles control physiologically unrelated movements. Currently available prosthetics are cumbersome and slow to use (Ajiboye and Weir, 2005).

As for electromyography signals, they cannot be detected for a long time to prevent infection because they need to be implanted into the body. Therefore, the way to improve the signal strength is particularly important.

Thus, an excellent amplified and corrected measure is ought to need to increase the number of signal sources measure and reduce the phenomena of residual muscles control physiologically unrelated movements. At that time, some authors came up with a surgery method to solve the problem.

Increase the intensity of signal

In order to solve these problems, signals have to be amplified to increase the intensity so that it can be acquired and recognize by computers successfully. Meanwhile, increasing the number and intensity of signal sources conforming to physiological characteristics is the difficulty and hot spot in the field of intelligent bionic prosthesis research. At this moment, TMR appeared, which is a surgical technique called targeted muscle reinnervation (TMR) transfers residual arm nerves to alternative muscle sites, which means the EMG signal of the amputation site would transfer to other exist position even be amplified because of an increase in the number of nerve bundles. In addition, it has been proved that a potential treatment for postamputation neuroma pain. Meanwhile, it is most suitable for the transhumeral and shoulder disarticulation patient (Gart et al., 2015).

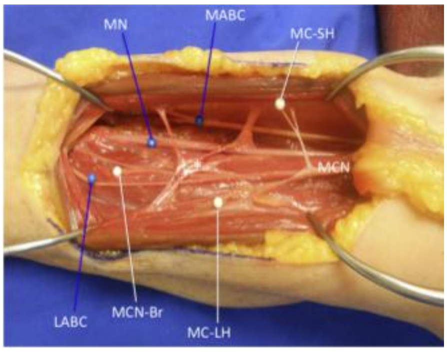

Fig.3 Left arm viewed from the head shows the anterior exposure of the MCN and MN (Michael et al.,2015).

Besides, to be more effective, in this method, the procedures need close coordination between the surgical, prosthetic and rehabilitation teams. Therefore, instead of complicated control, a surgery has to be taken in order to recognize EMG signals correctly. Fortunately, there is minimal surgical morbidity, which means potentially be performed outstanding and in the outpatient setting.
Because the patient's nerves are transplanted to multiple places during this process, the number of sources increases dramatically. Therefore, after nerve transplantation, these target muscles generate EMG signals on the skin surface of different muscle sites, thus achieving more easily measured multi-source signal input and being used to control prosthetic arms (Kuiken and Todd, 2009).

Surgical procedure with cases

There is a surgery example for some details of TMR. In a surgical case at 2015, based on Lowery’s certification when a ten-millimeters radius which is seldom or no subcutaneous fat, the areas where mutually interfere that bipolar electrodes picked would quite small, (Lowery et al., 2003).T. A. Kuiken et al started a new research when he and his group found a proper candidate who suffered severe electrical burns before and received a bilateral shoulder amputation. He received bilateral prostheses and underwent extensive prosthesis training. Through his efforts, he was able to operate these devices very well. His shoulders moved freely, his pectoral muscles contracted vigorously, and there was no sign of brachial plexus disease. But his pectoral muscle lost its insertion point on the dislocated humerus. They were ready to carry out targeted muscle reinnervation in this patient. If the TMR take effect, it will effectively improve his prosthesis. On the hand, even though the TMR experiment will fail, he also can use i-pad to control his prosthesis as long as release his pian in skin graft position. In order to try a targeted muscle reinnervation, T. A. Kuiken and his groups' objectives were three points:

Firstly, it needs safely identified the composition of the brachial plexus, it can avoid interference of irrelevant nerve signals. Secondly, based on the muscle innervation and vascularity, muscles of the chest should be divided into units; Its aim to produce multiple source points and get rid of noises.

Multiple source points can also be obtained by moving the brachial plexus down to the muscle segment, eliminating non-antineural signals (Almstrm et al., 1981).The median nerve, musculocutaneous nerve, radial nerve, and ulnar nerve are found within a few centimeters of the shoulder joint.(Figure 4) The pectoral muscle (Kuiken et al., 2004) traces the pectoral nerve into the pectoral muscle, including pectoralis major and pectoralis minor. In this process, the musculocutaneous nerve is transferred to the upper pectoralis major, and in some cases the median nerve is anastomosed to the middle pectoralis major. When the ulnar nerve is transferred to the pectoralis minor, the inferior pectoralis major is attached to the radial nerve. As these pectoral nerves enter these muscles, their branching patterns are successfully established. Finally, the remaining nerves are mobilized and directed to the position where the pectoral nerve branch is inserted into the muscle.

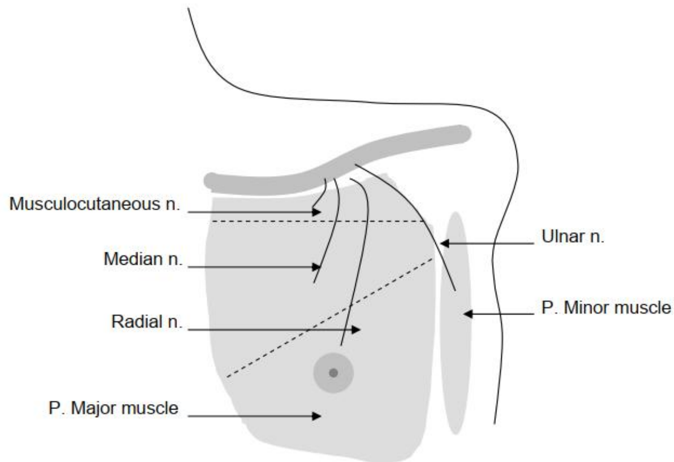

Fig.4 The median nerve, musculocutaneous nerve, radial nerve, and ulnar nerve are found within a few centimeters of the shoulder joint and then reinnervated by the target muscle. (Kuiken et al., 2004)

For a rough surgical procedure of TMR. It can be divided into five parts roughly.

First, under general anesthesia, the thick skin was excised and the large flap raised to expose the pectoralis major and pectoralis minor muscles.

Second, nerve location recognition (first from the head of uninjured tissue to the amputation site, and then from the distal end). The position of the brachial artery and the nerve of this artery is important in identification. The nerve endings are very long and can be cut off to the distal end of the pectoral muscle to restore it to a healthy nerve bundle. Functional length is increased as nerves are transported more directly to new muscle units rather than moving more laterally in the axilla. The pectoralis major is made up of three parts because the nerve has enough length. The clavicle has its own blood and nerve supply and is separated from the pectoralis major by its gross margin. The lateral nerve is divided into upper and lower fascicles, which can be used for the separation of pectoral muscle and chest bone. And then the beginning of the pectoralis minor is organized and transferred to the midaxillary line. These are all to avoid myoelectric signals from myonerve regeneration units. The entire nerve bundle of these new muscle units separates close to where the nerve enters the muscle. The proximal ends of these nerves are tightly ligated and removed from the new demineralized muscles. It needs to clear other deceptive nerve grafts. After these, excision of the majority of subcutaneous fat at associated sites, which is efficient to record electrodes that close to interested regions with the strongest surface EMG signals and the very little noise. (Kuiken et al., 2003)

Finally, all nerve fascicles to these newly created muscle units were divided close to the site and creates clear multiple source points without interference.

After three weeks, the patient's pectoralis couldn't contract voluntarily after the surgery. So, he was encouraged to exercise his hand, flex and extend his wrist and his elbow on his daily life.

After few months, the median, radial and the musculocutaneous nerves successfully contract. And through tried again and again, they were detected the EMG signals when he was moving his hand and wrist. It shows this advanced method had its preliminary effect (Kuiken et al., 2004).

Besides the method and procedures of TMR's surgery, we want illustrate some tests for assess the efficacy of this newborn technology.

More TMR Surgical cases introduction

Patient S1 had a shoulder disarticulation and patient T5 had trans-humeral amputation (Kuiken and Todd, 2009).

Target muscles include the pectoralis major, pectoralis minor, serratus anterior, and latissimus dorsi muscles, you could find the location of these muscles on the diagram of the normal anatomy.

In patient S1, the pectoralis major, which is the muscle of our chest, is divided into three functional areas, the clavicular head and two sternal bones.
Move the pectoralis minor muscle laterally to the chest wall as another muscular area of the 4 brachial nerves.
As for the patient T5, the median nerve is transferred to the medial biceps, which allowed the providing EMG signal frpm lateral biceps to an to the flexor elbow. The radial nerve of distal end metastasizes to the lateral triceps, which left the long triceps to provide the EMG signal for the elbow extension
The most common displacement (dislocated shoulder) is shown below:

- Musculocutaneous nerve to pectoralis clavicular head movement point
- Median nerve supplies the pectoral bone of the pectoral muscle pointing to the maximum point of movement
- The radial nerve to the sternal dorsal nerve (reinnervating the latissimus muscle)

Ulnar nerve to the motor point on the lateral and deep aspect of the pectoralis minor or long thoracic nerve (to reinnervate serratus anterior) In these pictures (Fig.5), the patients were performing tests with their prosthesis. Patient T5 was required to pick up a plastic bottle cap with a fine pinch grip. Patient S1 was tested by moving a ring to across a geometric wire while patient S2 was required to move a box made by tissue.
Every new technology needs a big sample and long-term assessment analysis to show its effectiveness. Here we introduced 30 cases long-term research and assessment was implemented.
Patients with TMR performed three tests, which are the action research arm test, the Southampton hand assessment procedure and the clothespin-relocation test, to show the benefits of TMR and these are the results.
Action Research Arm Test. 20.4 ± 1.9 of 57.
Southampton Hand Assessment Procedure. 40.5 ± 8.1.
Clothespin-Relocation Test. a mean time of 34.3 ± 14.4 seconds.
The Southampton Hand Assessment Procedure indicated an improvement of 131.8 -146%.
However, the Action Research Arm Test just elucidated only minimal improvement of 0 - 4.6%.

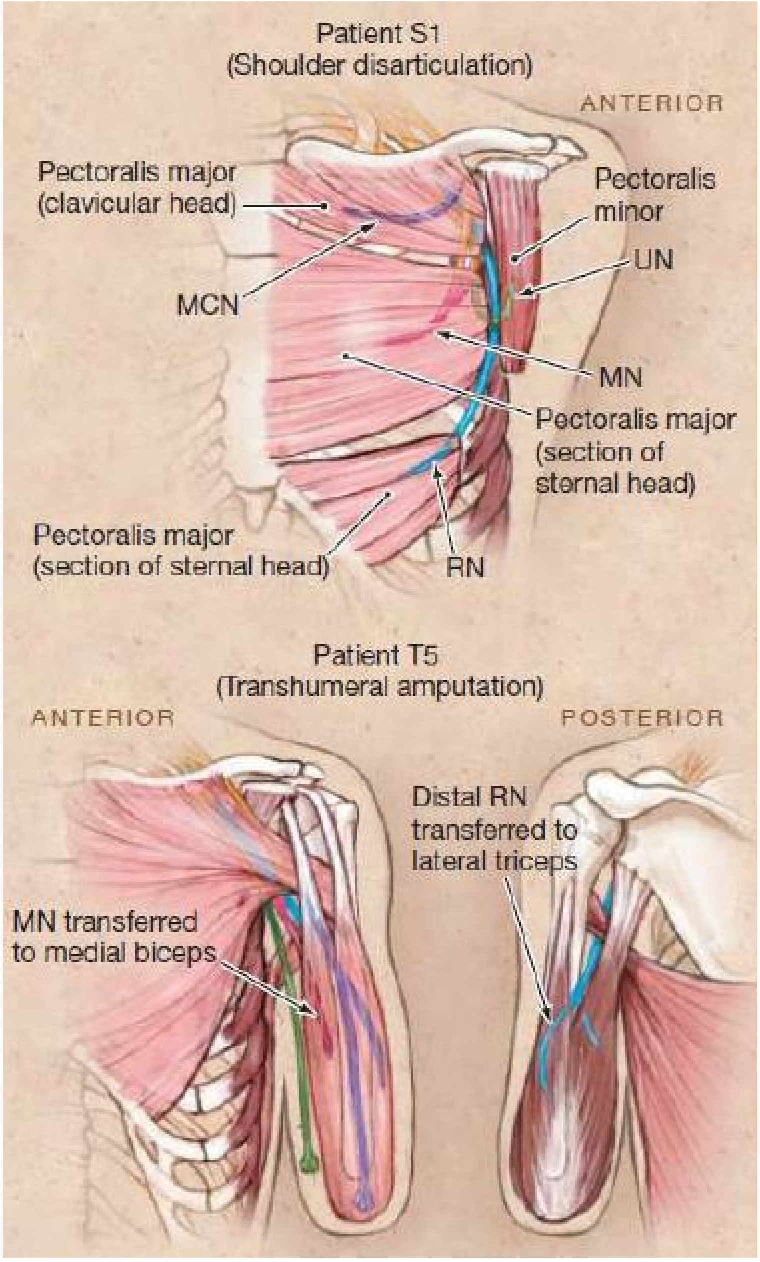

Fig.5 Schematic diagram of Patient S1 and T5 TMR operation (Kuiken et al., 2009)

Cons and pros of TMR:

This procedure produces more physiological signals by transferring the discarded nerve to the muscle of the stump

It increases the number of motion signal sources of the human body, and feeds back the movement instructions directly sent by the brain at the proximal end of the residual limb, so that the intelligent prosthetic limb can accurately complete more body movements by recognizing corresponding signals. It could also provide sensory feedback. Additionally, it brings a lot of convenience to the life and work of high-level amputees.

However, every technology has its limitations and TMR is no exception. There isn't an ideal method to increase the signal source of human motion intention for too low-level amputees with the amputation plane located at the distal end. Like the picture on the right. And it is easily interfered by external factors and other limitations like magnetic field (Based on EMG). The success of TMR also depends on the availability of intact nerves and we still don’t know whether the reinnervated or transferred nerves could survive permanently.

Also, there are also standard risks with performing the surgery, in addition to those, permanent paralysis of the target muscle, recurrence of phantom limb pain, and development of painful neuromas could also occur.

MTR, a new technology based on capacitance signal

TMR may also have a lot of disadvantage in application. So, are there any new and better technology to improve or compensate it? MTR is the one of the most excellent potential advanced methods we considered.

Muscle redistribution technique (MRT) is a very new technology and for Upper limb application, the first case just were reported at 2017(Xu et al., 2017).

Its principle based on capacitive coupling principle which it means detected the capacitive signals in human movement intention and recognized by Methods of machine learning or deep learning with signals from sensors on skin (C-Sens) (Xu and Wang, 2019; Xu et al., 2017; Xu et al., 2019).

The surgery processes (Yang et al., 2020) of MRT is that the muscles and tendons in the affected limb were displaced according to the pre-operative design, and the tendons were anchored in different areas of the skin in the affected limb stump.

After the Muscle redistribution technique surgery, the corresponding muscle contractions can through the tendons to pull obvious deformation. This apparent deformation causes a change in the capacitance field. Through the capacitive sensing system and other data acquisition, the intelligent bionic prosthetic system can know the movements intention of human body and perform corresponding movements. And finally control the bionic upper limb prosthetic movements. However, the muscle movement deformation of the short terminal upper stump is always not obvious. So MRT surgery make it obvious. this also is the surgery example we mentioned before, and we can see a clear sag in here this place. (Fig.6)

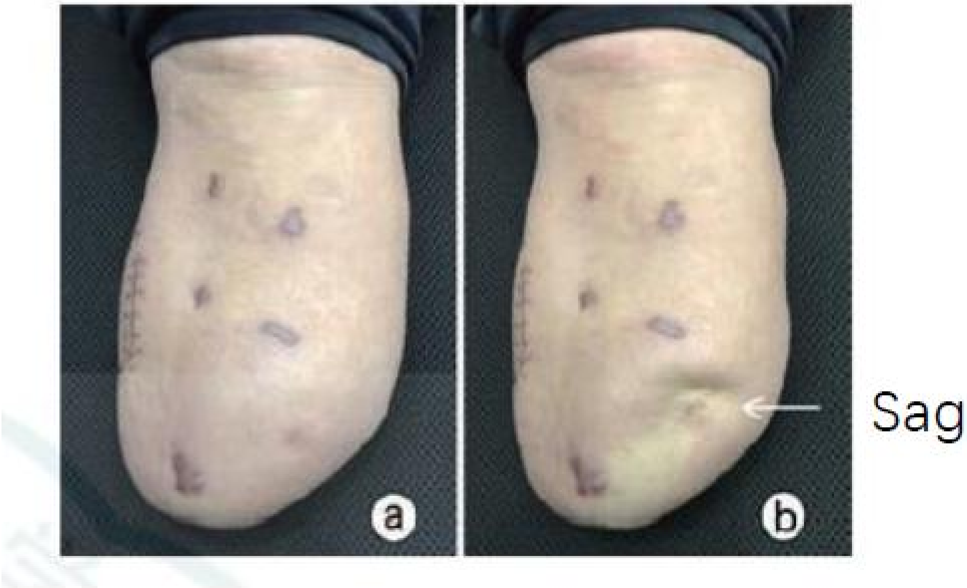

Fig.5 Apparent muscle deformation after TMR

MRT device structure consist of copper film and stump sock. The capacitive electrode consists of a copper film fixed on the inner surface and on the human body. The stub of the sock in the middle forms the dielectric of the coupling capacitor

During the movement, the contact force between the stump and the dimple changes periodically. At the same time, the effect of force will lead to periodic deformation of the stump socks. Therefore, capacitance can reflect the motion of lower limbs. Combine information from other sources, such as sensors or nano piezoresistive resistors used in hand prosthetics or foot insole lower limb prosthetics. In this way, the signal representing the user's action intention can be entered into the recognition system through the capacitance change recognized by the capacitance sensor. After processing by artificial neural network (ANN) or deep neural network (DNN) (Xu and Wang, 2019), which have passed machine learning training, the user's intention is judged by the computer. A computer controls the movement of a mechanical prosthesis according to intent. With above process MRT can guide the upper limb bionic prosthesis finish lots of motion of hand and movements of arm as we intention.

A kind of technology must be tested. In the assessment of MRT, two classifiers, linear discriminant analysis (LDA) and quadratic discriminant analysis (QDA) (Yang et al., 2020), were used to identify and evaluate the accuracy of various actions. The overall recognition accuracy of the upper limb was 97.27% and 100% respectively. The recognition accuracy of each movement was 100% respectively. Linear discriminant analysis (LDA) (Xu and wang,2019) is a generalized Fisher linear discriminant method that combines statistical, pattern recognition and machine learning efforts to find the characteristics of a linear combination, considering two types of objects or events or distinguishing them. Its principle is given a training sample set, try to project the sample onto a line. QDA is also a Linear method and used in different samples variance condition.

Cons and pros of MTR:

From the test it showed an amazing result in bionic prosthetic controls.

MRT based on Capacitive signal (C-Sens) and it has the advantages of short delay, strong anti-interference ability and good stability in human motion signal recognition (Xu and Wang, 2019; Xu et al., 2019).

But However, as MRT it is a very new technology in this range.

- Few reported cases and the lacks of long-term, multiple ways benefit analysis. Besides, it depends on certain machine learning processes (problem of training model accuracy)
- The theoretical research on C-Sens is still limited in MTR utilized in upper limb prosthetic
- Lack of correlation evaluation between time delay and human motor intention (Maybe weaker than EMG based).
- In addition, there are standard risks associated with the operation. MRT operations are performed in fewer cases than TMR operations. This may also lead to greater potential risks.

Technology comparison (TMR vs MRT)

In the comparison between TMR and MRT technology, there are a lot of difference between this two.

TMR and MRT depend on different signal recognition principles.

TMR depends on EMG.MRT depends on C-SENs

Both, though, can be operated on with a conscious mind. Quick response to user intent

Although EMG based TMR solves the problem of internal muscle signal interference and mixing. But it's essentially electrical signals on the surface of the skin. So, it's very easy to be disturbed in complex electromagnetic conditions.

MRT is based on C-SENs

Its essence is capacitive signal, which is the combination of electrical signal and limb distance. Better anti-interference ability.

Moreover, white TMR is quite sophisticated and have a lot of application cases, MRT is a relatively recent development. It still needs to be tested.

Advanced expectations

So, in our opinion, and also as our conclusion, for the question what kind of bionic prosthetic control mode will we need in the future? We considered it should be with the features about:

High precision and accuracy of bionic signal identification

Bionic Prosthetic's ability to move in accordance with user intentions is a fundamental requirement.

Effective and immediate response to user intention

Bionic Prosthetic can quickly move in accordance with users' intentions without prolonged delay and prosthetic, thereby enhancing users' sense of use by timely recognition and feedback.

Good anti-interference ability

Be able to adapt to the user's activities under various environmental conditions and scenarios. Have good reliability without causing problems due to environmental changes.

Reasonable Fraud and cost

Price is always an important factor for the mass production and promotion of bionic prosthesis.

No discomfort for patients (willing to use)

It is not enough to achieve basic functions but bring discomfort or sequelae to patients and make users unwilling to use them daily.

Here we purpose a hypothesis that the application with combination of EMG(TMR) and (C-Sens) MRT based technology can achieve it.

And in the future the upper limb bionic prosthetic is able to restore basis daily function of health upper limb function and even directional enhance some additional function like the prosthesis of winter soldier.

Tables

Table 1. A comparison of box block experiments between a touch pad control prosthesis and a neuromuscular graft control prosthesis.

	Touch pad control Number of blocks	Myoelectric control Number of blocks
Trial 1	5	10
Trial 2	5	14
Trial 3	7	18
Average	5.7	14

Table 2. Comparison of touchpad-controlled prosthesis and neuromuscular graft-controlled prosthesis clothespin test.

	Touch pad control Time (sec)	Myoelectric control Time (sec)
Trial 1	153	83
Trial 2	137	122
Trial 3	121	99
Average	137	101

Table 3. The corresponding nerve, target muscle, prosthetic limb function control

Nerve	Target Muscle	Prosthetic Function
Musculocutaneous	Biceps, long head (native innervation)	Elbow flexion
Median	Biceps, short head (nerve transfer)	Hand close
Radial (distal)	Triceps, lateral head (nerve transfer)	Hand open
Radial (proximal)	Triceps, long head (native innervation)	Elbow extension
Ulnar	Brachialis (if available)	Wrist function

References:

Ajiboye, A.B., and R.F.H. Weir, 2005: A Heuristic Fuzzy Logic Approach to EMG Pattern Recognition for Multifunctional Prosthesis Control. Ieee T Neur Sys Reh 13, 280-291.

Almstrm, C., P. Herberts, and L. Krner, 1981: Experience with swedish multifunctional prosthetic hands controlled by pattern recognition of multiple myoelectric signals. Int Orthop **5**, 15-21.

Gart, M.S., J.M. Souza, and G.A. Dumanian, 2015: Targeted Muscle Reinnervation in the Upper Extremity Amputee: A Technical Roadmap. The Journal of Hand Surgery.

Kuiken, and A. Todd, 2009: Targeted Muscle Reinnervation for Real-time Myoelectric Control of Multifunction Artificial Arms. Jama **301**, 619.

Kuiken, T.A., M.M. Lowery, and N.S. Stoykov, 2003: The effect of subcutaneous fat on myoelectric signal amplitude and cross-talk. Prosthetics & Orthotics International **27**, 48-54.

Kuiken, T.A., G.A. Dumanian, R.D. Lipschutz, L.A. Miller, and K.A. Stubblefield, 2004: The use of targeted muscle reinnervation for improved myoelectric prosthesis control in a bilateral shoulder disarticulation amputee. Prosthetics & Orthotics International **28**, 245.

Kurosaka, K., S. Fukunishi, T. Fukui, S. Nishio, Y. Fujihara, S. Okahisa, Y. Takeda, T. Daimon, and S. Yoshiya, 2016: Assessment of Accuracy and Reliability in Acetabular Cup Placement Using an iPhone/iPad System. Orthopedics **39**, 1-6.

Lowery, M.M., N.S. Stoykov, and T.A. Kuiken, 2003: Independence of myoelectric control signals examined using a surface EMG model. Ieee T Bio-Med Eng **50**, 789-793.

Rafiee, J., M.A. Rafiee, F. Yavari, and M.P. Schoen, 2011: Feature extraction of forearm EMG signals for prosthetics. Expert Systems with Applications: An International Journal **38**, p.4058-4067.

Xu, D., and Q. Wang, 2019: Capacitive Sensing Based Knee-Angle Continuous Estimation by BP Neural Networks.

Xu, D., Y. Yang, J. Mai, and Q. Wang, 2017: Muscle redistribution surgery based capacitive sensing for upper-limb motion recognition: Preliminary results 2017 IEEE International Conference on Cyborg and Bionic Systems (CBS).

Xu, D., Y. Yang, J. Mai, and Q. Wang, 2019: Capacitive Sensing Based Recognition of Ankle Movement Imagery in Patients after Amputation Surgery.

Xu, K., Y.M. Li, H.F. Zhang, C.G. Wang, Y.Q. Xu, and Z.J. Li, 2014: Computer navigation in total hip arthroplasty: A meta-analysis ofrandomized controlled trials. Int J Surg **12**, 528-533.

Yang Y, WANG Q, XU D, MA Jg, Sun L, Chen S, Tian W, and Tian G, 2020: Application of muscle redistribution technology in signal recognition of intelligent bionic prosthetic limbs.Chinese Journal of Physical Medicine and Rehabilitation 42, 541-545.

Ilizarov techniques

The cross-century invention of the science of orthotics (Mainly focus on low limb orthotics)

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Ilizarov methods used in lower limb

Ilizarov technique is a cross-century invention of the science of orthotics. It has been almost 70 years since it was first proposed. In this report, we purpose to introduce this the most historical and still most effective technology. We will mainly focus on low limb orthotics.

Firstly, it stems from 1951, Ilizarov's resident physician was an orthopedic surgeon originally, during which time he developed an external fixation system. At that time, Ilizarov as a doctor of military found that by carefully cutting off a bone without cutting off the periosteum around the bone, the two halves could be slightly separated and held in place, and the bone would grow to fill the gap (Ilizarov G A, 1989)[1].

These experiments led to a design known as the Ilizarov device, which uses a frame and nails to hold the severed bone in place and separate it slightly; Over time, by repeating this process at the rate bone regrowth, it is possible to achieve the desired length of bone (Young N L et al., 1993)[1-2].

Inspired by the stable structure of bicycle wheels, Ilizarov invented a circular external fixer with fine steel needle penetrating bone and fixed under tension in 1951. During a knee arthroplasty, the patient mistakenly rotated the external fixation pressure device and drew it in the opposite direction. Ilizarov was surprised to find X-ray changes in bone formation in the gradually opened osteotomy space during the review. Therefore, through the drafting experiment after the fracture of dog leg and the push-pull osteogenesis study under the external fixation of the broken end of human trauma bone, he proved that giving a sustained, stable and slow pulling stress to the broken end and the metaphysis of long diaphysis can stimulate the regeneration of bone tissue.

In 1963, Ilizarov reported for the first time 15 cases of bone nonunion and limb shortening deformity treated with the instruments and techniques he invented at the orthopaedic academic conference of the former Soviet Union, which attracted the attention of orthopaedic experts (Ilizarov G A, 1989)[1]. For long time, Ilizarov faced skepticism, resistance and political intrigues from the medical establishment in Moscow until 1968 when Ilizarov operated successfully on a man who had spent about three years receiving unsuccessful treatment at different clinics and had undergone seven invasive and 25 non-invasive surgeries before coming to Ilizarov.

In 1965 and 1971, the Soviet government in kurgan and LieNingGeLe respectively established, institute of orthopaedic surgery, trauma of Ilizarov found pull osteogenesis phenomenon is the basis and clinical application of carried on the thorough research, drafting, in slow motion, for sustained, stable living tissues can stimulate or activate certain tissue regeneration and active growth, its growth mode similar fetal tissues, are of the same cell division, namely the control force of tensile stress, bone and soft tissue regeneration. This is known as Distraction osteogenesis (DO) technology, or osteogenesis tissue regeneration. Human bone and soft tissue have strong regenerative plasticity. As long as the doctor master the development and growth law and apply the stress slowly in three-dimensional space, the limb can grow, shorten or change the line of force according to the doctor's will, so that the deformity can be corrected and repaired. Its orthopedic surgical technique and traction osteogenesis theory is hailed as a new milestone in the history of orthopedic development by the international orthopedic community (Robert Rozbruch S et al., 2006)[3].

Ilizarov has created more than 100 external fixator accessories and can be assembled into more than 600 configurations, which can meet the needs of the treatment of most orthopedic diseases. The device can be installed on the limb to adjust the movement on multiple planes. It can be pulled on one plane and compressed on another plane at the same time, so as to correct various deformities on one limb at the same time. Ilizarov pierced the bone with a fine steel needle of 1.5 ~ 1.8 mm, and was fixed on the steel ring of the external fixator in multiple planes and directions under tension, which could significantly reduce the puncture wound and postoperative infection of the needle canal. During the treatment, axial micro-motion effect can be exerted on the weight of the affected limb, which is beneficial to bone healing (Robert Rozbruch S et al., 2006)[3].

From then on, Ilizarov has showed a very vigorous vitality. Until 2018 there still is the Ilizarov techniques use case reports been published.

Principle of Ilizarov method

The principle of Ilizarov technique orthotics is tension-stress law. The tension-stress law is a biological theory discovered by Ilizarov in the 1960s through extensive animal experiments. It means Biological tissues are subjected to slow and continuous drafting to produce certain tension, which can stimulate tissue regeneration and active growth, and the growth pattern is the same as fetal tissues, all of which are the same cell mitosis. It applies the tension-stress effect or law of tension-stress to stimulate growth.

The Ilizarov apparatus externally stabilizes bone and its surrounding soft tissue while the tension produced stimulates active growth of osseous tissue and soft tissue through gradual traction. Its growth mode is the same as that of fetal tissues, all of which are the same cell divisions.

Dig a little deeper, the Ilizarov technique mainly acts on the bone by changing the way it grows. It based on the principle about Osteogenesis mechanism. The mechanism of bone growth is caused by osteoblasts proliferating with osteocalcin. In bone regeneration process, the osteoblast-based synthesis, secretion, and mineralization of bone matrix are essential for bone formation (Li J et al., 2007)[4].

Therefore, when we exert force on a cell, different cells are affected by the force and grow in a particular direction.

Bone associated cells are no exception. Previous research indicated tensile strain can increase the DNA content of osteoblasts, accelerate cell proliferation, accelerate cell mitosis rate and synthesis rate of extracellular matrix, and increase the synthesis of collagen and non-collagen. In other previous research, when the researcher applies a lateral force to the bone incision site. The fascial microscopic appearance indicated that the fascial growth is affected by the force and is shifted to one side in 28 days or 14 days, 1mm/day or 0.5mm/day treatment.

This showed force has a great influence on bone development, which shows its potential as a correction and orthotics for lower extremity malformation (Li J et al., 2007)[3-4].

A case study

Since Ilizarov applied the tension-stress theory, which can stimulate the regeneration and active growth of some tissues by slow drafting in the growing tissue. The growth pattern is the same as that of the fetus, which is the same cell division (Qin Sihe et al., 2014)[5]. In this research, there are many examples and technological breakthroughs of using it to treat bone defects and incomplete bones such as some multiple external fixation for the Charcot neuroatthropathic foot deformity, which are also used this method as a crucial application. As fig1. shown, we will elaborately illustrate a case related to Charcot neuroarthropathic foot deformity which have used Ilizarov technology.

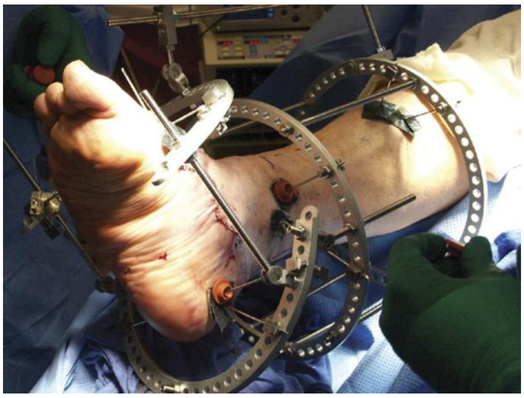

Fig1. Case study of a Charcot neuroarthropathic foot deformity.

There is a diabetic patient that has complicated Charcot deformities of lower limb. His foot was remarkably swollen and his ankle joint was bony prominent. Both of them are complications of Charcot neuroarthropathy. As shown in the figure 2, the X-ray picture c: showed dislocation of his tibiotalar joint and fracture of his talus (Wang Peng-hua et al.,2007)[6].

Fig2. Patient's foot

Zgonis T, Stapleton JJ et al have explored that," Diabetic patients who acquire Charcot neuroarthropathy will have multiple challenges in their treatment period and daily life. Apparently, their propensity for serious bone deformity, poor bone quality, impaired wound ulceration and immune deficiency are strongly increased. These complications place diabetics increase the risk of surgical infection and they may suffer from the loss of limbs in their life. The Ilizarov external fixation ring method gives a minimally invasive procedure with sufficient bone stabilization and soft tissue protection, therefore, using this technology with certain plastic surgery techniques will be an efficient and effective treatment for them. (Z gonis T et al.,2008) [7]"

Steps of surgery

Next, the details of the whole process would be explained specifically.

Before the surgery, each patient has unique needs depending on his or her situation and the genre of surgery requested to treat that situation. At the initial contact with patient, the medical care personnel should make an assessment that covers acquiring an exhaustive medical history and evaluating the anxiety level of the patient and intellectual form of perioperative coping modalities. This enables medical staff to better make specific plans for specific patients, and to effectively explain the condition and operation to patients. With a preliminary understanding and prediction, the medical staff began to plan the following operations. After the patient has understood the procedure and risks and obtained the patient's informed consent, the medical care personnel can begin to prepare the patient for the operation at a specified time. At the beginning of this surgery, doctors need to evaluate and radio-graphically map the surgical site in all three planes – the sagittal plane, the coronal plane and the transverse plane of deformity or fracture pattern. The idea is to get a better idea of the patient's skeletal condition and pinpoint the location of the lesions so that surgery can be performed later. Secondly, regional anesthesia with intravenous sedation to this patient. This combined anesthesia method allows for analgesia and acute pain management. Although general anesthesia is also an option, local anesthesia combined with intravenous sedation is more harmless and precise. Next, the Ilizarov external fixator is put by the surgeons by placing transosseous wires across the proximal ends of the site, besides, another direction, the distal ends of the fracture site also need to put. Kirschner wire is a kind of internal fixation material commonly used in orthopedics. Its original specification is generally fixed at about 20cm and its diameter is between 0.5-2mm. However, actually, compared to the standard Kirschner, wires used in this surgery are longer, which may be 1.8 mm to 2 mm thick. Then, it is notable that, through the nuts and bolts, by utilizing tension, doctors ought to ensure the safety of transosseous wires to the ring frames, subsequently, they connect each ring segment to the next one with graduated rods, struts and hinges. At the process of aggregating the rings would be simple and quick, in case of achieving the results of deformity or fracture because of consuming much long time. Therefore, complicated progress and time-consuming surgeons are supposed to be avoided, which depends on what kind of surgeon would be like. When the surgeon has carried out the total fixator system, gradual or acute correction would be realized. (Lee Daniel K et al.,2010) [8].

After surgery

After above surgery, the postanesthesia nursing care is supposed to be used to monitor the patient's physical recovery such as vital signs, whether they are painful, whether there is infection and so on. Meanwhile, if the surgeon believes that the limb is at risk for compartment syndrome, the nurse monitors the patient's compartment pressure. When the patient is comfortable, he or she is allowed to walk a while or crutches. Postoperative weight bearing is dependent on individual, different patients own different physical fitness, therefore the time of recovery depends on multiple factors such as pathology, compliance, and fixator configuration. Except this, because the Ilizarov fixation device is applied externally, occasionally some components may become loose or fall off the apparatus, doctors need to check it regularly and fix it again (Lee Daniel K et al.,2010) [8].

After 7-12 d incubation period, patents may start to adjust according to 1 mm/d pull the sliding bone segment at a rate, approaching the bone stump, and gradually fill the bone defect area. Under the action of traction force, the body regeneration signal system is activated. The callus gradually generated, increased, aggregated, mineralized, filled and moved, and finally healed the bone defect. It's a slow process, and as the bones grow, the patient feels itchy. Last but not least, according to radiographs of patients taking at periodic intervals until radiologic evidence of union occurs: intervals of three weeks, the following up would observe the status of patients, or six weeks and finally every six months thereafter. If there are any signs of healing, the patient can gradually stop using crutches and use crutches instead (Lee Daniel K et al.,2010) [8].

The Ilizarov apparatus externally stabilizes bone and its surrounding soft tissue while the tension produced stimulates active growth of osseous tissue and soft tissue through gradual traction (He Guoyu et al.,2020) [9]. And it has been confirmed by numerous histological studies that the process of osteogenesis in the traction zone of human bone is simple intrathecal ossification to form new bone. So far, Ilizarov technology is still the most advanced orthopedic technology in the world. By using this technique, the condition of the diabetic patient that has complex Charcot deformities of lower limb has been well controlled and alleviated. Their joint lesion became very well treated.

Another case study

Move to the second case study for example, as fig3. shown, the patient is a little girl who is about seven years old. She had a congenital pseudoarthrosis in the distal 3rd of the right tibia.

She had a history of trauma and underwent plate fixation at a local hospital(Kong, L.D et al., 2018)[10].

Unfortunately, 3 months later, the patient felt painful while walking, and her skin was swollen after being examined by the doctor, at that time, X-ray examination as fig4. shown revealed broken internal fixation and tibia angular deformity.

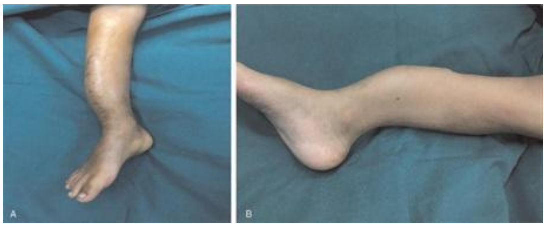

Fig3. 7-year-old girl with a congenital pseudoarthrosis

Fig4. X-ray examination

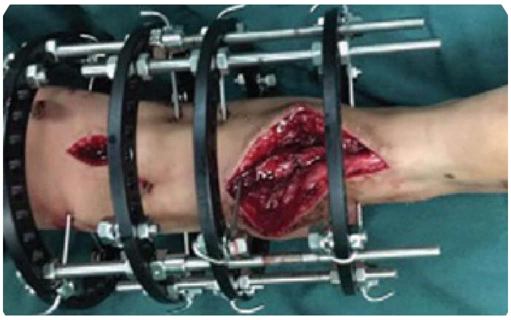

Fig.5 Surgical frame

When it comes to surgical Procedure, it may be nearly similar to the former case. Firstly, the steel plate would be removed. Then, after truncation, a fibula section was taken and inserted into tibia which may be 3 cm length. At that time, doctors place the Ilizarov frame at the center of the lower leg, and then, surgeons would cut off the proximal end of the tibia with a swing saw, bone knife, and electric drill. The installation of the extension ring of Ilizarov is the next step, and the cancellous bone would be Extracted the cancellous subsequently, which was cut into strips and paved on both sides of the fractured end of the lower tibia and compacted.

Actually, to be notable that, there are some Postoperative Examination need to do at first to ensure there are no any problems which may lead to the failure. The first one is the deformity of the lower limbs, which was supposed to be was corrected and the line of force was restored.

At that time, the girl with external fixation began extending her affected extremity after 1 week. During this week, after the treatment of doctors, her bones were extended by approximately 1 mm per day.

During the treatment, the rod she used ought to be screwed 4 times a day and each rotation about 90° , in other words, a quarter of a turn. And then, the knee and ankle of the girl were moved simultaneously to acquire strength. This process may last quite a long time until her lower limbs gradually regrow.

After 9 months, with the new bone regenerate, the external fixator was removed. At the time, her foot and leg would be free, however, the treatment was not over, there were still some training to maintain.

Subsequently, doctors may have to follow up her three months after removal. By testing her recovery level, doctors have to asked her did some training, such as weight-bearing walking. Therefore, she began to carry out partial weight-bearing training that was gradually more and heavier and heavier and finally accepted full weight-bearing training.

After training, with a year of follow-up records, the girl's lower limb strength line is normal, lower limb shortening is eliminated, which means Ilizarov did work very well although the progress is a bit of slow.

After the subsequent diagnosis, the patient's knee joint was not stiff, but the ankle dorsiflexion was slightly limited. At the same time, the patient can hold full weight-bearing walking be but not painful. However, there is still something to take account, for example, the occurrence of refracture.

Occurrence of refracture

It is undeniable that, the CPT is still a challenge for the treatment of orthopedics because it is hard to obtain and sustain a firm healing. As a result, the cure rate was maintained a low level, which was approximately 60% after reaching bone maturity.

In a research study, the researchers discovered that the most popular and acceptable method for treating patients with CPT was utilizing Ilizarov technology and vascularized fibular graft. However, these methods do not always guarantee a reliable combination. The authors of these studies emphasized the importance of fibular fixation and suggested that nonunion of fibula is beneficial to valgus deformity.

In this case study, doctors considered a variety of different surgical approaches, but in the end, considering the role of the knee joint, such as balance and flexibility. Finally, for their patients, they cut off the fibula and transplanted it to the tibia, preserving the knee joint to improve the integrity.

Although the upper and lower ends of the fibula are not recovery, and the fibula is inhomogeneous, there is no valgus deformity in the lower end of the tibia.

The purpose of surgical treatment is to treat the bone of the prosthesis joint and restore the leg layout to avoid new fractures. Therefore, Ilizarov's method has been used perfectly in this case. Another goal of surgery is to reserve the function and growth of the long legs.

In conclusion, Ilizarov technique is an effective and practical method, especially in the CPT disease involved in this case. First of all, compared with other methods, this technology can achieve multiple goals. The first point is to maintain the stability of the ankle joint, which is conducive to balance control. The second point is to promote the synthesis of bone at the same time. Patients with stable postoperative condition have vehicle adjustment method traction device, which can freely walk with external fixation device, and even go home. However, due to the long treatment time and the high surgical skill required during the operation, it may increase the length of stay and the cost of hospitalization. Therefore, perhaps in future research, researchers should improve Ilizarov technology to facilitate tractor adjustment.

Benefit assessment

As shown in the case above, Ilizarov is really an effective method to patients. The figure 6 below is the benefit block which is used to assess the surgery success rate. At this block, since some authors divided results into different evaluation method, in order to judge whether the surgery is success or not, the fair and above results are considered as the patients satisfaction(Daniel K. Lee et al.,2010)[8]

. Using this judgment, all the assessments below are above 80%, which means most of patients would get a considerable therapeutic result. Especially in the research of Catagni et al, the satisfactory rate has reached 98.3% . That means, Ilizarov method does do a good job and it is worth prioritizing rather than an amputation.

Author	Number of Cases	Outcome
Catagni et al	59 98.3%	All fractures healed 30 excellent results 27 good results 1 fair results 1 poor results
Mekhail et al	19 89.5%	2 excellent results 11 good results 4 fair results 2 poor results
LaBianco et al	45 82.2%	37 good results 8 experienced intermediate type complications
Sen et al	11 81.9%	9 fair results 4 poor results(required surgical intervention)

Fig6.Ilizarov benefit assessment[8,11-14]

Lengthening assessment

Therefore, at that time, when it comes to how much patients benefit, the question turns out to be how long can the length of limb gained. The following figure 7 is the results from five different authors(Aaron Lam et al.,2016)[13]. They assessed some patients and followed up them to record the length gained within the last 15 years. To be notable that, all the patients belonged to TTA, which means they ever got a trans-tibial amputation. Admittedly, compared to transfemoral amputation(TFA), there are a lot of advantages to maintaining a transtibial amputation (TTA), thus doctors tend to avoid the amputation converting from TTA to TFA.

Author	Year	Number of patients	Initial length (cm)	Length gained (cm)	% Lengthening
Mertens et al.	2001	2	4.0 6.0	6.5 7.0	163% 117%
Villarruel	2003	1	8.0	7.0	87.5%
Bowen et al.	2005	8	4.8(avg)	6.9(avg)	144%(avg)
Tellisi et al.	2008	1	11.8	5.0	42.4%
Savage et al.	2014	1	8.6	2.3	26.7%

Fig7. Ilizarov lengthening assessment[]

Fig8. the appearance of the residual limb after lengthening[15]

Apparently, lower levels of amputation can get better clinical outcomes, the advantages are better balance, nicer proprioception and easier to control of the prosthesis compared to TFA because of the preservation of the knee joint so that patients can stand and walk. Then, from the block, all the cases of patients got extra length, especially in Mertens's group, which is the earliest cases compared other authors. The data means even with the time pass through, their residual limb may extend more, apparently one can notice that the surgery earlier, the length gained longer.

Deformity assessment

However, there are still some problems we never solved. As the figure 8 shown, it is deformity assessment about equinus ,which is a kind of deformity tending to get at the progress of treatment during the growth of lower limbs (Yoshino Akira et al.,2011)[16]. E means equinus deformity and NE means no equinus deformity. Firstly, all the cases of patients didn't have this kind of disease before they got tibial osteomyelitis, congenital psudoarthrosis of the tibia or tumor. Having calculated the p value, which means the correlation between E and NE, the final gain in length, lengthening rate and final percentage gain of tibial length of Group E and Group NE is respectively 0.4002, 0.5276, 0.0625 and all of them are above 0.05.Therefore, Group E and NE is correlative from the result,which means whether the patient belongs to Group E or NE, there is a similar final result and both of them would get almost equal length and lengthening rate is nearly the same. Even so, deformity is still avoided in the surgery and it is proved that there's a potential risk after surgery. Although the case is rare, doctors need to take it into account.

	Group E	Group NE	p value
Number of cases	8	94	
Tibial osteomyelitis	6	51	
Comminuted lower leg fracture	2	36	
Congenital psudoarthrosis of the tibia		6	
Benign tibial tumor		1	
Final gain in length(mm)	15-80 (median 39.5)	7-110 (median 32.3)	0.4002
Lengthening rate(min/day)	0.2-1.9 (median 1.0)	0.1-1.9 (median 0.5)	0.5276
Final percentage gain of tibial length(%)	4.9-21.2 (median 113)	1.8-31.9 (median 9.2)	0.0625

Fig9.Ilizarov deformity assessment[16]

Future promotion

And then, the conclusion is, ilizarov method is an alternative choice to amputation, it is an effective treatment for both adults and children and it can treat multiple disease such as tumor, peripheral vascular disease. Meanwhile it lengthen limb and reconstruct large bone, build muscle strength and prevent joint stiffness. However, undeniable that, the progress of this surgery is hugely complicated, which means it needs a high quality surgeons teams so that the surgery can operate successfully because of a great sort of expertise to perform. Moreover, a large amount of time would be spent to reach the necessary training criterion means there are few doctors suitably trained to perform this technique, so it is hard to popularize to primary hospitals. Meanwhile, it needs long time to follow up, not only for recording the residual limb length gained, but also because of nursing care. Patients need to wear the frame for long time, so the treatment progress is slow and painful. Besides, the pin site may get infection, which leads to multiple surgeries to adjustment.

Therefore, considering these side effect, the promotion we think of is divided into 5 parts. Firstly, the bone transport, in most cases, the efficiency is a bit little low, so the bilateral bone transport may be considered in the future. Meanwhile, some new disinfectant would solve the problem of pin site infection. Besides, some authors came out a technology called accordion (He Guoyu et al.,2020)[9], which may bring the new life for Ilizarov. This technology may treat the delayed union of tibial fracture and large bone defect. Meanwhile, the new ring frame structure designing may relieve the suffering of patients so that they don't have to tolerance the pain of weight training. Moreover, for the new generation of CT and MRI instruments, with the resolution is getting higher and higher, the image processing will get more and more effective and advanced. Hence, although so many things need to concern, but the prospect is wonderful. We believe that there will be an increasing number of patients benefiting from this method.

Reference

[1]Ilizarov G A . The tension-stress effect on the genesis and growth of tissues: Part II. The influence of the rate and frequency of distraction.[J]. Clin Orthop Relat Res, 1989, 238(239):263-285.

[2]Young N L , Davis R J , Bell D F , et al. Electromyographic and Nerve Conduction Changes After Tibial Lengthening by the Ilizarov Method[J]. J Pediatric Orthop, 1993, 13(4):473.

[3]Robert Rozbruch S , Weitzman A M , Tracey Watson J , et al. Simultaneous treatment of tibial bone and soft-tissue defects with the Ilizarov method.[J]. Journal of Orthopaedic Trauma, 2006, 20(3):197-205..

[4]Li J , Li H , Shi L , et al. A mathematical model for simulating the bone remodeling process under mechanical stimulus[J]. Dental Materials, 2007, 23(9):1073-1078.

[5] Qin Sihe, Li Gang. Progress in the application of Lizarov technology in orthopedics [M]Beijing: People's Military Medical

Publishing House,2014:33.
[6] Wang Peng-hua, CHU Yu-jie, DING Min, XU Jun, Chang Bai, ZHANG Shi-ming, WANG Jia-chi, REN Hui-zhu, YU Demin.Clinical characteristics and analysis of 7 cases of diabetic charcot joint disease [J]. Chinese Journal of Diabetes,2007(04):204-206.
[7] Zgonis T, Stapleton JJ, Jeffries LC, Girard-Powell VA,Foster LJ. Surgical treatment of Charcot neuropathy.AORN J. 2008
[8] Lee Daniel K,Duong Elizabeth Thu Anh,Chang Douglas G. The Ilizarov method of external fixation: current intraoperative concepts[J]. AORN journal,2010,91(3).
[9] He Guoyu, ZHANG Yonghong, WANG Dong. Advantages and improvement strategies of Ilizarov technique in the treatment of tibia defect [J]. Tissue engineering research in China, 2020, 24(24):3870-3876.
[10]Kong, L. D., Cheng, H. X., & Nie, T.Treat the congenital pseudarthrosis of the Tibia with Ilizarov technology: Case report. Medicine, 2018,97(49), e13384.
[11]Catagni MA, Ottaviani G, Maggioni. Treatment strategies for complex fractures of the tibial plateau with external circulat fixation and limited internal fixation. J Trauma.2007;63(5):1043-1053;
[12]Mekhail AO, Abeaham E, Gruber B, Gonzalez M. Bone transport in the management of posttraumatic bone defects in the lower extremity. J Trauma,2004;56(2):368-378;
[13]LaBianco GJ,Vito GR, Kalish SR. Use of the Ilizarov external fixator in the treatment of lower extremity deformities, J Am Podiatr Med Assoc.1996;86(11):523-531;
[14]Sen C, Kocaoglu M, Eralp L, Cinar M. Correction of ankle and hindfoot deformities by supramalleolar osteotomy. Foot Ankle Int.2003;24(1):22-28;
[15]Aaron Lam, BA·Glenn Garrison, CPO·S. Robert Rozbruch, MD. Lengthening of Tibia after Trans-Tibial Amputation: Use of a Weight Bearing External Fixator-Prosthesis Composite. HSSJ.2016;12:82-90;
[16]Yoshino Akira, Takao Masato, Innami, Ken, Matsushita, Takashi. Equinus deformity during tibial lengthening with ankle orthoses for equalization of leg-length discrepancies. Journal of orthopaedic science: official journal of the Japanese Orthopaedic Association.2011;16(6):756-759;