Am J Transl Res 2020;12(7):3917-3925
www.ajtr.org /ISSN:1943-8141/AJTR0108461

Original Article

A novel reduction device for the minimally invasive treatment of femoral shaft fractures

Wei Jiang[1], Yan Lin[1], Ronak Naveenchandra Kotian[2], Wen-Qing Xie[3,4], Yu-Sheng Li[3,4], Guang-Heng Li[1], Xin-Jia Hu[1], Jin-Hu Xie[1], Wen-Tao Liu[1], Xiao-Ming Zhang[1]

[1]Department of Bone and Joint, Shenzhen People's Hospital, The First Affiliated Hospital of Nanfan University of Science and Technology, The Second Clinical Medical College of Jinan University, Shenzhen 518020, Guangdong, P. R. China; [2]Department of Orthopaedic Surgery, Victoria Hospital, Bangalore Medical College and Research Institute, Bangalore, India; [3]Department of Orthopaedics, Xiangya Hospital of Central South University, Xiangya Road 87, Changsha 410008, Hunan, P. R. China; [4]National Clinical Research Center for Geriatric Disorders, Xiangya Hospital, Central South University, Changsha 410008, Hunan, P. R. China

Received January 29, 2020; Accepted June 16, 2020; Epub July 15, 2020; Published July 30, 2020

Abstract: Objective: In this study, a new type of reduction device for femoral shaft fractures was developed and designed. The reduction procedure was also standardized and is expected to be useful in clinical practice. Methods: A bone traction retractor that consisted of a special traction needle, a resistant sleeve, a crossbar and an arc-adjusting bar was designed. Forty-eight patients (32 males and 16 females, mean age 33.21±7.03 years old) with femoral shaft fractures treated in our hospital from January 2016 to December 2017 were selected. According to the AO classification, there were 15 patients with type A, 24 patients with type B and 9 patients with type C fractures. All patients were treated with transverse bone traction for closed reduction of femoral shaft fractures and femoral reconstruction with intramedullary nails for final fixation. The injured side, preoperative delay time, reduction and operative times, operative blood loss, drilling frequency, number of open reduction cases, hospitalization days, fracture healing time, postoperative HSS function score and complications were recorded. Results: All 48 patients were treated with transverse bone traction using our novel device to obtain reduction. The average time needed for reduction was 19.98±4.66 min. The operating time was 60-100 min, with an average of 78.65±16.81 min, and the average intraoperative blood loss was 131.91±30.22 ml. Open reduction was performed in 8 patients: 1 patient in the experimental group and 7 patients in the control group. The average hospitalization days was 7.78±2.81 days, the fracture healing time was 10 to 15 weeks, with an average of 12.44±2.63 weeks, and the postoperative HSS score was 80-95 points, with an average of 86.52±6.03 points. None of the patients had coxa vara, nonunion, internal fixation failure, infection, nerve injury, limb length discrepancy or other complications. Conclusion: In this study, the transverse bone traction reduction technique and the design of a proprietary reduction device system were proposed, with high clinical application. The transverse bone traction reduction technique has the advantages of simple operation, reliable reduction and limited intraoperative fluoroscopy in the minimally invasive treatment of femoral shaft fractures.

Keywords: Reduction device, femoral shaft fracture, closed reduction, locked intramedullary nailing

Introduction

Femoral shaft fractures are common orthopedic fractures, and closed reduction and interlocking intramedullary nail internal fixation is considered to be the best choice of treatment because it can effectively protect the blood supply at the fracture end and can greatly improve the fracture healing rate [1-8]. The main challenge of closed reduction of the femoral shaft is to achieve good reduction despite the strong muscle pull that leads to obvious displacement of the fracture. Additionally, due to high-energy injury shortening of the femur, rotational, angular and lateral displacement of the fracture ends leads to increased surgical time, increased fluoroscopy time, increased bleeding due to manual reduction, increased possibility of open reduction and increased risk of infection [9-14]. Xu H et al. applied a new type of reduction device for the femoral shaft that could rapidly and effectively reduce and protect

the blood supply at the fracture. However, their reduction device caused additional soft tissue damage, increased blood loss and had low reproducibility [15]. Some surgeons use a robot-assisted reset procedure to achieve the benefits of limited bleeding and rapid reset, but it is very expensive [16]. To achieve rapid, effective and convenient reduction, we developed a new fracture reduction instrument. From January 2016 to December 2017, we conducted a prospective randomized study to evaluate the efficacy of the provided instrumentation for intramedullary nailing versus traditional treatment for femoral shaft fractures. Our new reduction instrument can be used for rapid and effective reduction that protects the blood supply at the fracture end, causes minimal blood loss and has high reproducibility [5, 15].

Materials and methods

Patients

A randomized controlled trial was conducted on patients with femoral shaft fractures hospitalized in Shenzhen People's Hospital from January 2016 to December 2017.

Inclusion criteria

(1) femoral shaft fractures were diagnosed, and the fracture was classified according to AO [17]; (2) patients less than 60 years old; (3) internal fixation with closed reduction and interlocking intramedullary nails; and (4) surgical treatment within 7 days after injury.

Exclusion criteria

(1) did not meet the above diagnostic criteria; (2) the fracture was pathological, tuberculous, infectious, etc.; (3) severe osteoporosis and bone metabolism diseases; (4) aggravated illness or serious complications during treatment; (5) patients with severe primary diseases, such as complicated diseases of the cardiovascular, cerebrovascular, liver and kidney, hematopoietic or endocrine systems; (6) open and multiple fractures; and (7) patients who refused to participate in this study.

General information

In this study, all patients diagnosed with femoral shaft fractures admitted to our hospital from January 2016 to December 2017 were selected, and all patients were classified by at least 2 surgeons according to the AO classification. Enrolled patients were randomly allocated to one of the treatment groups, with or without the novel instrument to be used in the operative process, using sealed, opaque envelopes. In the control group, the new reduction instrument was not used during the operation, and in the experimental group, the new reduction instrument was used during the operation. Data were collected, medical histories were noted, physical examinations were performed, and relevant preoperative examinations were performed for each participant. Moreover, the progression of fracture healing was evaluated at least 1 year after the procedure. Clinical and imaging follow-up examinations were conducted at 1 day and 1, 3, 6, 9, and 12 months after the operation. Sex, left and right sides, AO classification, preoperative delay time, operation time, reduction time, intraoperative blood loss, drilling frequency, open reduction cases, hospitalization days, fracture healing time, postoperative HSS score, complications and other data were recorded [7, 17-21].

Ethics statement

This study was approved by the ethics committee of Shenzhen People's Hospital. Patients were selected independently at admission, and all participants signed written informed consent forms.

Statistical analysis

SPSS 19.0 statistical software was used for statistical analysis, and the measurement data met a normal distribution. For the comparison of differences between the two groups, independent sample t tests were used, expressed as (X±S), which did not meet the normal distribution, and the U-test was used, expressed as the median. The counting data were represented by the composition ratio and frequency, and the chi-square test was used for comparisons between the two groups. All test results were statistically significant with $P < 0.05$.

Structure of the instrument

Fracture reduction device

The bone traction retractor, which consisted of a special traction needle, a resistant sleeve,

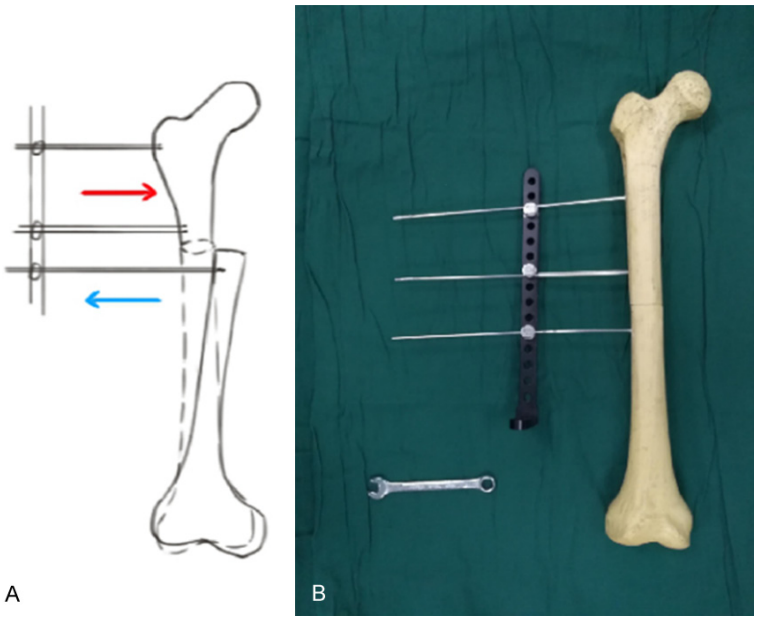

Figure 1. Schematic diagram of the design of the reductor, which was composed of a crossbar, three bone traction needles, and a resistant sleeve (A). During the operation, the No. 1 and No. 2 traction needles were driven into one end of the fracture and fixed to the crossbar, and the third traction needle was driven into the other end of the fracture. After traction reduction was completed, the reductor was fixed to the crossbar (B).

a crossbar and an arc-adjusting bar, was designed. The special traction needles were fixed at both ends of the fracture and proximal femur. The resistant sleeve was resistant at the proximal end of the fracture. The special traction needles were fixed on the crossbar, reset and fixed with the arc-adjusting bar (**Figure 1**).

Surgical procedures and techniques

1. First, a traction bed was used to correct the shortening, angulation and rotation displacement of the fracture (**Figure 2**). 2. The C-shaped arm was used to search for the maximum displacement plane and the minimum displacement plane of the fracture (**Figure 2**). 3. The characteristics of fracture displacement were defined (**Figure 2**). 4. The 3 special traction needles and resistant sleeve were installed at the best plane and level, the installation of the remaining part was finished, and the third traction needle was removed for fixation (**Figures 3**, **4**). 5. Fracture reduction was confirmed with fluoroscopy, and the routine femoral intramedullary nail operative steps were followed (**Figure 5**).

Results

Basic information

According to **Table 1**, in the analysis of the randomized controlled trial, a total of 48 patients with femoral shaft fractures were admitted to Shenzhen People's Hospital from January 2016 to December 2017. They were randomly assigned to two groups and were treated with closed reduction and internal fixation with intramedullary nails. Patients in the different groups were similar in terms of age, sex, affected side and preoperative delay time, without statistical significance. In terms of the AO classification, there was no significant difference in fracture morphology between the two groups ($P > 0.05$).

Observation indexes

As shown in **Table 2**, the comparison of operation time between the two groups showed a significant difference ($P < 0.05$). The operation time of the experimental group was 65.63±7.39 min, which was significantly lower than that of the control group (91.67±10.71 min). The blood loss in the experimental group was significantly lower than that in the control group ($P < 0.05$). The number of boreholes and open reduction cases in the experimental group was significantly lower than that in the control group ($P < 0.05$). In the experimental group, most operations were completed with 1 borehole, 5 needed 2 borehole reductions, and only 1 needed open reduction due to difficult reduction.

There were no statistically significant differences in length of stay, fracture healing time or postoperative HSS scores between the two groups ($P > 0.05$). All patients achieved fracture healing after surgery, and there was no obvious abnormal movement of the hip or knee joint, and no complications such as coxa vara, bone nonunion, internal fixation failure or infection occurred.

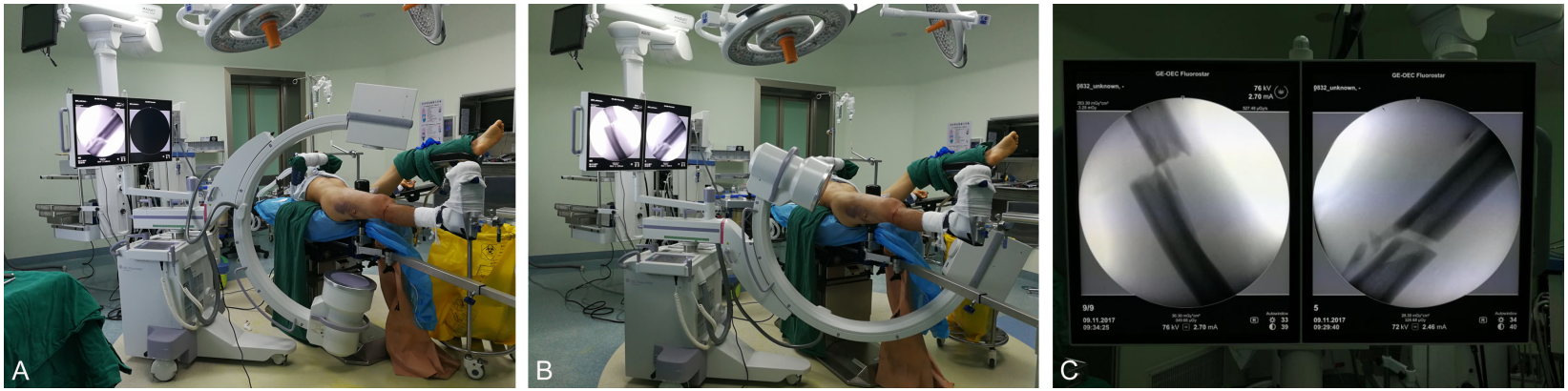

Figure 2. The traction bed assisted with traction and corrected the displacement of femoral shortening, rotation and lateral displacement in the remaining femur. C-arm fluoroscopy was used to find the plane where the lateral displacement of the femoral fracture was most obvious. This plane was the plane in which the three bone traction needles in the reducer were placed (A, B). In this case, the patient was displaced anteroposterior and laterally, and the maximum displacement plane was from anterior inner to outer inferior and formed an angle of approximately 70 degrees with the ground (C).

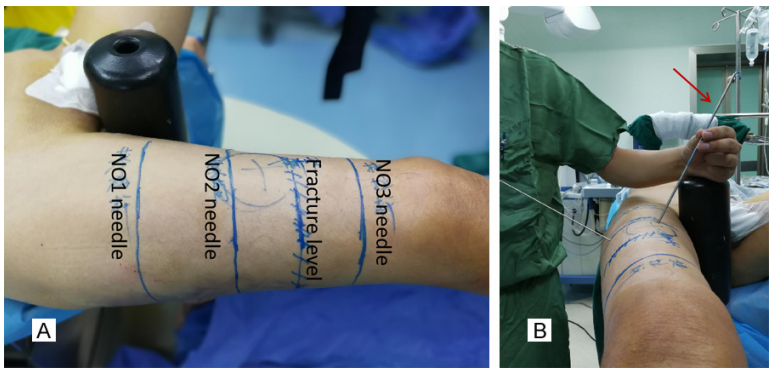

Figure 3. The level of the femoral fracture and the level of the three bone traction needles to be placed on the skin were marked (A), and the needling direction of the bone traction needle was defined again (B). In this case, the needle was inserted from anterior inner to outer inferior, and the angle with the ground was approximately 70 degrees.

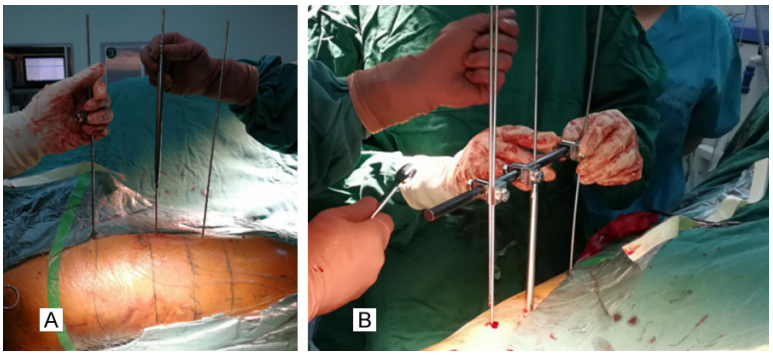

Figure 4. Three bone traction needles were placed in sequence. The top rod sleeve of the No. 2 bone traction needle was sheathed (A), the No. 1 and No. 2 bone traction needles were connected to the cross rod and fixed, and the No. 3 bone traction needle was also fixed to the crossbar after pulling (B).

Discussion

Closed reduction and interlocking intramedullary nail internal fixation has been the gold standard for the treatment of femoral shaft fractures, and intraoperative closed reduction is the key step in surgery [22-24]. Open reduction will inevitably damage the blood supply of the fracture end and affect the natural process of fracture healing. Therefore, closed reduction and internal fixation can effectively protect the blood supply of the fracture end and the original blood supply containing growth factors, greatly improving the fracture healing rate [8]. The femur is the hardest bone in the human body and is also a bone with well-developed muscle attachment. Fractures are mainly due to violent injuries, and due to muscle pull, they often show shortening, rotational, angular and lateral displacement of the fracture end, making it extremely difficult to perform closed reduction [9-11, 25].

However, traction beds and traction stents have been used in clinical practice to effectively correct the shortening, rotation and angular displacement of fractures, but lateral displacement is the main reason for the difficulty in reduction. Many surgeons mainly rely on manual reduction to solve lateral displacement during surgery. However, there is more thigh muscle bulk, and the femur lies deep to this bulk, making it difficult to maintain closed reduction for a long time, or sometimes, the fracture cannot be completely reduced. Many scholars use several closed femoral fracture reduction methods, such as grams, homemade brackets, needle intraoperative gram joystick needle technology applications and robot-assisted reduction. Unfortunately, these reduction methods have low reproducibility, long operative times, and high risks of iatrogenic injury and infection [16, 19, 26-29]. Therefore, a new traction reduction instrument with simple operation, reliable reduction, and reduced operative and fluoroscopy times is needed.

In this study, transverse bone traction reduction technology was proposed, and a proprietary reduction device system was designed, which consisted of a special traction needle, a resistant sleeve, a crossbar and an arc-adjusting bar. First, the maximum displacement plane of the fracture was defined by fluoroscopy and positioning, and the reference fracture end and reduction fracture end were determined in the plane. Then, a reduction traction needle was placed in the plane, and transverse traction was used to reduce the fracture end. After the alignment was satisfactory, the reduction

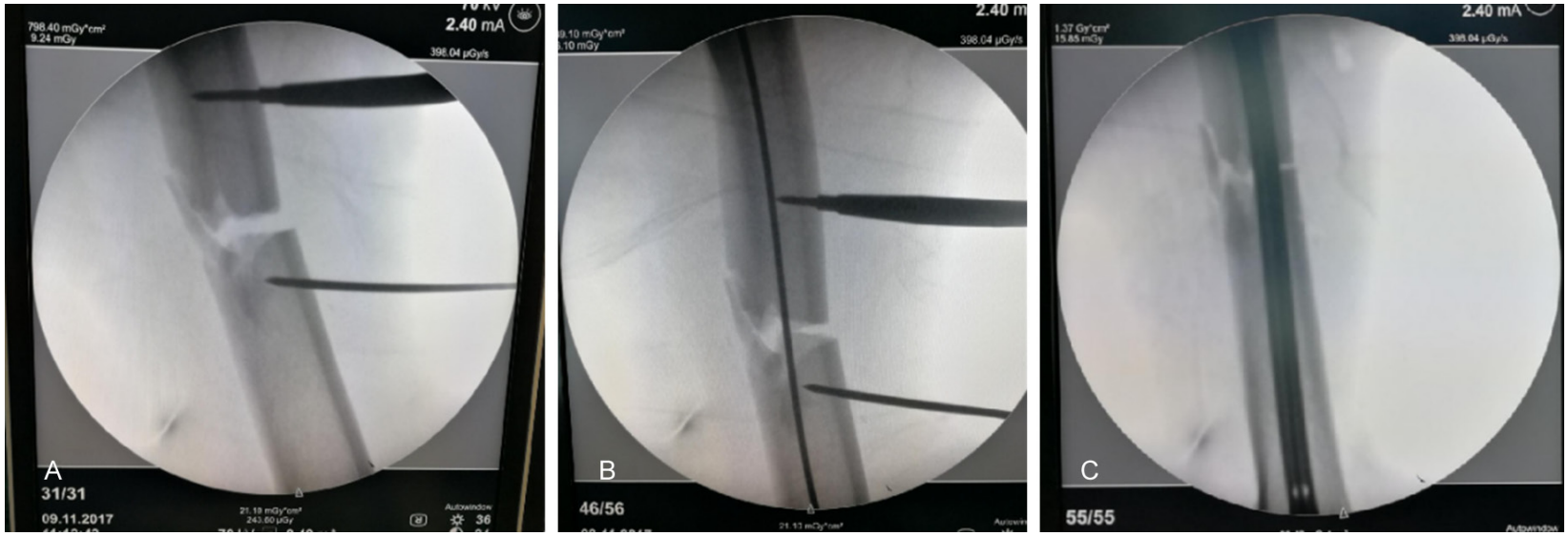

Figure 5. C-arm fluoroscopy confirmed satisfactory fracture reduction (A). The reduction device maintained reduction, the femoral intramedullary nail guide needle was conventionally inserted, and the intramedullary nail reamed and installed (B, C).

Table 1. Analysis of the basic situation of patients in the two groups

		experimental group	control group	P
sex	male	15	17	0.540
	female	9	7	
age	years	34.78±6.34	31.64±8.17	0.144
injured side	left	13	10	0.386
	right	11	14	
AO classification	A	8	7	0.842
	B	11	13	
	C	5	4	
Preoperative delay	Days	4.49±1.58	4.53±1.77	0.935

Table 2. Analysis of the observation indexes of patients in the two groups

	experimental group	control group	P
Operation time (min)	65.63±7.39	91.67±10.71	0.000
Reduction time (min)	12.71±2.18	27.24±5.89	0.000
Operative blood loss (ml)	105.71±16.66	158.11±25.64	0.000
Frequency of drilling (median)	1	3	0.000
Number of open reduction cases	1	7	0.048
Hospitalization (days)	7.44±1.89	8.11±2.44	0.293
Fracture healing time (weeks)	13.21±2.64	14.42±4.40	0.256
Postoperative HSS score	89.33±6.08	85.13±9.47	0.075
The number of complications	0	0	/

device system was locked, and routine intramedullary nailing steps were followed.

In this study, the reduction time and operation time in the experimental group were significantly lower than those in the control group. The operative blood loss in the experimental group was 105.71±16.66 ml, which was significantly lower than that in the control group. The reasons for the above findings could be the small incision size of the traction Kirschner needle, the short operative time that reduced the chances of iatrogenic bleeding, the high success rate of reduction, and the decreased rate of open reduction. The number of intramedullary drilling and open reduction cases in the experimental group was significantly less than that in the control group, which indicates that the new fracture reduction technique is very effective. In the experimental group, 19 cases were successfully drilled once, and 5 cases needed to be drilled twice, which may be related to inaccurate intraoperative fluoroscopy, failure of complete fracture end reduction, and poor experience of the operator. However, the control group usually required drilling 3 times, and the drilling frequency in 3 patients was 5 times, which increased the operation time, affected the blood supply of the fracture end, and increased the chances of iatrogenic injury. Only 1 case in the experimental group required open reduction, which can be attributed to the inexperience of the surgeon, the difficulty in fracture end reduction, and the instability of the fracture. In the control group, there were 7 patients who needed open reduction due to unstable and difficult reduction of the fracture site. Open reduction inevitably destroys the local periosteal blood supply due to the fracture incision, thereby affecting natural fracture healing [18-21]. When comparing the other parameters, such as hospitalization days, postoperative fracture healing time, postoperative HSS score and postoperative complications, there was no statistical significance between the two groups. This shows that the new device does not affect postoperative recovery. The device and the technique help reduce the operation time and iatrogenic injury and help improve fracture healing.

Xu invented a new reduction device that could rapidly reduce femoral shaft fractures and effectively protect the blood supply at the fracture end. The operation time, drilling times and chances of open reduction were reduced. However, the number of incisions and the amount of bleeding were increased along with the low reproducibility of the instrument [15]. With scientific advances, many surgeons currently use robot-assisted reduction, which may also be effective by protecting the blood supply and reducing intraoperative bleeding, but it is very expensive and difficult to apply in common procedures [16].

In conclusion, the new closed reduction instrument adopted in this study can reduce femoral shaft fractures quickly and effectively with reduced operative time and blood loss. The simple operation of this reduction instrument reduces the dependence on the surgical experience of surgeons, which is conducive to young doctors, and it improves the reduction efficacy, shortens the operative time, improves the reproducibility and reduces the amount of X-ray radiation to doctors.

This study is not without limitations. If the sample size can be further increased, the experimental data will be more scientific. The comprehensiveness of data collection still has some limitations.

Acknowledgements

This work was supported by the National Natural Science Foundation of China (No. 81902233, 81874030), Innovation-Driven Project of Central South university (No. 2020CX045), the Key program of Health Commission of Hunan Province (20201902) and CMA-Young and Middle-aged Doctors Outstanding Development Program-Osteoporosis Specialized Scientific Research Fund Project (G-X-2019-1107-12).

Disclosure of conflict of interest

None.

Address correspondence to: Dr. Yu-Sheng Li, Department of Orthopaedics, Xiangya Hospital, Central South University, Changsha, Hunan, P. R. China. E-mail: liyusheng@csu.edu.cn; Drs. Wen-Tao Liu and Xiao-Ming Zhang, Department of Bone and Joint, Shenzhen People's Hospital, Shenzhen 518020, Guangdong, P. R. China. E-mail: 469590520@qq.com (WTL); 215529049@qq.com (XMZ)

References

[1] Kesemenli CC, Tosun B and Kim NS. A comparison of intramedullary nailing and plate-screw fixation in the treatment for ipsilateral fracture of the hip and femoral shaft. Musculoskelet Surg 2012; 96: 117-124.

[2] Sekimpi P, Okike K, Zirkle L and Jawa A. Femoral fracture fixation in developing countries: an evaluation of the Surgical Implant Generation Network (SIGN) intramedullary nail. J Bone Joint Surg Am 2011; 93: 1811-1818.

[3] Liu Y, Tao R, Liu F, Wang Y, Zhou Z, Cao Y and Wang H. Mid-term outcomes after intramedullary fixation of peritrochanteric femoral fractures using the new proximal femoral nail antirotation (PFNA). Injury 2010; 41: 810-817.

[4] Andrzejewski K, Panasiuk M, Grzegorzewski A and Synder M. Comparison of knee function in patients with a healed fracture of the femoral shaft fixed with retrograde and antegrade intramedullary nailing. Ortop Traumatol Rehabil 2013; 15: 395-405.

[5] Cameron CD, Meek RN, Blachut PA, O'Brien PJ and Pate GC. Intramedullary nailing of the femoral shaft: a prospective, randomized study. J Orthop Trauma 2014; 28 Suppl 8: S11-14.

[6] Vaidya R, Anderson B, Elbanna A, Colen R, Hoard D and Sethi A. CT scanogram for limb length discrepancy in comminuted femoral shaft fractures following IM nailing. Injury 2012; 43: 1176-1181.

[7] Harris I, Hatfield A and Walton J. Assessing leg length discrepancy after femoral fracture: clinical examination or computed tomography? ANZ J Surg 2005; 75: 319-321.

[8] Xu H, Xue Z, Ding H, Qin H and An Z. Callus formation and mineralization after fracture with different fixation techniques: minimally invasive plate osteosynthesis versus open reduction internal fixation. PLoS One 2015; 10: e0140037.

[9] Mehlman CT, Nemeth NM and Glos DL. Antegrade versus retrograde titanium elastic nail fixation of pediatric distal-third femoral-shaft fractures: a mechanical study. J Orthop Trauma 2006; 20: 608-612.

[10] Konstantinidis L, Papaioannou C, Hirschmuller A, Pavlidis T, Schroter S, Sudkamp NP and Helwig P. Effects of muscle-equivalent forces on the biomechanical behavior of proximal femur fracture models: a pilot study on artificial bones. Proc Inst Mech Eng H 2012; 226: 681-685.

[11] Dennis MG, Simon JA, Kummer FJ, Koval KJ and Di Cesare PE. Fixation of periprosthetic femoral shaft fractures: a biomechanical comparison of two techniques. J Orthop Trauma 2001; 15: 177-180.

[12] Lin SJ, Chen CL, Peng KT and Hsu WH. Effect of fragmentary displacement and morphology in the treatment of comminuted femoral shaft fractures with an intramedullary nail. Injury 2014; 45: 752-756.

[13] Gosselin R and Lavaly D. Perkins traction for adult femoral shaft fractures: a report on 53 patients in Sierra Leone. Int Orthop 2007; 31: 697-702.

[14] Bali K, Gahlot N, Aggarwal S and Goni V. Cephalomedullary fixation for femoral neck/intertrochanteric and ipsilateral shaft fractures:

surgical tips and pitfalls. Chin J Traumatol 2013; 16: 40-45.
[15] Xu H, Yin W, Hsu P, Qin H, An Z, Zhang C and Sheng J. Improve the efficiency of surgery for femoral shaft fractures with a novel instrument: a randomized controlled trial. PLoS One 2016; 11: e0154332.
[16] Weber-Spickschen TS, Oszwald M, Westphal R, Krettek C, Wahl F and Gosling T. Development of a fixation device for robot assisted fracture reduction of femoral shaft fractures: a biomechanical study. Technol Health Care 2010; 18: 207-216.
[17] Marsh JL, Slongo TF, Agel J, Broderick JS, Creevey W, DeCoster TA, Prokuski L, Sirkin MS, Ziran B, Henley B and Audige L. Fracture and dislocation classification compendium - 2007: orthopaedic Trauma Association classification, database and outcomes committee. J Orthop Trauma 2007; 21: S1-133.
[18] Zhu ZG, Yu YY, Hou LJ, Gai W and Yang Y. Treatment of femoral shaft fractures by closed reduction and interlocking intramedullary nailing. Zhongguo Gu Shang 2014; 27: 819-822.
[19] Gao Y, Qiao NN, Zhang YH, Lv X and Liu JY. Application of fracture-sustaining reduction frame in closed reduction of femoral shaft fracture. J Orthop Surg Res 2019; 14: 147.
[20] Chen W, Zhang T, Wang J, Liu B, Hou Z and Zhang Y. Minimally invasive treatment of displaced femoral shaft fractures with a rapid reductor and intramedullary nail fixation. Int Orthop 2016; 40: 167-172.
[21] Fan KJ, Chen K, Ma WL, Tian KW, Ye Y, Chen HG, Tang YF and Cai HM. [Treatment of multisegment fracture of complex femoral shaft with instrument-assisted reduction combined with intramedullary interlocking nail fixation]. Zhongguo Gu Shang 2018; 31: 472-476.
[22] Mingo-Robinet J, Valle-Cruz JA, Ortega-Medina L, Fuentes-Ferrer M and Lopez-Duran Stern L. Effect of intramedullary reaming and nailing on the production of growth factors in the femur fracture callus in rats. Rev Esp Cir Ortop Traumatol 2013; 57: 384-390.
[23] Neumann MV, Sudkamp NP and Strohm PC. Management of femoral shaft fractures. Acta Chir Orthop Traumatol Cech 2015; 82: 22-32.
[24] Yun HH, Oh CH and Yi JW. Subtrochanteric femoral fracture during trochanteric nailing for the treatment of femoral shaft fracture. Clin Orthop Surg 2013; 5: 230-234.
[25] Latif A, Mukherjee K, Ranjan AK and Mukhopadhyay KK. The concept of valgus under reduction in fixation of displaced trochanteric femoral fractures with sliding hip screw. J Indian Med Assoc 2013; 111: 833-834.
[26] Wang J, Han W and Lin H. Femoral fracture reduction with a parallel manipulator robot on a traction table. Int J Med Robot 2013; 9: 464-471.
[27] Lin H, Wang JQ and Han W. Parallel manipulator robot assisted femoral fracture reduction on traction table. Conf Proc IEEE Eng Med Biol Soc 2013; 2013: 4847-4850.
[28] Naraghi FF, DeCoster TA, Moneim MS, Miller R and Ferries JS. The reduction clamp: a simple device for closed reduction during intramedullary nailing. Orthop Rev 1994; 23: 611-613.
[29] Wang ZY, Chen K, Tian KW and Ye Y. Application of double joystick technique in reduction-internal fixation for femoral shaft fracture in adults. Zhongguo Gu Shang 2015; 28: 606-608.