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Effectiveness in the Treatment of Intertrochanteric Fracture in Geriatric Patients by A Novel Prototype Carbon Composite External Fixator

Quang-Tri Le

ABSTRACT

Background: Intertrochanteric fracture is a common injury in seniors. Senior patients taking surgical interventions suffer from prolonged bed-rest complications such as pressure ulcer, thromboembolism, or pneumonia, which may lead to high mortality rate. A treatment using external fixators is, therefore, recommendable, and has shown satisfactory outcomes such as early weight-bearing, short hospitalization time and quick union time. Fracture treatments in Vietnam mainly use metal and imported fixation, raising concerns of compatibility and financial issues from patients. **Objective:** This study investigated the *in vivo* effectiveness in treating an intertrochanteric fracture in Vietnamese geriatric patients by a novel prototype carbon composite external fixator (whose shaft screws near the fracture site) and an available stainless steel external fixator (shaft screw far from the fracture site) already used in Vietnam. **Methods:** Fifty-five patients treated with the metal fixator and 54 patients treated with the composite fixator – all aged 60 – 99 – were monitored for treatment results until one year after surgery. **Results:** The results demonstrated the external fixator's effectiveness, especially the composite prototype, which minimized blood loss, shortened operation time, reduced pain, and provided stable fixation that promoted proper bone union. **Conclusion:** The novel composite fixator prototype in this study was also superior to the current metal fixator in many aspects. Proper application of this method could prove its effectiveness in the surgical cure for fracture in older people. It should be a viable choice for intertrochanteric fracture treatment for senile people in Vietnam.

Keywords: Intertrochanteric fracture, geriatric patients, carbon composite, external fixator, metal fixator.

1. BACKGROUND

Intertrochanteric fracture is a common injury in geriatric people, account for approximately half of all hip fractures in the elderly population (1), especially postmenopausal women were especially susceptible to osteoporosis due to changes in estrogen level (2, 3). Early rehabilitation was crucial to prevent dangerous bed-rest complications including pressure ulcer, thromboembolism, or pneumonia, which may lead to high mortality rate especially for old people.

Works in intertrochanteric fractures, therefore, proposed internal stable bone fusion which causes less or less severe complications, guarantees early rehabilitation and reduce bed-rest complications (4, 5). Internal bone fusion devices and techniques have been used in Vietnam (6, 7), however they was performed mainly in large medical centers for young people or senior patients without internal diseases, had long operation, significant bleeding and surgical trauma, required specialized equipment such as C-Arm, and had risks of nail extrusion in osteoporotic senior patients (8). Moreover, fixation nails, screws and plates in Vietnam are imported rather than self-manufactured, hence material supply and compatibility is a major concern (9).

Other studies implemented external fixators (1, 10-14) to minimize blood loss, anesthetic risks, and operation length, and early weight-bearing, short hospitalization time and quick union time. In cases such as when surgical trauma presents a life threat (15), external fixator is considered a proper choice. In Vietnam there have been studies on metal external fixator (16-18)

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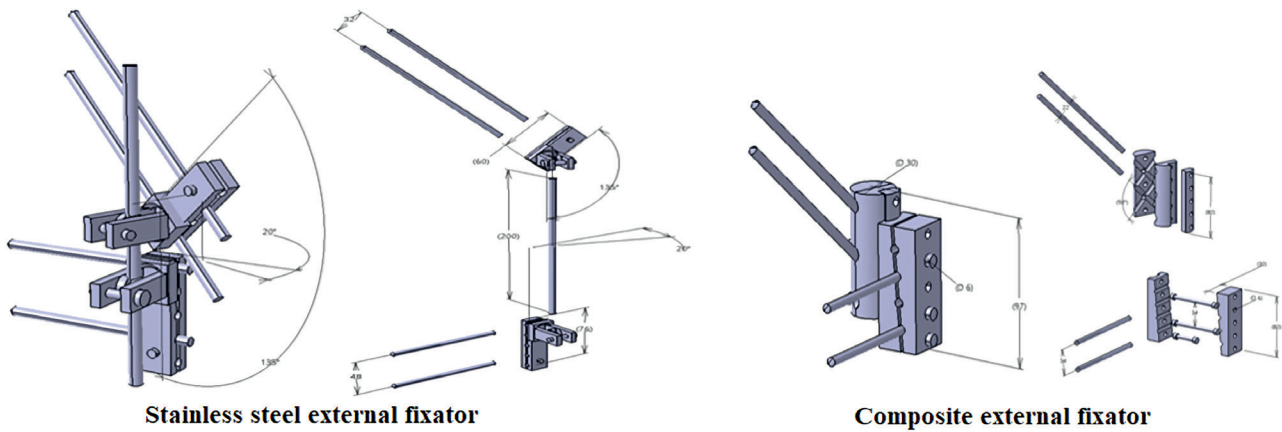


Figure 1. Designs of the stainless steel (left) and the studied composite external fixators (right).

whose initial results were encouraging. Moreover, domestically manufacture of external fixators is possible in developing countries with limited financial resources.

However, the weight and bulkiness of metal fixator necessitated the use of alternative materials, amongst which carbon composites is a potential candidate thanks to its advantageous weight, mechanical traits and biocompatibility. Le Quang and Nguyen-Tan (*Quang-Tri Le and Bao-An Nguyen- Tan, 202X, Designing External Fixator for Intertrochanteric Fracture Treatment Based on Vietnamese Femur Morphological Parameters submitting*) based on measurements of dried femurs had designed a carbon composite external fixator applied for Vietnamese patients which showed favorable traits in mechanical strengths. Therefore, our study would investigate the *in vivo* effectiveness of the composite fixator prototypes on geriatric patients, in comparison with the available metal fixator used in Vietnam.

2. OBJECTIVE

This study investigated the treatment effect of the designed composite fixator prototypes, in comparison with the available metal fixator used in Vietnam, on intertrochanteric fracture in old patients.

3. MATERIAL AND METHOD

3.1 Experiment Participants

The study was performed on 109 intertrochanteric patients. The participants were over 60 years and suffered from closed intertrochanteric fracture Ib – III type based on Jensen classification, ASA status class I – IV, prior ambulatory injury, still had full awareness, and shown good cooperation during the treatment. The student excluded the ASA class V and VII patients and refused to receive the studied treatment.

The participants were divided into two groups. The first groups included 55 patients treated at the Hospital for Traumatology and Orthopaedics (Ho Chi Minh City, Viet Nam) from June 2018 to December 2019 by a modified Hoffmann stainless steel external fixator (Hao Nam Company, Vietnam), whose surgical screws should be inserted into the femoral shaft, far from the fracture site and penetrated the vastus lateralis. The second group consisted of 54 patients treated at Quan Dan Mien Dong Hospital, Saigon Emergency Aid Hospital, and 7A Mil-



Figure 2. The patient posture.

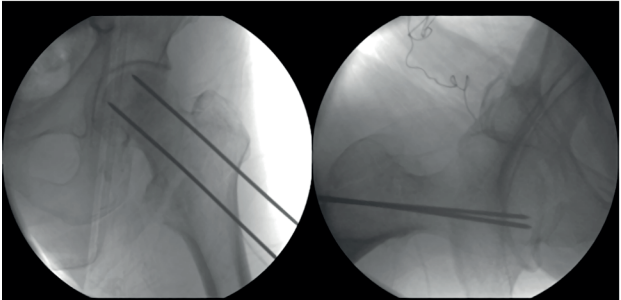


Figure 3. Inserting the directing K - nails.

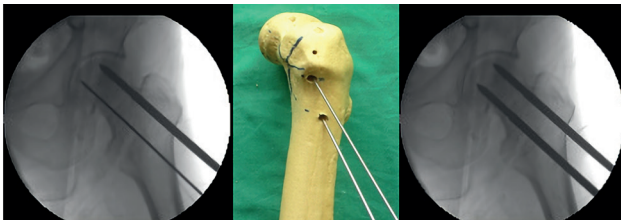


Figure 4. Drilling the holes.

itary Hospital ((Ho Chi Minh City, Viet Nam) from August 2018 to February 2020 by an Orthofix-styled composite external fixator manufactured in this study (by Hanoi New Material Company) whose surgical screws could be inserted very close to fracture site. (Figure 1)

3.2. Methods

The study followed a descriptive, prospective approach with vertical monitoring. Two types of external fixator were compared and evaluated. All the participant’s data, clinical history, medical history, treatment process and

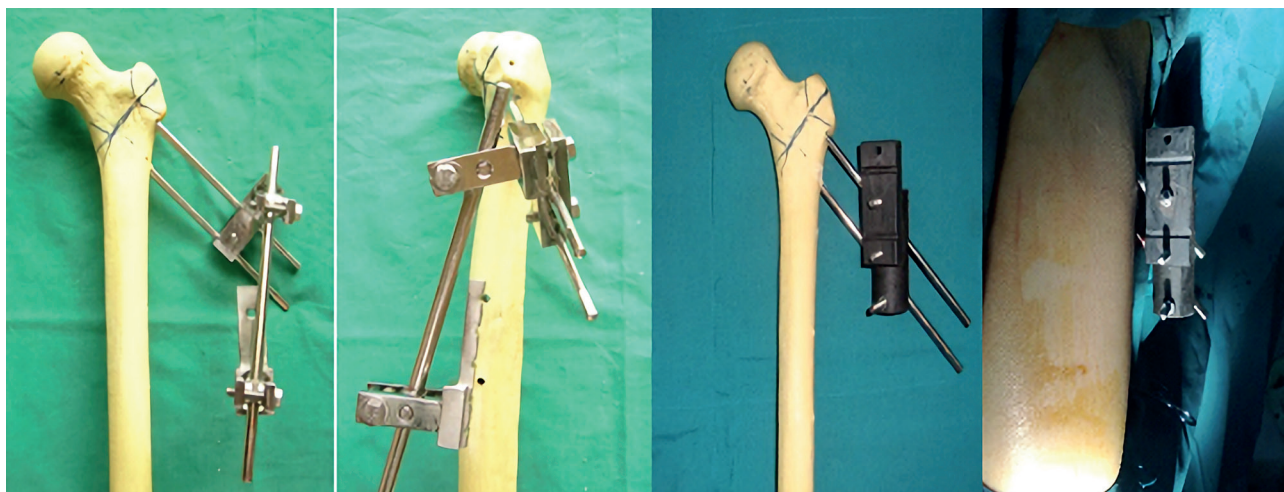


Figure 5. Assembling the fixator to the screws.

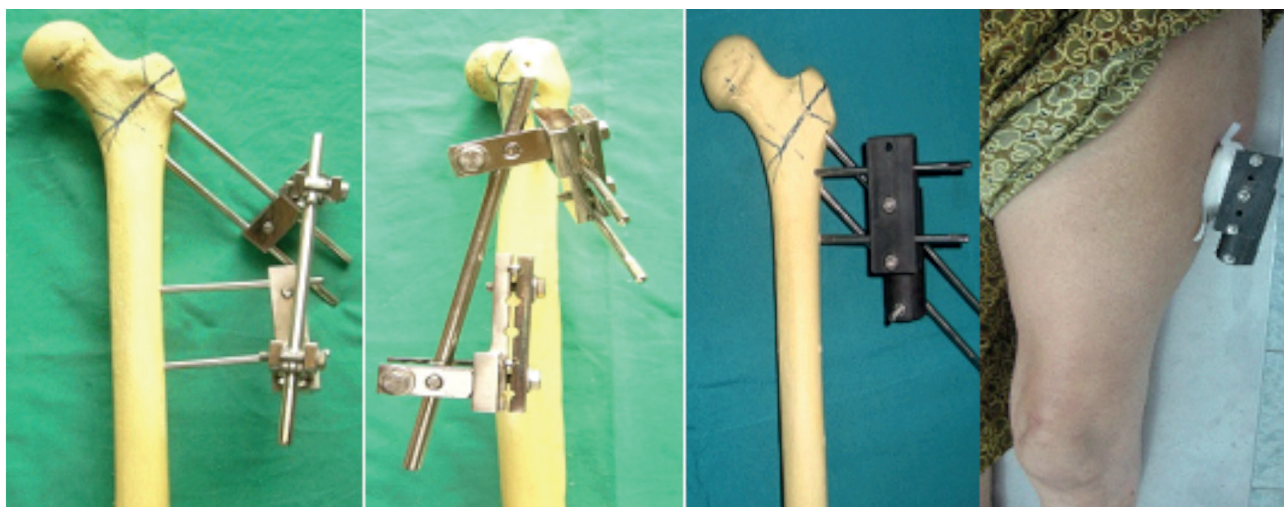


Figure 6. The wholly assembled external fixator.

monitored results were recorded in a pre-designed clinical form. The participants were monitored for one year.

Bone fusion treatment: the patient lied down in a supine position with the injured leg, was slightly abducted and medially rotated to provide adequate space for the C-Arm. The patient body and pelvic area were fixed into the surgical table (Figure 2). Fixed the injured limb at the fully pulled posture and re-checked the body posture. The axial deviation was revised. Based on anatomical landmarks (Schmoeker marks, Peter line, the midpoint of the groined arch, and the anteversion angle), inserted two 2.0 Kirschner nails to the femoral neck, one parallel to and 2.5mm apart from the neck superior surface, once penetrated through the calcar and 2.5mm apart from the femoral neck inferior surface (Figure 3). Made an incision 1cm apart from the nail insertion and dissected the skin to expose the bone. Drill the holes into the femur corresponding to the nail penetration and replaced the K – nails with the Schanz screws. The screws tips must be 10mm apart from the acetabular cartilage (Figure 4). Assembled the external fixator parts, excluding the posterior clamps into the screws (Figure 5). Inserted the remaining K-nails through the appropriate ditches on the fixator parts for making the second incision, bone exposure, and drilling of the other two holes on the femoral shaft (using the 3.5 bits with soft tissue

buffers) for their corresponding screws there. The shaft screws and nails were inserted at the middle third of the shaft for the metal fixator, while the composite fixator had them inserted right next to the fracture site. Assembled the remaining posterior clamps and tightened the fastening bolts (Figure 6). Released the limb and tried moving the hip and knee joint. Opened the skin surrounding the screw by the hook shape if it was stretched and performed suturing if necessary. Dry-dressed the screw location.

Postoperative care: patients could sit up and moved after the anaesthetics worn out, although assistance might be required. *In situ* rehab exercises were performed after one day and dischargement was possible after two days. Re-examinations were carried out monthly or when abnormal symptoms occurred until disassembly of the fixator. Another two re-examinations were done after six months and after one year.

Recorded data: operational risks based on the ASA six classes (21), osteoporosis situation based on Singh Index (20), fracture classification, and treatment results based on Jensen (21) consisted of three-level based on Evans (22).

Bone reduction results right after the operation were recorded and evaluated based on C-Arm images and radiographs based on the method of Baumgaertner and

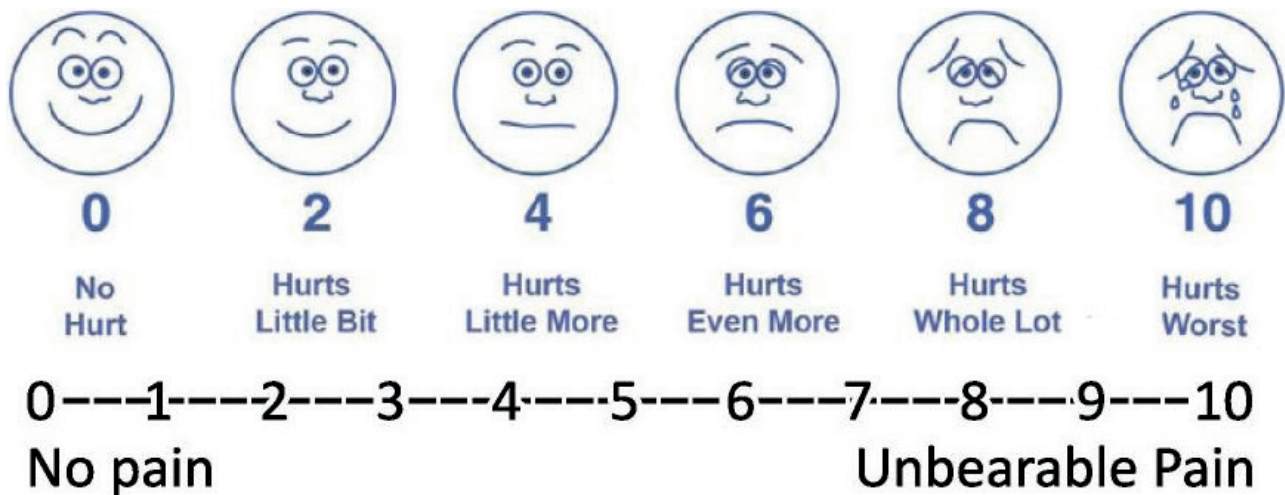


Figure 7. Pain scores based on the patient expression. [32]

colleagues (1995) (23) with three levels of “good” (no or slight deviation, flexion should not exceed 20° , the distance between the fragments should not exceed 4 mm), “acceptable” (failed to meet one of the above criteria), and “poor” (none of the criteria meets). Neck-shaft angle was recorded on the radiograph.

Pain level was recorded and evaluated based on VAS (visual analogue scale) score, NRS (numeric rating scale) score and facial expression (Figure 7), with three-level of pain based on WHO were: mild (level 1, score 1 – 3, treated with acetaminophen, NSAID, drug combo if possible), moderate (level 2, score 4 – 6, treated with the weak opioid, drug combo if possible), and severe (level 3, score 7 – 10, treated with the potent opioid, might be combined with Acetaminophen, NSAID, local anesthesia, and drug combo if possible). The pain was also scored during rehabilitation movement with fixator, only with two levels: pain and no pain.

Limb shortening was scored (25) with three levels of deviation between the femoral neck and the greater trochanter: mild (3 – 9 mm), moderate (10 – 24 mm), and large (20 – 35 mm). The anteversion angle was scored with three levels of ordinary ($15^\circ - 20^\circ$), excessive ($< 15^\circ$), and retroverted ($> 20^\circ$). Neck-shaft angle was scored with three-level (in comparison with Asiatic morphology) of normal ($125^\circ - 135^\circ$), coxa vara ($< 125^\circ$), and coxa valga ($> 135^\circ$).

In-bed rehab activities (limb exercises, sitting up, bed *in situ* exercises), knee and hip flexion at re-examination were recorded.

Deviation based on Baumgaertner and colleagues (1995) and bone healing based on radiographs was recorded and evaluated.

Infection at screw insertion sites was scored at two levels: shallow (opaque fluid at the screw, treated by proper dressing replacement) and deep (mucus from the bone, required debridement and antibiotics administration, or even premature screws and fixator removal). Other complications must be recorded if they occurred, including delayed union (union duration 15 weeks or above), false union (non-union even after doubling the average union duration of 12 – 14 weeks), and apparatus

failures (screw fracture, displacement, or extrusion, broken of the femoral head, or fixator displacement).

Ambulatory recovery was evaluated based on Kyle's criteria (26): excellent (no or minimum limp, absence of pain, rarely using crutch), good (mild limp, occasional mild pain, using crutch), fair (moderate limp and pain, using two crutches or walker frame), and poor (pain on any position, nonambulatory, wheelchair-bound).

3.3. Data Processing

The data was processed by STATA 12.0 using appropriate algorithms.

3.4. Ethical Declaration

The participants and family were informed of the necessary information, goals, aims, and scope of this study. Participation was strictly voluntary verified by signed documents. Participants' data were strictly confidential and was used only for research purposes.

4. RESULTS

4.1. General information

The participants included 34 males and 75 females. The average age was 77.3 ± 8.6 years (age range 60 – 99), of males was 75.6 years and female were 78.1 years. The aged 70 – 79 patients made up the largest group (51 patients, 46.8%, 15 males, 36 females), followed by the aged 80 – 89 group (30.3%, nine males, 47 females), then aged 60 – 69 groups (15.6% eight males, nine females), and the aged over 90 groups (7.3%). The female ratio was higher due to osteoporosis. The most frequent cause for fracture was domestic accidents (94 cases, 86.2%), followed by traffic accidents (13 cases, 11.9 %) and labour accidents (2 cases, 1.9%). The difference between the metal and composite fixator groups were insignificant ($p = 0.687$).

Right femur fractures comprised 43 cases (39.4%), and left femur consisted of 66 cases (60.6%). Most patients belonged to fracture type II (45%) and III (45%) based on Jensen, Ib type was few (10%). Class IV (Singh) made up of the most significant portion (45.9%), followed by class III (34.9%), V (13.7%), II (4.6%), and VI (0.9%), no class I was recorded. Osteoporosis in females was significantly higher than in males ($p = 0.001$).

Accompanying diseases occurred in 75 patients, including hypertension (50 cases, 45.9%), cardiovascular illnesses (12 cases, 11.0%), diabetes (12 cases, 11.0%), others (33 cases, 30.3%), two and above accompanying illnesses (32 cases, 29.4%). Six patients (5.5%) had accompanying injuries, including 3 cases of upper limb fracture (distal radius), two pelvic fracture cases at the same side, and one case of traumatic brain injury. Before fracture, 34 patients (31.2%) already required crutches and canes. Class I ASA included 24 patients (22%), 23 patients were at class II (21.1%), 43 at class II (39.5%), and 19 at class IV (17.4%).

Operation time of the stainless steel fixator group was averagely 5.76 ± 3.9 days after injury (earliest within the first day and latest were after 15 days), and of the composite fixator, group was averagely 4.15 ± 4.1 days (within the first day and after 15 days, the latest case was due to late admission).

4.2. Surgical results

There were 85 “good” bone reduction cases (77.9%), 19 “acceptable” cases (17.5%), and 5 “poor” cases (4.6%). There was no significant difference between the metal and composite fixator groups (p > 0.05). Patients with Jensen Ib fractures all had “good” reduction, with Jensen II fractures, had 47.1% “good”, 36.8% “acceptable”, and 40.0% “poor”, with Jensen III, had 40.0% “good”, 63.2% “acceptable” and 60.0% “poor”, the differences between the groups were significant (p = 0.034) (Figure 8). The average distance between the screw tips and acetabular cartilage was 6.4 ± 3.1 mm (min. 1mm and max. 13mm). The distance was shorter in the composite fixator group, but the difference was not significant (p = 0.092).

Amongst the metal fixator group, 39 patients had good bone reduction result; the average time until surgery was 5.4 days. The data for acceptable and poor results were 11 patients and 5.4 days, five patients, and 9.2

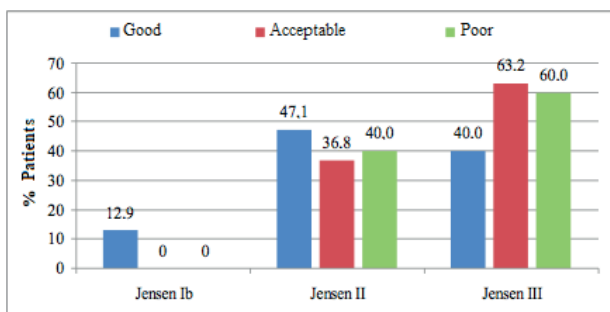


Figure 8. Bone reduction results between Jensen fracture types

Time recorded	Metal fixator (n=55)		Composite fixator (n=54)		p-values**
	Healthy	Injured	Healthy	Injured	
Preoperational (n=109)		96.8±6.8		92.5±6.9	0.001 ^a
Right after surgery (n=109)	130.6 ±2.0	130.5±5.9	129.9 ±1.6	130.2±3.3	0.158 ^b
After 1 month (n=108)*		130.1±6.6		130.1±3.4	0.212 ^b
After 2 month (n=108)*		130.2±6.6		130.1±3.2	0.158 ^b
Fixator removal (n=108)*		130.2±6.6		130.2±3.3	0.147 ^b

Table 1. The average neck-shaft angle of the patients *The 14th patient died two weeks after the operation due to another illness; ** p-values for the injured femur between two groups a: T-student test; b: Mann-Whitney test

Time evaluated		Group		Total	p
		Metal fixator (n=54)*	Composite fixator (n=54)		
1 month after surgery	Partial	39 (72.2%)	43 (79.6%)	82 (75.9%)	0.37
	Total	2 (3.7%)	0 (-)	2 (1.8%)	0.15
Two months after surgery	Partial	42 (77.8%)	48 (88.9%)	90 (83.3%)	0.12
	Total	5 (9.3%)	2 (3.7%)	7 (6.5%)	0.24
Three month after surgery (n=53)	Partial	18/23 (78.3%)	6/30 (20%)	24/53 (45.3%)	<0.001
	Total	3/23 (13.0%)	22/30 (73.3%)	25/53 (47.2%)	<0.001
Four month after surgery (n=53)	Partial	14/29 (48.3%)	4/24 (16.6%)	18/53 (33.9%)	0.07
	Total	9/29 (31.0%)	20/24 (83.3%)	29/53 (54.7%)	<0.001
Five month after surgery (n=2)	Partial	0	0	0	
	Total	2/2 (100%)	0	2/2 (100%)	
After fixator removal					
One month (n=108)	Partial	4 (7.4%)	1 (1.8%)	5 (4.6%)	0.17
	Total	43 (79.6%)	51 (94.4%)	94 (87.0%)	0.002

Table 2. Femur weight-bearing in amongst the patients (n=108) *The 14th patient died two weeks after the operation due to another illness

days. Amongst the composite fixator group, the data for good and acceptable reduction were 46 patients and 3.7 days, and eight patients and 6.6 days, respectively, with no poor reduction. There was a significant difference in average time until surgery between the mentioned results (p = 0.0105, Kruskal Wallis test).

The preoperational average neck-shaft angle between healthy and injured femurs and between injured femurs of the two investigated groups was significantly different (p < 0.01). The average neck-shaft angle of the injured femurs between the two groups right after the surgery, 1 and 2 months after surgery, and at fixator removal was similar, closed to the angle of the healthy femurs, and had no significant difference (p > 0.05). (Table 1) The average surgery duration was 23.4 ± 3.6 minutes (min. 17, max. 40 minutes), the corresponding duration of the composite fixator group was 23.2 minutes, and of the metal, fixator group was 23.6 minutes, the difference was not significant (p = 0.6371).

4.3. Post operational rehabilitation results

Most patients could sit up and perform in-bed rehabilitation exercises, with no significant difference between the two groups. Amongst the 108 studied patients (the 14th ones died two weeks after surgery due to other

illness) before fixator removal, 91,6% of cases could walk with crutches. At one month after surgery, 39 patients could walk with crutches in the metal fixator group (72.2%) and 43 cases in the composite fixator group (79.6%). At two months after surgery, 44 patients could walk with crutches in the metal fixator group (81.5%) and 50 cases in the composite fixator group (92.6%). There was no significant difference between the two groups ($p > 0.05$). At the time of fixator removal, 47 patients could walk with crutches in the metal fixator group (87.03%) and 52 cases in the composite fixator group (96.3%); the difference was significant ($p < 0.05$).

After one month, 77.7% of patients could perform weight-bearing in their femurs. After two months, 89.8% could, and at fixator removal, 90.7% could. The total weight-bearing

Jensen types	Metal fixator group (n=54)*		Composite fixator group (n=54)		Total		p-values
	n	Days	n	Days	n	Days	
I (n=11)	7	83 ± 7.5	4	77	11	80.8 ± 6.5	<0.001b
II (n=48)	30	90.5 ± 10.2	18	84.4 ± 6.9	48	88.2 ± 9.5	0.0004b
III (n=49)	17	93.1 ± 10.7	32	89.5 ± 6.6	49	90.7 ± 8.3	0.0382b
Total	54	90.4 ± 10.4	54	86.9 ± 7.4	108	88.6 ± 9.1	
p-values	p=0.0019a			c2=12.51			

Table 3. Average time until fixator removal (in days) amongst the Jensen types. * The 14th patient died two weeks after the operation due to other illness a. Kruskal – Wallis test b. T-student test

Screw insertion sites	Metal fixator (n=54)*		Composite fixator (n=54)		Overall	p-values
	Days	Range	Days	Range		
1st site	4.7 ± 1.2	(3 – 10)	4.2 ± 0.9	(3 – 7)	4.5 ± 1.1	0.0042a
2nd site	4.6 ± 1.1	(3 – 10)	4.1 ± 0.9	(3 – 7)	4.3 ± 1.03	0.007a
3rd site	4.3 ± 0.8	(3 – 7)	4 ± 0.8	(3 – 7)	4.1 ± 0.8	0.027a
4th site	4.2 ± 0.7	(3 – 5)	3.9 ± 0.7	(3 – 5)	4.1 ± 0.7	0.033a

Table 4. Screw insertion site healing time (in days). ** The 14th patient died 2 weeks after operation due to other illness. a: Mann-Whitney test

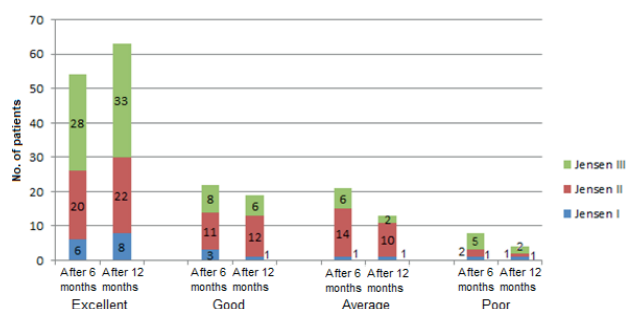


Figure 9. Rehabilitation results per Jensen fracture types.

rate was significantly higher in the composite fixator group ($p = 0.002 < 0.05$) (Table 2).

Within one month after surgery, 51 patients in the metal fixator group (92.7%) could perform knee flexion with an average degree of 12.5°, while all in the composite fixator group could perform the deed with an average degree of 50°. After one month, 50 patients of the metal fixator group (92.6%) could perform knee flexion (average 26.5°), and all of the composite counterparts could perform the deed (average 101.3°). The differences were significant ($p < 0.05$). At the time of fixator removal and six months after surgery, both groups had much better performance, but the knee flexion of the composite fixator group was still significantly better ($p < 0.01$).

There was no significant difference in the average time until fixator removal between the ASA classes ($p = 0.471$), the Singh osteoporosis levels ($p = 0.814$; however, Singh grade III and IV were significantly different, $p < 0.05$), genders ($p = 0.934$), and between the ambulatory and weight-bearing levels at different investigated times ($p > 0.05$). The composite fixator group had significantly earlier removal (average 90.4 ± 10.4 days, 70 – 126 days) than the metal fixator one (average 86.9 ± 7.4 days, 70 – 112

days) ($p < 0.05$), and removal was later in the more com-

plicated fracture based on Jensen ($p = 0.0019$) (Table 3). All the screw insertion sites of the composite fixator group healed significantly faster than the metal fixator group ($p < 0.05$; Table 4)

Rehabilitation results based on Kyle’s criteria were recorded for the 105 living patients at six months after surgery (4 patients died at two weeks, five months and six months after surgery) and 102 available patients at one year after surgery (3 patients had a femoral neck fracture at the 7th and 8th postoperative months). Amongst the 53 patients in the metal fixator group at six months after surgery, 20 patients had “excellent” (37.7%), 10 had “good” (18.9%), 17 had “fair” (32.1%), and 6 had “poor” result (11.3%). Amongst the 52 patients in the composite fixator group, the corresponding rates were 65.4%, 23.1%, 7.7%, and 3.8%, respectively. At 1 year after surgery, the respective rate amongst the metal fixator group were 52.0%, 18.0%, 20.0%, and 10.0%; and amongst the composite fixator group were 71.2%, 19.2%, 5.8% và 3.8%. The composite fixator group had a significantly higher “good” and “excellent” rate and lower “fair” and “poor” rate at both the investigation time ($p < 0.05$).

The 33 patients with accompanying diseases at six months after surgery had the rehabilitation results as 66.7% excellent, 15.2% good, 15.2% fair, and 3.0% poor, while the 72 without accompanying diseases had the corresponding results of 44.4%, 23.6%, 22.2%, and 9.7%. At one year after surgery, the available 30 accompanying diseased patients had 80.0% excellent, 13.3% good, 3.3% fair, and 3.3% poor, while the 72 remaining without accompanying diseases had the corresponding results of 54.2%, 16.7%, 16.7%, and 8.3%. The patients without accompanying diseases had significantly higher reasonable result rate ($p < 0.05$) and insignificantly lower fair and poor results rate ($p > 0.05$).

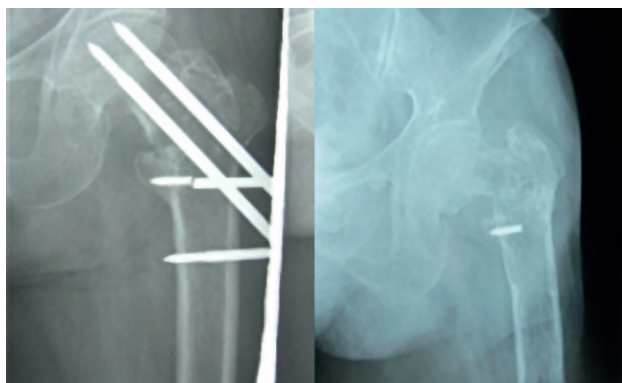


Figure 10. Screw fracture in patient no. 73

The rehabilitation results increased significantly over time, as the “excellent” rate increased from 51.9% at six months after surgery to 61.8% at one year, while the “poor” rate decreased from 7.9% to 6.9%. The “poor” patients were due to clinical history of poor ambulatory situation or stroke, geriatric issues, or poor cooperation in rehabilitation exercises.

As depicted in Figure 9, each rehabilitation result rate at six months and one year after surgery mainly increased from Jensen type I to type II and III, the “excellent” result at six months after surgery for Jensen I, II, and III types were 11.1%, 37.0%, and 51.9%, respectively. The difference was insignificant at six months after surgery ($p = 0.28$) and significant at one year after surgery ($p=0.037$).

The ASA I patients had the highest “excellent” (79.2% at six months and 85.7% at one year after surgery) and lowest “poor” rehabilitation results (4.2% and 4.8%). The ASA IV had the lowest “excellent” (25.0% at six months and 37.5% at one year after surgery) and the highest “poor” rehabilitation results (18.8% and 12.5%). No apparent difference was detected amongst ASA II and III. The difference between ASA groups was significant at six months ($p=0.041$) but not significant at one year after surgery ($p=0.199$).

4.4. Complications

There was neither record of early complications such as traumatic shock or clogged blood vessel nor any accidents or complications during surgery. Blood loss was also limited; six patients (no. 6, 7, 13, 19, 20, 45) from the metal fixator group and one patient (no. 82) from the composite fixator group required blood transfusion mostly were transfused preoperatively, and one case intraoperatively due to blood clotting disorder.

The neck-shaft deviation was monitored right after surgery, after six months, at the time of fixator removal. Right after surgery, eight patients were observed with coxa vara and limb shortening (7.3%) and ten patients were observed with malalignment at the time of removal (9.3%). No retroversion or excessive anteversion clinically detected.

Patients experienced severe and moderate pain on the 1st and 2nd postoperative days; from the 3rd day onward, the pain was mostly mild. In the metal fixator group, severe pain was experienced in 25 patients, six patients, and 14 patients on the 1st, 2nd, and 3rd postoperative day, respectively, while in the composite fixator group, the

respective number were only 10, 1, and 6 patients. The moderate and mild pain, on the other hand, occurred more in the composite fixator group.

At one month after surgery, 74.1% of the composite fixator group and 62.9% of the metal fixator group no longer felt pain while not moving, and the corresponding mild pain rate was 25.9% and 37.1%, respectively. No moderate or severe pain was observed. At two months after surgery, 90.7% of the composite fixator group and 92.6% of the metal fixator group no longer experienced pain; both had 7.4% patients with mild pain, and one patient with composite fixator had severe pain (1.9%). At the time of fixator removal, all patients in the composite fixator group and 98.1% of the patients in the metal fixator group no longer felt pain. One patient (1.9%) in the metal fixator group still had mild pain.

At one month after surgery, 2.5% of the composite fixator and 7.4% of the metal fixator group felt no pain during body movement. The mild pain rate was 96.4% and 81.5%, and the moderate pain rate was 1.9% and 11.1%, respectively. At two months after surgery, 1.8% of the composite fixator and 7.4% of the metal fixator group felt no pain. The mild pain rate was 98.5% and 87.0%, and the moderate pain rate was 3.5% and 5.6%, respectively. At the time of fixator removal, 98.2% of patients in both groups felt no pain, and 1.8% had mild pain. No severe pain in the movement was observed.

Limb shortening occurred in 12 patients (11.1%), including nine patients with metal fixator (16.7%, consisted of 5 patients shortened by 10mm, one patient by 15mm, and one patient by 20mm, average 13.09 ± 4.9 mm) and three patients with composite fixator (5.6%, consisted of one patient shortened by 10mm and two patients by 20 mm, average 16.7 ± 5.8 mm). The difference was not significant ($p = 0.066$).

Within the first postoperative month, no infection occurred at the screw insertion site. At one month after surgery, infection happened at 8/432 screw sites (five 1st screws and three 2nd screws on five patients, 4.6% patients and 1.9% screw sites). At one month after surgery, no infection was recorded. At fixator removal, only 1 screw site (1/432, 0.2%) was infected (1/108 patients, 0.9%). Only 1 scarred screw site (1/420, 0.2%) was infected (1/105 patients, 0.95%). None scarred screw site was infected 12 months after surgery.

One month after surgery, only two patients had apparatus failure (1.9%), consisting of 1 case of screw displacement in the metal fixator group and 1 case of screw fracture in the composite fixator group. At two month after surgery and at fixator removal, only one patient had apparatus failure (0.9%, 3rd screw fracture) belong to the composite fixator group.

Patients with low Singh index (severe osteoporosis) had higher infection fluid and mucus occurrence than the ones with high index (milder osteoporosis), but the difference was insignificant. People with standard bone quality (Singh VI) only had 1 case, and the screw status was normal. Fluidized screws occurred in 20% Singh V 6.1% Singh IV; 13.2% Singh III and 20.0% Singh II patients.

5. DISCUSSION

The studied participants were geriatric patients (aged 60-99), and the majority was female, corresponded with a high rate and risk for older women (27, 28). Intertrochanteric fracture in geriatric patients mainly resulted from a domestic fall in which the hip land on the floor (86.2%), traffic accidents only made up 11.9%. Tomak and colleagues (2005) provided a similar result of 93% and 7%, respectively (12).

The Jensen classification was used to predict the possible complication. Other studies instead focused on the overall physical status concerning treatment with an external fixator (29). Due to poor bone quality, the unstable fracture was high in geriatric patients despite the force's favourable impact. This study observed 49 Jensen II (45.0%) and 49 Jensen III patients (45.0%). Such fracture classification could be helpful, especially for treating an external fixator, since complicated fractures caused greater challenges and obstacles, and reduction results were mostly "poor" and "acceptable", for example, the corresponding 60.0% and 63.2% for Jensen III type. The difference was significantly different between the types ($p < 0.05$).

Poor bone quality in older people increases the risk of bone fracture and apparatus failure (10) (30, 31). Our study showed no relationship between bone quality and fluid and mucus occurrence at the screw insertion ($p = 0.538$). However, severe osteoporosis tended to have higher fluid occurrence. Barrios (1993) also warned of the risk of apparatus failure due to infection at the screw in osteoporotic patients and made no solid affirmation on the issue (30).

Existing and potential accompanying health issues in geriatric patients should have careful attention during the planning and performance of fracture treatment, the prediction of potential risks, complications, recovery results, and to minimize the mortality and morbidity rate (13, 29, 32). In our study, 75 patients (68.8%) had accompanying illnesses and had poorer rehabilitation than others. In our study, the risky surgical groups (ASA III and IV) (34) also were the majority (56.8%).

Many participants had surgery early, but many others had to be postponed due to prolonged treatment of other issues and other involuntary factors, including a case with 18 days. The average waiting time was 4.96 days. Kourtzis and colleagues (2001) commented that the external fixator was not highly invasive; hence it could be performed very soon after hospitalization (33). Lengthy preoperative preparation and incompatibility between facilities could lead to worse results. The waiting time over ten days could lead to an inadequate reduction ($p < 0.05$). The composite fixator group had earlier surgery time, had no lousy reduction case and a high rate of excellent and acceptable reduction, while the stainless steel fixator group had five poor reduction cases and an average waiting time of 9.2 days. The reason was because of the difference in facilities between the two groups, and the treatment with composite fixator was performed later in chronological order. Hence the surgeons were more experienced in operation preparation.

Baumgaertner and colleagues (1995) (23) proposed their criteria for bone reduction. However, the authors did not present the detailed reduction results on intertrochanteric treatment with an external fixator. Baumgaertner and colleagues provided, amongst the 198 studied intertrochanteric internal bone fusion, 45.9% good, 39.3% acceptable, and 14.6% inadequate reduction. Our study recorded higher-good reduction (77.9%) and only 4.6% insufficient, probably because closed reduction was less challenging than open reduction during Baumgaertner and colleagues' study.

Our study used two parallel K – nails at the superior and inferior femoral neck surfaces. The corresponding screws were less than 10mm apart from the acetabular cartilage (average 6.4 mm). Among the 108 patients with fixator removal, two cases had apparatus failure at one month and two months after surgery and one case at the removal time. One patient with a composite fixator had a screw fracture (Figure 10). Our result was compatible with Verkis and colleagues (2011) (1), who concluded that parallel femoral neck screws provided similar stability to the convergent pins while they were more straightforward, with significantly less radiation exposure and shorter intraoperative time.

Many studies recorded operational duration over 40 minutes for open bone reduction with internal apparatus like compression plates and hip-screws (36, 37), while external fixators usually required over 20 minutes or 34 minutes at most (10, 15, 33). K – nail insertion's operation duration to finishing fixator assembly was averagely 23.4 ± 3.6 minutes, similar to other authors.

The normal Vietnamese neck-shaft angle was $130^\circ - 135^\circ$ (38). In our study, the angle before and after surgery for the metal fixator patients was 96.8° and 130.5° , respectively, for composite fixator patients were 92.5° and 130.2° , respectively. Hence the resulted neck-shaft angle remained in the normal range, and the fixators provide proper fixation for the bone to regain its original union.

In-bed rehabilitation was rarely mentioned in other studies, and our study wanted to research the effect of this factor on the bone union. Moreover, rehabilitation was essential to prevent bed-rest complications. All the 108 patients available for monitor participate in in-bed rehabilitation, and the time for the union was 90.4 days amongst the stainless steel fixator patients and 86.9 days for the composite patients. Knee movement improved clearly over time (31.8° during the first postoperative days, 65.3° after one month, 95.9° after three months, and 128.8° after six months), similar to other researches such as Dhal and colleagues (1991) (29) or Barrios and colleagues (1993) (30). However, knee flexion of the composite fixator patients was significantly better than the metal fixator ($p < 0.05$), which was similar to other studies (13, 32) who concluded that the shaft screws closer to the fractured trochanteric region were less obstructive towards knee movement since the screws could avoid the vastus lateralis. Shaft screws inserted further from the trochanteric fractures, on the other hand, could limit knee movements (15, 29, 32).

Weight-bearing statistics during rehabilitation had not been published in many studies on intertrochanteric treatment in geriatric patients (10, 15, 29, 32). In our study, excluding the 14th patient who died after two weeks due to other diseases, 82 patients (75.9%) could walk with crutches and frames at the end of the 1st postoperative month. Additional 12 patients could perform similarly on the 2nd month. As weight-bearing was performed by most patients (89.8%), the external fixator was proved to enable stable fixation and quick bone healing. At the time of fixator removal, 98 patients (90.7%) could perform weight-bearing and walk with a crutch. At one month after removal, 99 patients could perform weight-bearing, and 94 patients could perform full weight-bearing (87.0%). The composite fixator patients had a significantly higher weight-bearing rate than the stainless steel ones (94.4% and 79.6%, respectively) ($p = 0.002$).

Our study recorded an average bone union time of 88.6 days (70 – 126 days), similar to other researches (~ 12 – 16 weeks) (1, 12, 29, 33). The average time until fixator removal of the metal fixator patients (90.4 ± 10.4 days) was significantly longer than the composite one (86.9 ± 7.4 days) ($p < 0.05$). Bone union time had no relationship with genders, different position of the shaft screws (close to or far from the fracture site), surgical risks and bone quality, but it was related to Jensen fracture types. Moreover, the ability to perform early rehabilitation and walking with a crutch promoted the union process. On the other hand, apparatus failure and the occurrence of screw fluid and mucus hampered the process. The fixator could be removed when the union was observed clinically and on the radiograph, similar to other studies (34, 35). However, premature removal had to be performed in severe screw infection or complications such as screw displacement and extrusion (29, 33).

Rehabilitation results at six months and one year after surgery showed clear functional improvement. Amongst 102 available patients at one year after surgery (excluding four mortality cases and three re-fractured cases), the excellent, good, fair and poor patients were 63 (61.8%), 19 (18.6%), 13 (12.8%) and seven patients (6.8%), respectively, with significant difference between two fixator groups at six months after surgery ($p = 0.003$) but not significant at one year ($p = 0.072$). The rehabilitation results also depended on assistance from crutches or frames and pre-injury ambulatory status, as patients with ambulatory issues and accompanying illnesses beforehand or high surgical risks had more insufficient recovery than the healthy ones.

Studies on internal and external fixators for intertrochanteric fractures mentioned improvement in pain relief and the ability to perform early rehabilitation. However, none had provided details in pain level during postoperative care and rehabilitation process, both in rest and movement. Our study investigated these aspects to evaluate the functional recovery of the patients. The results showed that the severe pain could be dealt with within the first four postoperative days. From the 5th day onward, the pain significantly decreased, no oral

analgesic administration was needed, and discharge-ment was possible. The metal fixator patients experienced significantly more pain than the composite ones within the first postoperative three days, but the difference afterwards was not significant.

Vekris and colleagues (2011) assessed that limb shortening is a frequent mechanical complication amongst internal or external fixation of unstable or severely osteoporotic intertrochanteric fractures (1). This study recorded 12 cases of limb shortening, nine from the stainless steel fixator patients and three from the composite fixator patients, at the average amount of 1.62 cm, which is milder than in some other studies (13, 29, 32). Six cases had less than 1 cm shortening, five of which had inadequate bone reduction due to late surgery time (later than ten-day), which caused difficulties for reduction and realignment – an important issue that needed to be kept in mind closed bone reduction. Amongst the 6 cases of 1.5 – 2cm, 2 cases were due to secondary malalignment because of improper rehabilitation of the injured limb during the 1st postoperative month, and 1 case was due to premature fixator removal resulted in cox vara. Hence proper postoperative rehabilitation and bone union monitoring were essential to prevent shortening due to secondary malalignment. Kourtzis and colleagues (2001) (38) observed a 14% rate of mechanical complication resulted in the loss of proper initial reduction and commented that these complications were acceptable for geriatric people with low demand of daily movements.

Our study recorded seven blood transfusions cases, but mostly was transfused preoperatively due to anemia, and only one case was performed intraoperatively due to blood clotting disorder. The surgical blood lost, hence, was mild and mainly did not required operational blood transfusion, which was generally agreed as the main advantages of the external fixator (10, 13, 29, 32, 33, 39). Meanwhile, the internal fixators caused significant blood lost (150 – 450 ml average) and required frequent transfusion (5, 40).

Within the 1st postoperative month, fluid occurred at 42.6% screw sites, but no superficial infection observed. After one month, 4.6% of the sites had superficial infection, and only 1 case of shallow infection (0.9%) and 8 cases of fluid were recorded at the time of removal. Our study had significantly lower infection than other works such as Alcivar (2001) (29.68%) (32), Tomak and colleagues (2005) (52.38%) (12), or Vossinakis and Badras (2001) (15.91%) (13). To reduce the infection, screw insertion must be done appropriately from the beginning. Multiple insertions may cause screw loosening and should be avoided, stretched skin at screw sites should also be avoided. Moreover, cooperation between the hospital and the patient and patient family was critically important.

Four deaths were recorded in this study (3.7%), all within the 1st postoperative year and were due to other illnesses; the mortality rate was less than in the works of Alcivar (2011) (14% within the first six months) (32) or Mitkovic and colleagues (1997) (14.75% for internal

bone fusion and 19.45% for external bone fusion) (15). No death occurred during the operation in our study. Complications like blood vessel damage, femoral head necrosis, or embolism were not detected during the surgery in our study, either. An external fixator's treatment was safe and minimally invasive; ASA III and IV patients could endure the surgery.

6. CONCLUSION

The external fixator was a suitable treatment for intertrochanteric fracture in geriatric patients. It is minimally invasive, had a short operational duration, limited blood loss, provided stable fixation for pain relief and early rehabilitation, and reduced risks of dangerous complication in senile people. The novel composite fixator prototype in this study was also superior to the current metal fixator in many aspects. Proper application of this method could prove its effectiveness in the surgical cure for fracture in older people.

- **Institutional Review Board Statement:** The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Institutional Ethics Committee of the 7A Military Hospital (protocol code Number: 50/QĐ-HĐYĐ-BV7A, date: 18.04.2018). Every patient signed an informed consent form before inclusion in the study.
- **Data availability statement:** The clinical data used to support the findings of this study are restricted by Institutional Ethics Committee of the 7A Military Hospital (protocol code Number: 50/QĐ-HĐYĐ-BV7A, date: 18.04.2018) in order to protect patient privacy. Data are available from Quang-Tri Le (lqtri@ntt.edu.vn) for researchers who meet the criteria for access to confidential data.
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