Plate Fixation Technique for Reducing Osteoarticular Allograft Fracture: A Preliminary Report

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Background: *Osteoarticular allograft is now commonly used as a reconstructive biomaterial to replace bone defect following removal of aggressive bone tumors and for revision of failed arthroplasty. Good long-term clinical result of allograft replacement has been demonstrated. However, the rate of complications is high, including deep infection, allograft fracture, delayed union or non-union, and joint instability. Prevalence of allograft fracture ranges from 12 - 54 percent. Many studies recommend avoiding plate and screw fixation, or they advise the use of a modified screw fixation technique that minimizes the number of screws and changes screw alignment.*

Objective: *The objective of this study was to compare the efficacy of the conventional technique with a new method of plate and screw fixation in osteochondral allograft following removal of aggressive bone tumors.*

Material and Method: *From September 1988 to February 2015, 52 patients with primary aggressive benign or malignant bone tumor underwent massive bone allograft reconstruction. There were 25 males and 27 females with a mean age of 27-years. Giant cell tumor and osteosarcoma comprised most of the diagnoses. Thirty-five of the tumors were located around the knee. Average length of allograft was 12.9 cm. Twenty-nine patients were reconstructed using standard technique and 23 patients were fixed using only one dynamic compression plate with limited and 15-degree divergent-angle screw fixation at the allograft.*

Results: *Mean follow-up time in the group treated by conventional fixation was 84.5 months. There were 13 fractures (44.8%) in the conventional fixation group, with a median time to graft fracture of 4.9 months. The 23 patients with new technique fixation were followed-up for a mean duration of 60.5 months. Six fractures (26.1%) occurred in this group, with a median time to graft fracture of 10.40 months. Differences between groups for incidence of allograft fracture and median time to fracture were not statistically significant (p = 0.163 and p = 0.244, respectively). Most patients with allograft fracture were treated surgically using autogenous bone grafting and revision of internal fixation.*

Conclusion: *The new method of osteochondral allograft fixation using single plate, fewer screws, and divergent screw fixation yielded a lower fracture rate and a longer median time to fracture than the conventional method; however the differences between groups did not achieve statistical significance. The results of this preliminary study should be confirmed in a larger group of allografts over a longer follow-up period.*

Keywords: *Allograft, Tumors, Giant cell tumors, Osteosarcoma, Fracture, Osteoarticular allograft fracture, Plate fixation*

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Osteoarticular allograft is now commonly used as a reconstructive biomaterial to replace bone defect following removal of aggressive bone tumors and for revision of failed arthroplasty. Good, long-term clinical results of allograft replacement in the management of bone tumors and salvage of failed arthroplasty has been demonstrated(1-6). In addition to use in adults, this reconstruction technique has also been used in children and adolescents with primary malignant bone tumors(7,8). The rate of complications is higher among patients who undergo limb salvage, as compared with those who have amputations. Most of the complications that follow allograft reconstruction are deep infection, allograft fracture, delayed union or non-union, and joint instability. In addition, articular fragmentation with secondary osteoarthritis and mal-alignment has been associated with osteoarticular allograft(4,5).

The reported prevalence of allograft fracture ranges from 12-54 percent(3-9). Berry et al classified patterns of allograft fracture into 3 types. Type I fractures consist of almost complete dissolution of the

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graft without infection or recurrence of the tumor. Type II fractures occur through the diaphysis of the graft. Type III fractures are condylar or subchondral fractures in osteoarticular grafts[10]. Host bone and graft junction non-union was found to be strongly associated with allograft fracture[4]. Some authors also reported that the rate of allograft fracture was significantly higher in patients who were young, treated by chemotherapy, and who had allograft fixation with a plate and screws[8,11]. Most of the allograft fractures occurred within 3 years following the operation[3,10]. Allograft fracture may require at least one corrective surgical intervention, with amputation sometimes necessary as a final treatment[8,9]. Many studies have recommended avoidance of plate and screw fixation, or advised the use of modified screw fixation technique by minimizing the number of screws and changing screw alignment[9,11,12]. The aim of this study was to report the preliminary results of both the conventional technique and a new technique of plate and screw fixation in osteochondral allograft following removal of aggressive bone tumors.

Material and Method

We retrospectively reviewed the medical records of 52 patients with primary aggressive benign and malignant bone tumors who underwent massive bone allograft reconstruction following wide resection at Siriraj Hospital during September 1988 to February 2015 study period. Only large fragments of fresh frozen osteoarticular allografts were included in this series. Allografts were procured and processed under sterile conditions and stored until needed at -70 degrees centigrade at the Bangkok Biomaterial Center, Department of Orthopedic Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University, according to the guidelines of the Asia Pacific Association of Tissue Banks (ASASTB)[13]. All grafts were sterilized by gamma radiation at a dose of 25 kGy. All tumors were excised using intra-articular technique. Allografts were measured using plain radiographs in the anteroposterior and lateral views to match within less than 15% of the length of the host bone. Patient records, radiographs, pathology, current oncologic status, and functional outcomes were retrospectively reviewed. Disease staging according to Enneking's classification was determined in all patients[14].

There were 25 males and 27 females with a mean age of 27 years (range: 10-61). Twenty-nine patients had giant cell tumor of the bone, 12 had osteosarcoma, 3 parosteal osteosarcoma, 2 malignant fibrous histiocytoma, 1 osteoblastoma, 1 adamantinoma, 1 desmoplastic fibroma, 1 well-differentiated osteosarcoma, 1 Ewing's sarcoma, and 1 mal-union. All giant cell tumors were benign grade 3. Of the 22 malignant tumors, 7 were in stage IB, 2 in stage IIA, and 13 in stage IIB. Tumor locations included 7 proximal humerus, 8 distal radius, 2 proximal femurs, 25 distal femurs, and 10 proximal tibias. All patients were treated with osteochondral allograft reconstruction following tumor removal. Patient demographic and clinical data are shown in Table 1. The average length of allografts was 12.9 cm (range: 4-28). The first 29 osteochondral allografts were reconstructed following tumor removal and were fixed to the host bone using a single or dual standard dynamic compression plate (DCP) (Synthes, Westchester, PA, USA) technique (at least 8 cortices/fragment in lower extremity and 6 cortices/fragment in upper extremity). The last 23 consecutive osteochondral allografts were fixed using only one dynamic compression plate. In these patients, a smaller number of screws was used and screws were canted in alternatingly divergent directions. At least 6 to 8 cortices were fixed with screws at the host fragment and 4 to 8 cortices were stabilized with screws at the allograft junction[15] (Fig. 1). No additional autogenous bone grafting was performed in either group.

Patients in both groups had similar postoperative rehabilitation programs. Patients with proximal humeral allograft reconstruction were kept in a sugar-tong splint with an abduction pillow for 4 weeks. During this period, active and passive motion of elbow, wrist, and hand was performed. After 4 to 8 weeks, the patient was allowed active, gentle passive motion and strengthening exercises of the shoulder joint until maximal range of motion was restored. Patients who had a distal radial reconstruction were immobilized in a U-slab for 4 weeks. A removable plastic splint was then worn for 4 to 8 weeks. Two Kirschner wire fixations at the distal radio-ulnar joint were removed at 6 weeks, postoperatively. Active and gentle passive motion of forearm, wrist, and hand was then allowed to facilitate achievement of maximal range of motion. Patients with distal femoral or proximal tibial allograft reconstruction were immobilized in a long leg cast for 4-6 weeks, then active and gentle passive motion of the knee joint was initiated. All patients with reconstruction at the lower extremity were allowed to have progressive weight bearing until bridging callus was demonstrated on radiographs. Most patients required gait support for at least 6 months.

All patients were radiographically evaluated

Table 1. Demographic characteristics of the patients

Characteristics	Group 1 (n = 29)	Group 2 (n = 23)	*p*-value
Gender			
Male	16	9	0.250
Female	13	14	
Median age (years)	23 (12-61)	27 (10 - 47)	0.632
Tumor types			NA
GCT	16	13	
Osteosarcoma	8	4	
Parosteal osteosarcoma	1	2	
MFH	1	1	
Osteoblastoma	1	-	
Adamantinoma	-	1	
Desmoplastic fibroma	-	1	
Well-differentiated osteosarcoma	-	1	
Ewing's sarcoma	1	-	
Malunion	1	-	
Site			NA
Proximal humerus	6	2	
Distal radius	3	5	
Proximal femur	1	-	
Distal femur	15	10	
Proximal tibia	4	6	
Mean length (cms)	13.61	11.78	0.169
Fracture allograft	13 (44.8%)	6 (26.1%)	0.163
Median time of fracture (months)	4.9 (1.4-16.5)	10.4 (2.0-22.0)	0.244

GCT = giant cell tumor; MFH = malignant fibrous histiocytoma; cms = centimeters; NA = non-applicable

at all follow-up visits. Any complications or additional surgeries after the first reconstruction were recorded. Condition of allograft-host junction union or fracture of the allograft was demonstrated by plain radiograph at the last follow-up visit. SPSS Statistics version 18 (SPSS, Inc., Chicago, IL, USA) was used to perform Chi-square test, Mann-Whiney U test and Fisher's exact test for statistical analysis in both groups. Kaplan-Meier survival analysis was used to analyze time to allograft fracture in both techniques. A p-value <0.05 was regarded as statistically significant.

Results

The mean follow-up time in the conventional fixation group was 84.5 months (range: 7.1-306.2). The average time to allograft-host junction healing was 5.3 months (range: 3.2-6.2). Forty-five patients are continuously disease free, 4 died of disease, 1 continues to live with disease and 2 patients show no evidence of remaining disease. There were 13 fractures (44.8%) in the conventional fixation group. Three of those patients sustained allograft fracture as the result of a major accident. Two patients with proximal humeral allografts fell on the ground and landed on their shoulders and one patient with proximal tibial allograft fell down and landed on his knee. There were 10 allografts (34.5%) in this group without history of accident before graft fracture. All 10 patients had fracture at screw holes or at the end of the plate (Fig. 2). All fractures were classified as type II, according to Berry's allograft fracture classification[10]. Median time to all graft fractures was 4.9 months (range: 1.4-16.5). Three patients with distal femur and 1 with proximal humerus allograft fracture were union with conservative treatment. One patient with proximal tibia allograft fracture was waiting for prosthetic reconstruction. Four patients with allograft fracture (2 distal femur, 1 proximal humerus, 1 distal radius) were treated successfully using autogenous bone grafting and revision of internal fixation (Fig. 3). Two patients with proximal femur sustained allograft fracture at femoral neck level. Both patients underwent hemiarthroplasty. One patient with parosteal osteosarcoma developed local recurrence 15 months postoperatively and was performed

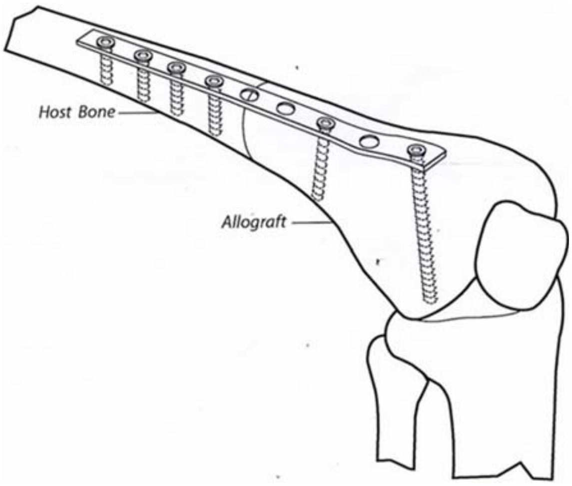

Fig. 1 A picture showing 15-degree divergent-angle screw fixation in the allograft. (Adapted by permission from Asavamongkolkul A. Fundamentals and complications of bone reconstructive surgery. In: Asavamongkolkul A, editor. Bone and soft-tissue tumors. Bangkok: PA. Living; 2013. P. 443).

Fig. 2 Lateral postoperative radiograph of a patient with distal femoral allograft reconstruction showing fracture along the screw holes (arrows).

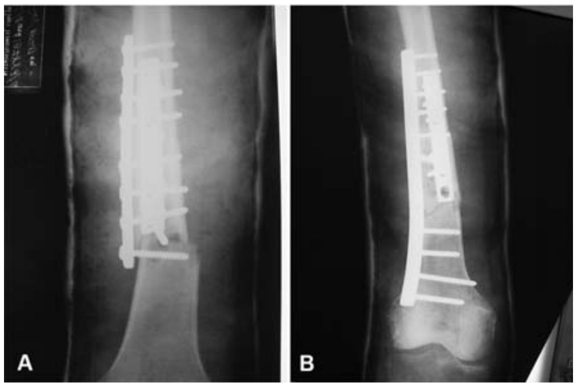

Fig. 3 Patient 2 with conventional plate fixation and allograft fracture. Anteroposterior radiograph of the knee showing fracture at distal part of plate fixation at 2.8 months, postoperatively (A); Postoperative plate revision with autogenous bone graft supplement showing good alignment of allograft fracture (B).

hemipelvectomy. Two patients with distal femur allograft fracture were revised with interlocking nail. Both of them had re-fractured and underwent arthrodesis (Table 2).

Mean follow-up for the 23 patients that were treated by the new fixation method was 60.5 months (range: 6-168.4). Average time to allograft-host junction healing was 4.3 months (range: 3-5) (Fig. 4). Six allograft fractures (26.1%) occurred in this group. All fractures were Berry allograft fracture classification type II. Median time to fracture in the new method group was 10.40 months (range: 2.0-22.0). Three patients were treated by revision of internal fixation and supplementation with autogenous bone grafting. One patient with distal radial allograft reconstruction underwent one-bone forearm arthrodesis with uneventful clinical outcome at 10 years following the surgery. Another 2 patients were immobilized by casting for 8 months and the fractures were completely healed (Table 2). Allograft fracture rates and median times to fracture were not significantly different between groups ($p = 0.163$ and $p = 0.244$, respectively) (Table 1). Patient allograft fracture data are summarized in Table 2. Kaplan-Meier survival analysis for 2-year allograft survivorship was 53% in the conventional fixation group and 70% in the new fixation group (Fig. 5). Log-rank test was used to compare survival between groups and the difference was not statistically significant ($p = 0.164$).

Discussion

Allograft fracture has been reported as a

Table 2. Patients with allograft fracture data summary

Patient	Age/ sex	Diagnosis/ grade[14]	Site of tumor	Type of allograft	Trauma (Y/N)	Time to fracture (month)	Treatment	Results	Comments
Group 1									
1.	29/M	GCT/3	Prox humerus	Osteoarticular	Y	16.5	Revision of plate and screws, bone graft	Healed	-
2.	34/M	GCT/3	Distal femur	Osteoarticular	N	2.8	Revision of plate and screws, bone graft	Healed	Local recurrence at 11 months, hip disarticulation
3.	18/F	OGS/IIB	Distal femur	Osteoarticular	N	3.3	Interlocking nail	Healed	-
4.	21/F	GCT/3	Distal radius	Osteoarticular	N	3.9	Revision of plate and screws, bone graft	Healed	-
5.	19/F	PAROGS/IB	Distal femur	Osteoarticular	N	1.4	Non-operative	Healed	-
6.	46/F	MFH/IIA	Prox femur	Osteoarticular	N	4.9	Hemiarthroplasty, revision of plate and screws, bone graft	Healed	Local recurrence at 15 months, hemipelvectomy
7.	26/M	GCT/3	Prox femur	Osteoarticular	N	10.3	Hemiarthroplasty	Healed	-
8.	13/M	OGS/IIB	Distal femur	Osteoarticular	N	5..4	Interlocking nail	Re-fracture	Arthrodesis
9.	33/F	Mal-union/NA	Distal femur	Osteoarticular	N	4.2	Non-operative	Healed	-
10.	26/M	GCT/3	Prox humerus	Osteoarticular	Y	9	Non-operative	Healed	-
11.	32/M	OGS/IIB	Prox tibia	Osteoarticular	Y	15.2	Non-operative	Non-union	Awaiting for tumor prosthesis reconstruction
12.	58/M	GCT/3	Distal femur	Osteoarticular	N	1.7	Interlocking nail	Re-fracture	Awaiting for arthrodesis
13.	25/F	GCT/3	Distal femur	Osteoarticular	N	8.5	Non-operative	Non-union	-
Group 2									
1.	27/F	GCT/3	Distal femur	Osteoarticular	N	17.1	Revision of angle blade plate and screws, bone graft	Healed	-
2.	41/M	GCT/3	Distal radius	Osteoarticular	N	9	One-bone forearm arthrodesis	Healed	
3.	36/M	GCT/3	Distal radius	Osteoarticular	N	7.3	Revised plate	Graft collapse	
4.	28/F	GCT/3	Distal femur	Osteoarticular	N	5	Non-operative	Healed	
5.	47/F	Desmoplastic fibroma/IB	Distal femur	Osteoarticular	N	22	Revision plate and screws, bone graft	Healed	
6.	22/F	PAROGS/IB	Distal femur	Osteoarticular	N	2	Non-operative	Healed	

M = Male; F = Female; GCT = Giant cell tumor; OGS = Osteogenic sarcoma; PAROGS = Parosteal osteogenic sarcoma; MFH = Malignant fibrous histiocytoma; Y = Yes; N = No; Prox = proximal

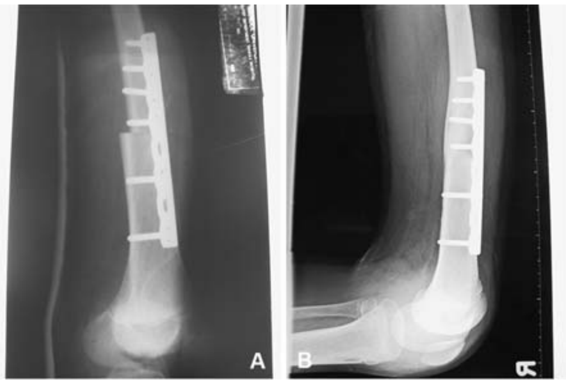

Fig. 4 Patient with distal femoral allograft reconstruction and new technique fixation following resection of well-differentiated osteosarcoma. Lateral radiograph after surgery (A); 20-month postoperative radiograph showing complete bone healing (B).

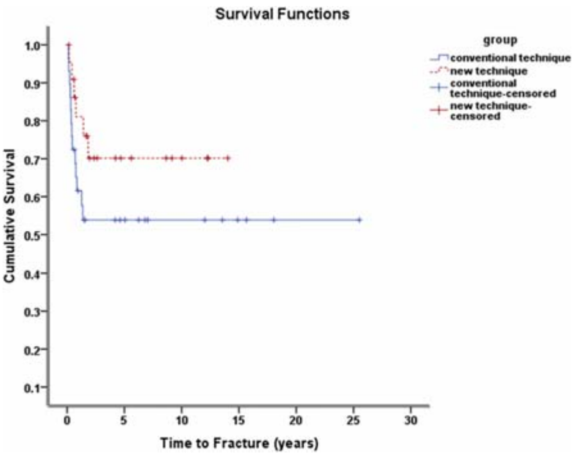

Fig. 5 Kaplan-Meier survival analysis for 2-year allograft survivorship in both groups.

common complication by several authors[4-8]. This study found a rate of allograft fracture in 29 patients who were treated with standard plate and screw fixation of 44.8% (13 patients). If the 3 patients who sustained fracture in a major accident were excluded and we evaluated only the 10 patients without history of accident, the rate of fracture would be reduced to 34.5 percent, which would be comparable to other reports[4,5]. All remaining fractures were classified as type II, according to Berry et al allograft fracture classification[10]. Most fracture lines passed through screw holes or were located at the end of the plate, which is the area that is susceptible to increased stress. Many authors reported fractures similar to the fractures found and described in this series[2,3,9-11,16]. However, the rate of fracture in this series was lower than the rates reported by Rodl et al and Alman et al because this series had a high proportion of benign giant cell tumor. These authors reported the results of massive allografts in children and adolescents who had high-grade malignant bone tumors and who were treated with chemotherapy[7,8]. Thompson et al found a significant association between graft fracture and patients who were receiving chemotherapy when internal fixation of the graft included devices that penetrated the cortices of the graft[11].

Quality of the bone allograft is another important factor that may affect the rate of fracture. The biomechanical strength and modulus of elasticity of the bone allograft is deteriorated by irradiation[17]. Although irradiation sterilization with doses of 10-30 kGy can increase the sterility of large bone allografts used in bone tumor surgery, this dose of irradiation can also produce a change in collagen type I crosslinks of the bone matrix. Lietman et al found a significant difference in the incidence of fracture between allografts that received high-dose irradiation and non-irradiated allografts[18]. In our series, grafts received from the Bangkok Biomaterial Center received an irradiation dose of 25 kGy, which may have affected the long-term stability of the grafts. This late instability effect combined with the revascularization process within the graft plays an important role in resorption, subchondral collapse and fracture.

Griend found a higher rate of allograft fracture in plate fixation than in intramedullary rod fixation[12]. Thompson et al recently revealed a strong correlation between allograft fracture and cortical penetration of the graft. Both of those studies found a higher incidence of fracture when tibial allografts were used[12,19]. Mankin et al found that host bone and graft junction nonunion was highly associated with allograft fracture[4]. However, other studies reported no significant difference in rate of union after fixation between these 2 fixation techniques[12,20]. Sorger et al reported the final results of their many allograft fracture experiences in a series of 1,046 allograft implantations[9]. Infection, non-union and longer grafts significantly worsened both fractures and outcomes. They suggested that a way to reduce the rate of allograft fracture is by minimizing the number of screws and by changing screw alignment. Gitelis et al and Aponte-Tinao et al suggested stabilization of the entire span of the allograft using metal[3,21]. They emphasized avoidance of positioning plates in sequence and leaving a gap between plates. They further recommended that metal not be removed after healing due to the stress risers in the allograft. In their series of 60 allograft reconstructions, only one fracture was found in the intercalary allograft of the proximal humerus (athletic injury)[21]. In this study and in our last 23 patients, we stabilized allografts using only one plate with fewer screws that were canted in alternating directions. The allograft fracture rate among patients treated with the new method was lower than the fracture rate among conventional method patients (26.1% and 44.8% respectively). However, the differences between groups were not statistically significant for either allograft fracture rate or time to fracture. Average time for bone healing at the bone-graft junction in the new treatment group was 4.3 months, which was faster than times reported in other studies. Griend reported an average host bone-graft junction healing time of 9 months (range: 5-18)[12].

Allograft fracture is not an uncommon complication and many factors contribute to a fracture outcome. Although most allografts were successfully salvaged, the fracture had a significantly negative effect on functional outcomes[9]. In this study, two allograft fixation techniques were compared to assess fracture rate and time to bone union. It should be noted and acknowledged that there is no ideal method for allograft fixation that guarantees bone union or that prevents late fractures. This study describes a new allograft fixation method that may yield a lower fracture rate than rates associated with conventional plate fixation. The results of this preliminary study should be confirmed in a larger group of allografts over a longer follow-up period.

What is already known this topic?

Using an osteoarticular allograft as a reconstructive biomaterial is one of the common alternative options to replace bone defect following removal of aggressive bone tumors. The rate of complication of limb salvage surgery especially in patients with osteochondral allograft is high.

What this study adds?

The prevalence of allograft fracture in limb salvage surgery is high. This study describes the new method of osteochondral allograft fixation using single plate, fewer screws, and divergent screw fixation yielded a lower fracture rate and a longer median time to fracture than the conventional method. Although the differences between groups did not achieve statistical significance, the results of this preliminary study should be confirmed in a larger group of allografts over a longer follow-up period.

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This was an unfunded study.

Potential conflicts of interest

None.

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เทคนิคการดามกระดูกปลูกถ่ายเอกพันธุ์ชนิด Osteochondral ด้วยแผ่นดามโลหะเพื่อลดการหักของกระดูก: การรายงานผลเบื้องต้น

อภิชาติ อัศวมงคลกุล, สารเนตร์ ไวคกุล

วัตถุประสงค์: *เพื่อศึกษาผลเบื้องต้นของเทคนิคการผ่าตัดโดยใช้โลหะแผ่นดามกระดูกในกระดูกปลูกถ่ายเอกพันธุ์ชนิด osteochondral ด้วยวิธีการลดจำนวนสกรูและเปลี่ยนทิศทางแนวยึดสกรูกับวิธีดั้งเดิม ในผู้ป่วยที่ต้องได้รับการบูรณะกระดูกภายหลังผ่าตัดเนื้องอกกระดูก เพื่อเปรียบเทียบอัตราการเกิดการหักของกระดูกปลูกถ่ายเอกพันธุ์ชนิด osteochondral ภายหลังการผ่าตัด*

วัสดุและวิธีการ: *เป็นการศึกษาย้อนหลังของผู้ป่วยจำนวน 52 ราย ที่ได้รับการผ่าตัดบูรณะกระดูกปลูกถ่ายเอกพันธุ์ osteochondral ภายหลังการผ่าตัดเนื้องอกกระดูกชนิดไม่ร้ายหรือมะเร็งกระดูกระหว่างปี พ.ศ. 2541-2558 ผู้ป่วยเป็นชาย 25 ราย หญิง 27 ราย มีอายุเฉลี่ย 27 ปี ผู้ป่วยส่วนใหญ่ได้รับการวินิจฉัยเป็น giant cell tumor และ osteosarcoma พบว่าเนื้องอกกระดูกมีตำแหน่งบริเวณหัวเข่า จำนวน 35 ราย กระดูกปลูกถ่ายเอกพันธุ์ที่ใช้บูรณะมีความยาวเฉลี่ย 12.9 ซม. ผู้ป่วย 29 ราย ได้รับการผ่าตัดดามโลหะด้วยวิธีดั้งเดิมผู้ป่วย 23 ราย ได้รับการผ่าตัดดามโลหะด้วยการลดจำนวนและเปลี่ยนแนวดามสกรูบริเวณกระดูกปลูกถ่ายเอกพันธุ์ ผู้นิพนธ์ใช้เครื่องมือ SPSS ในการคำนวณสถิติผู้ป่วยทั้ง 2 กลุ่ม โดยเปรียบเทียบความมีนัยสำคัญทางสถิติโดยใช้ค่า p-value <0.05*

ผลการศึกษา: *ผู้ป่วยกลุ่มที่ได้รับการดามโลหะด้วยวิธีดั้งเดิมมีระยะติดตามเฉลี่ย 84.5 เดือน พบกระดูกหัก 13 ราย (ร้อยละ 44.8) โดยมีระยะเวลามัธยฐานของการเกิดกระดูกหัก 4.9 เดือน ผู้ป่วยกลุ่มหลังมีระยะติดตามเฉลี่ย 60.5 เดือน พบกระดูกหัก 6 ราย (ร้อยละ 26.1) โดยมีระยะเวลามัธยฐานของการเกิดกระดูกหัก 10.40 เดือน เมื่อปรียบเทียบการเกิดกระดูกหักและเวลามัธยฐานของการเกิดกระดูกหักในผู้ป่วย 2 กลุ่ม พบว่าไม่มีความแตกต่างอย่างมีนัยสำคัญทางสถิติ (p-value = 0.163 และ 0.244) ผู้ป่วยที่มีกระดูกปลูกถ่ายเอกพันธุ์หักส่วนใหญ่จำเป็นต้องได้รับการผ่าตัดรักษาด้วยการปลูกกระดูกและดามโลหะใหม่*

สรุป: *การใช้เทคนิคการดามกระดูกปลูกถ่ายเอกพันธุ์ชนิด osteochondral โดยการลดจำนวนสกรูและเปลี่ยนทิศทางแนวการยึดสกรู มีแนวโน้มลดการเกิดกระดูกหักภายหลังการผ่าตัดได้มากกว่าการดามโลหะด้วยวิธีดั้งเดิม อย่างไรก็ตามการวิเคราะห์สถิติไม่มีความแตกต่างอย่างมีนัยสำคัญทางสถิติ ผลการศึกษาที่แน่ชัดจากการดามโลหะด้วยวิธีนี้สามารถยืนยันได้ดีขึ้นโดยมีผู้ป่วยจำนวนมากขึ้น และมีเวลาติดตามภายหลังการผ่าตัดที่นานขึ้น*