Comparison of Treatment Time Index for Management of Bone Defects between Distraction Osteogenesis and External Fixator with Cancellous Bone Graft

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Objective: *To compare the durations of treatment in management of bone defects between distraction osteogenesis and external fixator with cancellous bone graft.*
Method: *This retrospective study was conducted from October 2000 to August 2010. There were 32 cases of bone loss at the femur and tibia. They were divided into 2 groups: group 1 (15 patients were treated using distraction osteogenesis) and group 2 (17 patients were treated using an external fixator with cancellous bone graft). Both groups were compared based on the duration of treatment and clinical results.*
Results: *The first group, which was treated with the distraction osteogenesis method, had a duration of treatment of 33.99 days per 1cm of bone defect. The second group, which underwent an external fixator along with a cancellous bone graft, had a duration of treatment of 77.75 days per 1cm of bone defect.*
Conclusion: *Distraction osteogenesis method had a shorter duration of treatment than the external fixator with bone graft method in managing bone defects.*

Keywords: *bone defect, distraction osteogenesis, external fixator, cancellous bone graft*

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In cases of a severe injury or infection, excess bone loss can occur in the femur and tibia. Management of bony defects is a challenge for orthopedic surgeons. If bone loss is more than 3cm, the treatment becomes much more complicated. These problems have usually been treated by a series of different surgical treatments:

1. *Sequestrectomies, Debridement, and Massive Cancellous Bone Graft* – Maintains stability with the external fixator. These techniques are often unsuccessful because the infection is difficult to eradicate due to poor vascularization of the bone. In addition, the bone graft interface area may be nonunion, graft fracture[1], and there may be morbidity at the donor site from massive cancellous bone graft.

2. *Distraction Osteogenesis* – Extensive removal of all infectious tissue and application of a monolateral system bone lengthening instrument. Bone transportation is started about 1 week after corticotomy and the formation of new bone by intramembranous ossification[2].

3. *Free Vascularized Osseous Transfer* – This method requires microsurgery techniques and instruments. Contralateral fibula was commonly used. After surgery, external support was often required for a long time. The stress fracture or non union sometimes occurred at the bone graft interface[3].

The first and second methods are used in rural hospitals because of microsurgery limitations. These two methods are not complex, but healing time is prolonged with unclear treatment results. Most patients participating in the study are workers or family leaders, making it important for them to get back to work quickly, so surgeons should be choose a treatment method to reduce healing time as much as possible.

This study aimed to compare the duration of treatment in management of bone defects between distraction osteogenesis and external fixator with cancellous bone graft technique.

Material and method

A retrospective study was conducted in Damneonsaduak Hospital from October 2000 to August 2010. Patients who had bone defects >3cm from open fracture, osteomyelitis or infected nonunion of tibia or femur were included. Additional data was taken from an old study from 2000 to 2008[4]. Both groups had the same exclusion criteria: aged more than 60 years, diabetic mellitus, steroid used, multiple injuries, abnormal renal function, cardiovascular disease, and psychological problems.

This study consisted of 32 patients with bone defect more than 3cm and was divided into 2 groups.

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Group 1 – *Distraction Osteogenesis*

After extensive removal of all dead or infected tissues, a corticotomy was performed to create a segment of bone which was gradually transported by a monolateral system bone lengthening instrument (Wagner distractor). The bone gap at osteotomy site should be less than 2mm with anglulation less than 10-15°, and rotation less than 20-30°.

The skin around the pin was released if it was too stretched[5]. After one week, the patient started passive stretching exercises to prevent joint stiffness and muscle contracture. Distraction was started after the 7th day of osteotomy at the rate of 1mm/day. The patients were referred to physiotherapists for passive stretching exercise of the joint above and below to prevent joint stiffness and muscle contracture.

First radiograph of the involved extremity was made on the 7th day after distraction to document the site and adequacy of osteotomy. Then a radiograph was performed at the end of the second week. Regenerated new bone was seen in some, but not all patients. Distraction was performed at the same rate. The third radiograph was performed at the end of the third week. The rate of distraction was slowed down to 0.25 mm/12 hrs if there was no new bone regeneration. The fourth radiograph was performed at the end of the fourth week. The distraction gap was about 25mm, but in some cases it might be less than 25 mm because of resistance from muscle and soft tissue. The angulation was corrected at the same time as distraction.

The bone lengthening instrument was removed when the patient could ambulate without pain. Radiograph revealed good regeneration of new bone. Radiograph findings were a 2- to 3-mm thickening of the cortex and contained at least 3 cortices in the anteroposterior and lateral views or thickening of the cortex by more than 75% of the old cortex[6].

Group 2 – *External Fixator and Massive Cancellous Bone Graft*

External fixator (AO, Bangkok Unitrade) was used to maintain stability of the limb after multiple debridements to eradicate dead and infected tissue. Cancellous bone graft was harvested from the iliac crest to fill the bone defect. Clinical examination was scheduled every 2-4 weeks. The patients started a range of motion exercises. The criteria to remove the external fixator were the same as those in group 1.

Demographic data were collected between groups based on the treatment time index. The treatment time index was defined as the total time in days necessary for corticalization of each centimeter of the newly formed bone.

The results of each group were evaluated according to association for the study and application of the method of Ilizarov (ASAMI)[7]. as shown in Tables 1 and 2.

Table 1. Bony Results Criteria

Grade	Criteria
Excellent	Union, No Infection, Deformity <7°, Limb Length Discrepancy <2.5cm
Good	Union + any two of the following: absence of infection, <7° deformity and limb length discrepancy <2.5cm
Fair	Union + one of the following: absence of infection,<7° deformity and limb length, discrepancy <2.5cm
Poor	Non union/re-fracture/+infection+ deformity >7° + limb length discrepancy >2.5cm

Table 2. Functional Results Criteria

Grade	Criteria
Excellent	1. Active 2. No limp 3. Minimum stiffness (knee loss<70° flexion, <15° extension, hip loss <50% motion in comparison with the normal side) 4. No reflex sympathetic dystrophy 5. Insignificant pain
Good	Active with three or four of other criteria
Fair	Active with one or two of other criteria
Poor	Inactive (unemployed or unable to perform daily activities)

Statistical analysis

The data analysis was calculated using SPSS program and was divided into 2 groups according to their criteria. Independent t-test was used to compare the results between groups, and a p value less than 0.05 was considered statistically significant.

Results

The mean age of all patients in group 1 (distraction osteogenesis) was 26.73±10.7 years. Diagnoses were open fracture 46.70%, osteomyelitis 33.33%, and infected nonunion 20.00%. The locations were tibia in 73.33% of cases and femur in 26.07% of cases.

The mean age of all patients in group 2 (external fixator and cancellous bone graft) was 28.88±10.27 years. Diagnoses were open fracture 52.94%, osteomyelitis 29.41% and infected

nonunion 17.65%. Locations were 70.59% tibia and 29.40% femur.

Demographic data are shown in Table 3. There was no statistically significant difference between the two groups.

Patient details from each group are shown in Tables 4 and 5. Group 1 had treatment time index 35.99 days/cm, and group 2 had treatment time index 77.75 days/cm. Mean bone defect of group 1 was 5.20 cm with corrected bone defect 4.73 cm (90.96%), and mean defect of group 2 was 3.73cm with corrected bone defect 3.08 cm (82.57%).

Table 3. Demographics of Patient Sample

Variables	Group 1 Distraction Osteogenesis (N = 15)	Group 2 External Fixator and Bone Graft (N = 17)
Age (year), (mean±SD)	26.73±10.7	28.88±10.27
Gender:		
Male (%)	66.67	70.59
Female (%)	33.33	29.41
Diagnosis:		
Open Fracture (%)	46.67	52.94
Infected Nonunion (%)	20	17.65
Ostemyelitis (%)	33.33	29.41
Location:		
Femur (%)	26.67	29.41
Tibia (%)	73.3	70.59

Table 4. Distraction Osteogenesis Results

Patient Number	Bone Defect (cm)	Corrected Defect (cm)	Residual Shortening (cm)	Treatment Time (days)	Treatment time index (day/cm)
1	7.0	7.0	0.0	208	29.72
2	6.0	5.0	1.0	192	38.40
3	4.0	3.0	1.0	131	43.67
4	6.0	4.5	1.5	317	70.45
5	8.0	7.0	1.0	244	34.86
6	5.0	5.0	0.0	100	20.00
7	5.0	5.0	0.0	155	31.00
8	5.0	4.5	0.5	173	38.44
9	4.0	4.0	0.0	136	34.00
10	3.0	3.0	0.0	140	46.67
11	4.0	4.0	0.0	180	45.00
12	5.0	4.0	1.0	172	43.00
13	4.0	4.0	0.0	164	41.00
14	6.0	6.0	0.0	213	35.50
15	6.0	5.0	1.0	195	39.00
Mean	**5.2**	**4.73**	**0.5**	**181.3**	**39.4**

Table 5. External Fixator and Bone Graft Results

Patient Number	Bone Defect (cm)	Corrected Defect (cm)	Residual Shortening (cm)	Treatment Time (days)	Treatment time index (day/cm)
1	4.0	3.0	1.0	190.0	63.33
2	4.0	3.0	1.0	255.0	85.00
3	3.0	2.0	1.0	219.0	109.50
4	4.0	2.5	1.5	312.0	124.80
5	4.0	2.0	2.0	186.0	93.00
6	3.0	3.0	0.0	171.0	57.00
7	4.0	3.0	1.0	320.0	106.67
8	5.0	4.0	1.0	283.0	70.75
9	3.0	3.0	0.0	216.0	72.00
10	3.5	3.0	0.5	196.0	65.33
11	4.5	4.0	0.5	241.0	60.25
12	3.0	3.0	0.0	246.0	82.00
13	3.0	3.0	0.0	208.0	69.33
14	3.5	3.5	0.0	188.0	53.71
15	4.0	3.0	1.0	237.0	79.00
16	4.5	4.5	0	203	45.11
17	3.5	3	0.5	261	87.00
Mean	**3.74**	**3.09**	**0.65**	**231.3**	**77.75**

Table 6. Statistical Analysis in Treatment Time Index

Treatment Time Index (day/cm)	Mean	SD	t	P-value
Group 1	39.38	10.99	-6.262	< 0.001
Group 2	77.87	21.42		

Table 6. shows that the treatment time index of group 1 was significantly shorter than that of group 2.

According to the distraction osteogenesis method, bony results were excellent and good in 8 out of 15 patients (53.33%). The functional results were excellent and good in 7 out of 15 patients (46.67%) as shown in Table 7. The external fixator and bone graft method showed excellent and good bony results in 7 out of 17 patients (41.17%). The functional results were excellent and good in 5 out of 17 patients (29.41%) (Table 8). Each group showed non-significant difference by Chi-Square tests ($P<0.05$).

Table 7. Results According to the ASAMI Criteria (case/%) in Group 1 (Distraction Osteogenesis)

	Excellent	Good	Fair	Poor
Bone	4(26.67)	4(26.67)	5(33.33)	2 (13.33)
Functional	3(20.00)	4(26.67)	6(40.00)	2 (13.33)

Table 8. Results According to the ASAMI Criteria (case/%) in Group 2 (External Fixator and Bone Graft)

	Excellent	Good	Fair	Poor
Bone	1(5.88)	6(35.29)	9(52.94)	1(5.88)
Functional	1(5.88)	4(23.53)	10(58.83)	2(11.76)

Discussion

This study collected data over a period of 10 years and included data about additional patients from a previous study. There were a limited number of patients who met the study criteria because each patient required extended treatment. Four out of 36 patients denied treatment because the external fixator and bone lengthening instrument are bulky and uncomfortable, while others avoided treatment due to superstitions and eventually required amputation. The distraction osteogenesis method reduced the healing time, and thus can aid in patient's compliance and reduce the duration and cost of treatment. I propose that the distraction osteogenesis method should be performed earlier when the bone defect is less than 3cm.

Bone defect treatment by distraction osteogenesis took less time because an external fixator with debridement procedure must wait until infection is gone before a bone graft can be done.

This study used a monolateral system for distraction osteogenesis. Most problems were solved, but some patients required correction of deformities in more than one plane. This problem resulted in either deformity or limitation of motion. Future studies may use a tension wiring system such as an Ilizarov ring fixator. It can correct angulation in multiple planes and can attach to thin bones, small bones, and the juxta articular area.

A follow-up study should include techniques to reduce the distraction phase by double corticotomy sites and distraction at the same time.

The consolidation phase used more time than the distraction phase. It used about 2/3 of treatment time. Future studies should use recombinant human morphogenic protein-7 to fill in bone defects. It can increase the ossification rate and bone mineral density[8] or direct electrical stimulation bone mineral density[9].

Some patients did not like the bulky shape of the bone lengthening instrument and the long treatment time. Interlocking nails may be used to combine with the bone lengthening instrument at the same time which would allow the bone lengthening instrument to be removed at the end of the distraction phase instead of the consolidation phase[10,11].

Some patients in group 1 (distraction osteogenesis) needed a small amount of bone graft at the docking site to increase bone union. The duration of treatment may be reduced by inserting a bone graft at docking site earlier[12]. or the acute compression and lengthening technique[13] can be used to avoid secondary operation at the docking site.

Conclusion

Distraction osteogenesis reduced the duration of treatment compared to using the external fixator with bone graft method in the management of bone defect. Both methods had bony and functional result indifference.

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การศึกษาเปรียบเทียบระยะเวลาที่ใช้รักษาเนื้อกระดูกที่หายไป โดยวิธี distraction osteogenesis เปรียบเทียบกับการใช้ external fixator and cancellous bone graft

วันชัย จารุสมบัติ, พบ.

วัตถุประสงค์: เพื่อศึกษาเปรียบเทียบระยะเวลาที่ใช้รักษาผู้ป่วยที่เกิดภาวะสูญเสียเนื้อกระดูกไปโดยวิธีการ distraction osteogenesis และการใช้ external fixator ร่วมกับการผ่าตัดทำความสะอาดแผล จนไม่มีภาวะติดเชื้อ และเนื้อเยื่อโดยรอบดีแล้วจึงใช้ cancellous bone graft ใส่เข้าไปในบริเวณที่มีการสูญเสียเนื้อกระดูก

วัสดุและวิธีการ: ศึกษาย้อนหลังในคนไข้ ที่มีภาวะสูญเสียเนื้อกระดูก ที่กระดูก femur และ tibia ตั้งแต่ ตุลาคม 2543 ถึง สิงหาคม 2553 โดยแบ่งเป็น 2 กลุ่ม กลุ่มแรกรักษาโดย distraction osteogenesis มีผู้ป่วย 15 ราย และกลุ่มที่สองรักษาโดย external fixator and cancellous bone graft มีผู้ป่วย 17 ราย เปรียบเทียบระยะเวลาที่ใช้รักษาต่อปริมาณของกระดูกที่สูญเสียไป วัดเป็นวันต่อเซนติเมตร

ผลการศึกษา: กลุ่มที่ใช้วิธี distraction osteogenesis ใช้เวลาในการรักษาเฉลี่ย 35.99 วันต่อเซนติเมตร กลุ่มที่ใช้วิธี external fixator ร่วมกับ cancellous bone graft ใช้เวลา 77.75 วันต่อเซนติเมตร โดยมีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ

สรุป: ระยะเวลาที่ใช้รักษาส่วนของเนื้อกระดูกที่หายไปโดยวิธี distraction osteogenesis ใช้เวลาน้อยกว่าวิธีเดิมที่ใช้ external fixator ร่วมกับทำความสะอาดแผลทำแผล กำจัดภาวะติดเชื้อให้หมดไปก่อนแล้วตามด้วย cancellous bone graft