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Original Article

Clinical effect of three-dimensional printing assisted less invasive stabilization system (LISS) to treat femoral intercondylar fracture

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Abstract: *Objective:* The aim of this study was to investigate the clinical outcome of three-dimensional printing assisted less invasive stabilization system (LISS) to treat the femoral intercondylar fracture. *Methods:* A total of 62 patients with femoral intercondylar fractures from January 2015 to August 2015 were randomly divided into 3D printing group (n=31) and control group (n=31). All patients underwent surgical intervention, and preoperative X-ray and CT scan were examined regularly. Patients' CT data were saved as DICOM format in 3D printing group, and transferred into Mimics software to perform fracture reconstruction as well as fragment reduction. Fracture model was created by 3D printing. The implant fixation was established *in vitro*, meanwhile, the statistics of implants such as holes, lengths were recorded. Patients in control group underwent traditional treatment, and surgery time, intra-blood loss, fluoroscopy time, the length of hospital stay were collected. Postoperative knee function was evaluated by the Range of motion (ROM), Short Musculoskeletal Functional Assessment (SMFA) and Hospital for Special Surgery (HSS) score at 6 and 12 months of follow-up. *Results:* 3D printing group achieved shorter surgery time (61.25±14.28 min *vs*. 79.14±18.43 min), lower blood loss (81.74±23.50 mL *vs.* 106.80±22.75 mL), less intra-fluoroscopy (2.10±0.50 times *vs.* 4.10±0.70 times) and shorter LOS (8.45±1.20 d *vs*. 10.05±1.35 d) (P<0.05). Postoperative 6-month and 12-month function outcome with SFMA, ROM, and HSS showed no statistical significance. There were 1 failure in 3D printing group (3.2%) and 3 failures in control group (9.7%), and no infection case in both two groups. Conclusion: Three-dimensional printing assisted LISS to treat femoral intercondylar fracture obtained less trauma, more accurately fixation and satisfactory recovery when compare to traditional treatment. Such effective and feasible method deserved clinical promotion we had proved in our application.

Keywords: Three-dimensional printing, less invasive stabilization system, femoral intercondylar fracture, internal fixation, clinical outcome

Introduction

Femoral intercondylar fractures account for approximately 4%-6% in all body fractures, and such fractures used to appear mostly in young patients with high-energy trauma and osteoporosis in elderly [1]. With the increase of total knee arthroplasty (TKA), the incidence of postoperative periprosthetic femoral intercondylar fractures raised as well [2]. According to Orthopaedic Trauma Association classification system (AO/OTA) [3], femoral intercondylar fractures to be divided into 33. C1 (simple articular, simple metaphyseal), C2 (simple articular, multi-fragmentary metaphyseal), and C3 (multifragmentary). Anatomical reduction and fixation were the advocated for such fractures regardless of classification as preserve treatment may lead to traumatic arthritis and knee deformities.

It is important for surgeons to choose appropriate implant when conduct internal fixation. The less invasive stabilization system (LISS) had widely used in other areas of orthopaedic surgeries, and achieved a well outcome in femoral intercondylar fractures [4]. However, not all plates can match the specific bone structure,

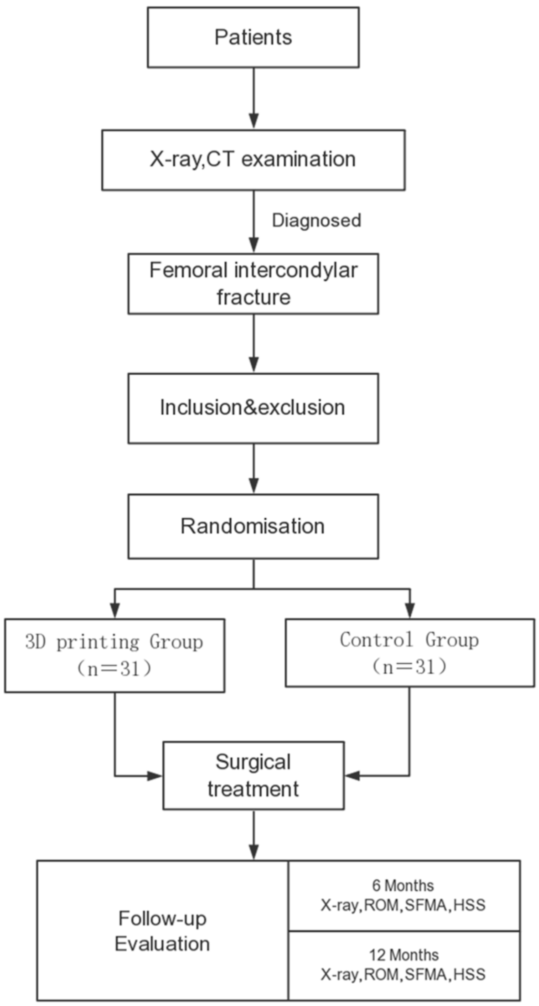

Figure 1. The route-way image of research.

Table 1. Demographic information comparison between two groups

	3D printing group	Control group	*P*
Cases	31	31	
Age	45.7 (24-67)	46.1 (22-68)	0.434
Gender			0.375
Male	16	14	
Female	15	17	
Injury mechanism			0.408
High-fall	8	7	
Traffic accident	15	16	
Crush injury	8	8	
AO classification			0.227
C1	7	8	
C2	16	16	
C3	8	7	

and with the expectation of patients and surgeons increasingly high, a more precisely and effectively surgery called "Personalized surgery" occurred. Meanwhile, digital medicine developed rapidly in recent years, three-dimensional printing technique had been used in personal surgery preoperative design and intraoperative guide [5, 6]. Moreover, there were fewer researches on clinical application of three-dimensional printing assisted in treating femoral intercondylar fractures.

The aim of our study was to investigate the clinical outcome of three-dimensional printing assisted less invasive stabilization system (LISS) to treat the femoral intercondylar fracture. We compared such new method with traditional treatment to explore whether LISS combined with personal preoperative planning could get a better outcome.

Materials and methods

Patients

Our study obtained approval by the Institutional Review Board (IRB) in our institution, and all patients provided their written informed consents to participate in this study (**Figure 1**). From January 2015 to August 2015, there were 84 cases of femoral intercondylar fractures treated in our hospital. The exclusion criteria were: 1) Age <18 years old, 2) Refused surgical treatment, 3) Open fractures, 4) Knee joint degeneration and injury previously, 5) Fractures above a total knee arthroplasty, 6) Pathologic fracture, 7) Combined with systemic autoimmune disease, severe circulation system disease and respiratory system disease, psychiatric patient.

Finally, there were 62 patients included in our research. They were randomly divided into 3D printing group (n=31) and control group (n=31). The demographic information showed in **Table 1**. The average age in 3D printing group was 45.7 years old (range 24-67 years old), and there were 16 males and 15 females. For mechanism of injury, high-fall injury met 8 cases, the traffic accident met 15 cases and crush-related injury met 8 cases. According to AO classification, there were 7 cases of C1 type, 16 cases of C2 type and 8 cases of C3 type. As for control group, the average age was

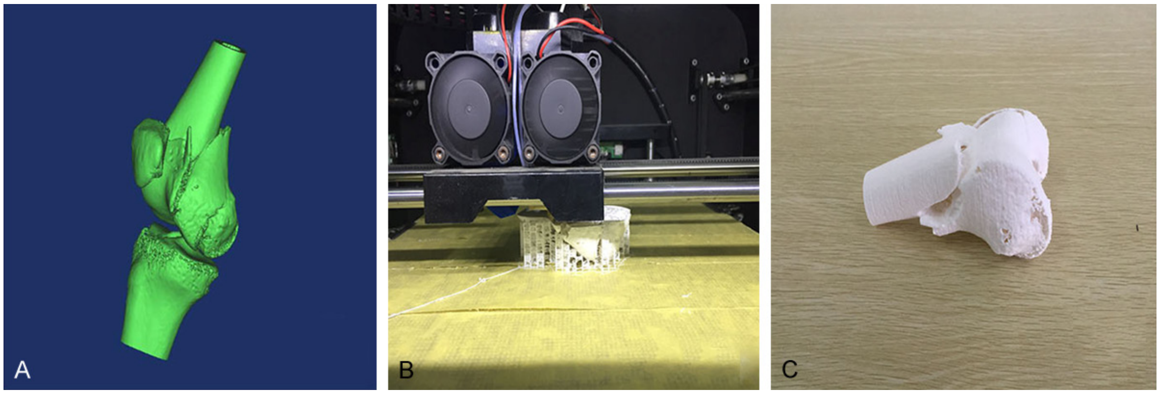

Figure 2. Three-dimensional printing process. A: Patient's CT data transferred to Mimics software to reconstruct fracture. B: 3D printing machine processing print fracture model. C: 3D printing fracture model.

46.1 years old (range 22-68 years old), and there were 14 males and 17 females. When analyzed trauma mechanism, we found 7 cases of high-fall injury, 16 cases of the traffic accident and 8 cases of crush-related injury. At the same time, there were 8 cases of C1 type, 16 cases of C2 type and 7 cases of C3 type. There was no significant difference between two groups in demographic information ($P>0.05$).

Preoperative preparation

All patients underwent biochemical examination, such as blood routine examination, blood coagulation function and so on. Radiological diagnosis as conventional anterior-posterior (AP) X-ray and computed tomography (CT) to evaluate the fracture displacement. Patients whose age above 55 years old should examine ultrasonic cardiogram (UCG), ultrasonic artery examination and pulmonary function test (PFT) in additional. Soft tissue swelling in patients was carried out tibial tubercle traction or calcaneus traction and other methods to reduce swelling. The surgery intervention started when relevant operation contraindication ruled out and soft tissue improved.

3D printing for simulated surgery in vitro

The CT data of patients in 3D printing group were saved as Digital Imaging and Communications in Medicine (DICOM) format. Then these statistics were transferred to Mimics 17.0 (Materialise Inc, Belgium) software to reconstruct the fracture model and reduction of the fragment (**Figure 2**). Afterward, the fracture models were printed by the 3D printer (SRP400B, Watson Inc, Changzhou, China). The fixation was done *in vitro*, and parameters of the implant (Length, holes, diameter) were recorded.

Surgical procedure

All patients used LISS (Depuy Synthes, Paoli, PA) for fracture fixation. A 5 to 10-cm lateral parapatellar or anterolateral approach was performed, the plate was inserted under the vastus lateralis muscle above the periosteum after fracture reduction completed. In 3D printing group, preoperative appropriately plate and screw were selected and inserted. In control group, the plate was chosen according to patient's fracture characteristic and screws were inserted to the depth measured. Incision sutured and drainage left after C-arm fluoroscopy examination confirmed well reduction and fixation.

Postoperative management

All patients routinely used antibiotics to prevent infection, and the drainage was removed after postoperative 24~48 h. Quadriceps exercise started on the second and third day after surgery. Flexion and extension function of knee exercise or used lower limbs CPM machine for joint passive exercise started on 1 week after surgery. Distal femoral AP X-ray examined on the postoperative 2~3 month to evaluate the fracture healing and decide weight bearing (**Figure 3**).

The surgery time, intra-blood loss, fluoroscopy time, length of hospital stay (LOS) were collected. Postoperative knee function evaluated by Range of motion (ROM), Short Musculoskeletal

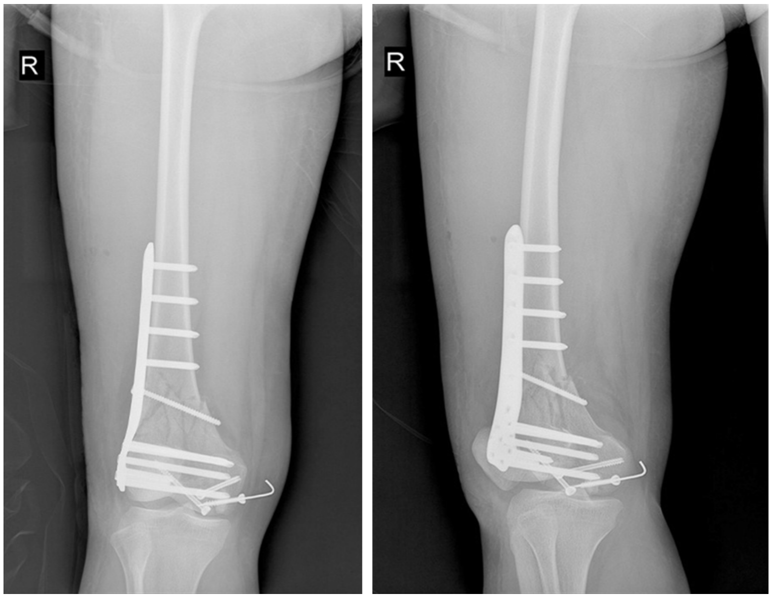

Figure 3. The postoperative distal femoral Anterior-Posterior (AP) X-ray view showed the fracture in well reduction and fixation.

Functional Assessment (SFMA) [7] score at 6 and 12 months of follow-up, and Hospital for Special Surgery (HSS) [8] scored at the last follow-up in postoperative 12 months. Any postoperative complications (as nonunion, malunion, infection and other) were recorded.

Statistics

All statistics were analyzed in SPSS 21.0 software (SPSS Inc, Chicago, USA). The Students *t*-test and the Fisher exact test were used to evaluating differences in demographic information, treatment information, and postoperative complication. Mean values were calculated for 6 and 12 months postoperative SFMA and ROM measurements. In HSS score, excellent defined as 80~100 score, good as 70~79, satisfactory as 60~69 and poor as above 59. The excellent and good rate defined as the percentage of cases from excellent and good in all patients. Significance was set at the $P<0.05$ level for all analyses.

Results

All patients obtained at least 12 months follow-up, at the average of 14.2 months (range 12-16 months). 3D printing group achieved shorter surgery time (61.25±14.28 min *vs.* 79.14±18.43 min), lower blood loss (81.74±23.50 mL *vs.* 106.80±22.75 mL), less intra-fluoroscopy (2.10±0.50 times vs. 4.10±0.70 times) and shorter LOS (8.45±1.20 d *vs.* 10.05±1.35 d). These categories showed significant differences among two groups ($P<0.05$, **Table 2**).

Postoperative 6-month and 12-month function outcome with SFMA showed no statistical significance ($P>0.05$, **Table 3**). As for HSS score, 3D printing group owed 18 excellent cases, 9 good cases, 4 satisfactory cases and none poor case. Control group owed 17 cases for excellent, 8 cases for good, 5 cases for satisfactory and 1 cases for poor (**Figure 4**). The excellent and good rate for 3D printing group was 87.1% while 80.6% in control group ($P>0.05$). When examined the range of motion, the mean ROM for 3D printing and control group were 109 degrees and 108 degrees, respectively, and showed no statistical difference.

Failure of treatment was defined as fixation failure or nonunion at 12 months. There was 1 failure in 3D printing group (3.2%) and 3 failures in control group (9.7%). They showed significant differences ($P<0.05$). The one failure patient in 3D printing group was nonunion (incomplete bridging of the cortex in 12-month follow-up), then treated with the removed prior implant, open reduction, bone graft and internal fixation. Two patients in control group had fixation failure and treated with the intramedullary nail. One patient met nonunion and treated as the same as 3D printing group. There were no infection cases in two groups.

Discussion

The operative intervention had become the standard treatment for femoral intercondylar fracture [9]. Despite common technique of intramedullary nail and open reduction internal fixation (ORIF), LISS had widely used in recent years because of reduction in soft tissue damage and preservation of periosteum blood supply [10]. Meanwhile, the self-drilling and self-tapping screws in LISS increase the contact

Table 2. Treatment information among two groups

Group	Surgery time (min)	Blood loss (mL)	Intra-fluoroscopy (time)	LOS (d)
3D printing group	61.25±14.28	81.74±23.50	2.10±0.50	8.45±1.20
Control group	79.14±18.43	106.80±22.75	4.10±0.70	10.05±1.35
t	1.525	1.421	2.128	2.374
P	<0.001	<0.001	<0.001	<0.001

Abbreviation: LOS: Length of hospital stay.

Table 3. Mean short musculoskeletal function assessment score of two groups

Function	6 months		12 months	
Assessment	3D printing group	Control group	3D printing group	Control group
Daily activity score	61.2	64.7	47.2	48.3
MMS	42.9	50.5	45.0	46.1
Arm and hand score	17.7	18.4	12.4	14.5
Mobility score	55.1	62.9	46.8	49.7
Functional index	43.2	48.1	37.2	39.1
Bothersome index	40.0	45.1	41.4	42.0
Average	43.3	48.2	38.3	39.9
P	0.529		0.836	

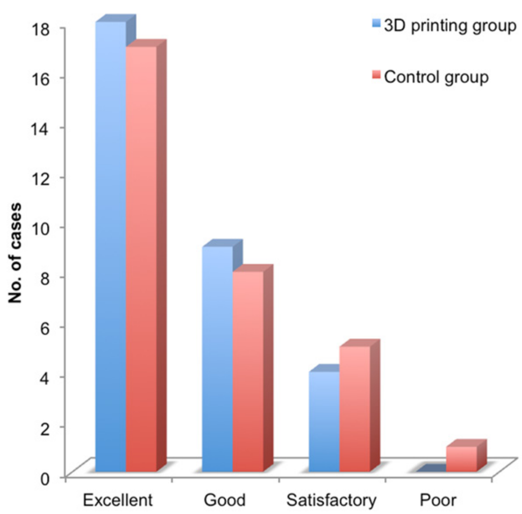

Figure 4. Postoperative Hospital for Special Surgery (HSS) score of two groups.

between bone and screws, thus obtained higher stability compared to conventional implant [11]. Whereas relative report had pointed that LISS still exist high rate of nonunion, and the comminution fracture is one of the risk factor [12]. In our study, the 3D printing group and control group owned 25.8% and 22.6% comminution fracture (AO 33-C3 type). As a result, there still exist a nonunion case in LISS combined 3D printing technique.

Three-dimensional printing got rapidly progress in orthopaedics field [13-17]. The fracture fragment reconstruction could display directly by such technique, and used for the preoperative plan. Also, patients make a well understand of their condition which benefits for communication between doctors and patients [18]. With the aid of 3D printing, surgery time and blood loss could be reduced for completed preoperative preparation and less intra-trauma in some prior studies [19, 20]. In our study, femoral intercondylar fracture treated with LISS combined 3D printing reduced approximately 22.6% surgery time and 23.5% intra-blood loss, respectively. We either found less intra-fluoroscopy time in 3D printing group, showed another advantage of less intra-X-ray exposure. When analyzed postoperative knee function outcome, there were no statistical differences in variation of observing indicator (SFMA, ROM, HSS) among two groups. We think such outcomes may due to small cases and short follow-up time.

There were some limitations in our study. Firstly, we failed to enhance the reliability of conclusion for enrolled small sample size; Secondly, the duration of three-dimensional printing technique may cost a lot of time, and could not perform in open fracture cases with emergency surgical treatment. For this, we excluded open fracture patients in our research.

In conclusion, three-dimensional printing assisted LISS to treat femoral intercondylar fracture obtained less trauma, more accurately fixation and satisfactory recovery when compare to traditional treatment. Such effective and feasible method deserved clinical promotion we had proved in our application. Obviously, these points of views need further larger sample size, a multi-central randomized controlled trail to confirm.

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Disclosure of conflict of interest

None.

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