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Indian Journal of Animal Sciences **92** (7): 819–824, July 2022/Article
https://doi.org/10.56093/ijans.v92i7.122810

Designing of double-threaded intramedullary pin and evaluation of *ex vivo* biomechanical resistance to axial compression load on the canine long bone fracture gap model

SHRUTI VORA[1], ASHWANI KUMAR[1✉] and KIRANDIP KAUR[1]

Guru Angad Dev Veterinary and Animal Sciences University, Ludhiana, Punjab 141004 India

Received: 30 March 2022; Accepted: 24 May 2022

ABSTRACT

Intramedullary (IM) pinning is a biological method of fracture fixation; but is associated with complications of pin migration, proximal fragment collapse and rotational instability. The study aimed to design double threaded (DT) IM pin and evaluated its biomechanical resistance to axial compression load in comparison to end-threaded (ET) and simple Steinman (SS) IM pin on the canine long bone fracture gap model. The DT IM pin was designed considering various morphometric measurements (17 femur and 8 tibia bones) on lateral radiographs of the routinely done healthy dogs. For *ex vivo* biomechanical study, a distal third fracture was created in the 17 (8 femoral, 9 tibial) canine cadaveric bones. A normograde IM pinning using SS, ET and DT was done keeping atleast 10 mm gap at the fracture site (fracture gap-model). A pin occupying 60-70% of the narrowest medullary canal was used for ET and DT, and >80% for SS models. The bone-implant constructs were subjected to axial compression load (N) till 5 mm displacement of the proximal bone fragment or till dislodgement of the implant using 0.5 mm/min velocity on a servo-hydraulic testing machine. The magnitude of the axial compression load/mm displacement was influenced by the bone (femur vs tibia) and implant types. In femur, the DT pins sustained higher compression loads followed by SS and ET. However, for tibia, the load required was highest with DT followed by ET and SS pin. The study reports the first of its kind indigenously designed biomechanically superior double threaded pin for the canine long bone fracture fixation.

Keywords: Biomechanical, Bone, Canine, Fracture gap model, Innovation, Internal fixation, Intramedullary implant

Dynamic and biological fixation techniques requiring minimal dissection to achieve near normal anatomical fracture reduction are emphasized in literature (Palmer 1999, Hudson *et al.* 2009). The simple Steinmann (SS) pinning is the most primitive and biological method (Beale 2004) for canine long bone fracture fixation and is also simple, easy and economical (Palmer 1999, Stiffler 2004). However, it is also associated with certain inherent complications of pin migration, collapse of the proximal bone fragment, rotational instability and delayed fracture union due to its smooth surface (Kerwin 2014, DeCamp *et al.* 2016).

The end-threaded (ET) pin (Shanz pin) however, shows superior cortical bone holding strength (Degernes *et al.* 1998, Kaur *et al.* 2016, Gill *et al.* 2018) and higher force for removal than the simple pin (Ogurtan 2006). The bone proliferation at the pin insertion point impregnate threads and increases the holding power of ET pins but are prone to bending (Bennet *et al.* 1987). Though, the positive profiled ET self-tapping pin provides excellent stability in long bone fracture of dogs (Channa *et al.* 2018), it limits their intramedullary placement in the retrograde fashion only. The retrograde method of intramedullary pinning is either not preferred (in femoral fractures) or contraindicated (in tibial fractures) (Palmer *et al.*1988, Pardo 1994). Such concerns led to a need to design an innovative, adequately stable, dynamic and cost effective intramedullary (IM) pin that could be placed in a normograde fashion.

Along with biological osteosynthesis, bone and implant with superior biomechanical stability play crucial role in the fracture healing. The proximal smooth portion of the end threaded pin may be customized to augment its hold within the medullary canal of the proximal bone fragment (Kumar *et al.* 2020). This may increase its retention and thus prevent complications such as collapse of the proximal bone fragment, particularly in case of unstable fractures.

Lack of literature on the availability and biomechanical stability of double threaded (DT) IM pin encouraged the authors to plan this study with the objectives to design double threaded intramedullary pin and to test its biomechanical stability to resist axial compression load in comparison to the ET and SS pin on the canine long bone fracture gap model.

Present address: [1]Department of Veterinary Surgery and Radiology, Guru Angad Dev Veterinary and Animal Sciences University, Ludhiana, Punjab. ✉Corresponding author email: drashwanikumar@rediffmail.com

MATERIALS AND METHODS

This study was conducted during the year 2020-22 at the Guru Angad Dev Veterinary and Animal Sciences University, Ludhiana, Punjab, India with latitude and longitude coordinates of 30°89'4.67" N and 75°80'5.47" E.

Objective 1

Radiographic measurements for designing of DT pins: The 25 lateral radiographs (17 femur and 8 tibia) of various dog breeds (10 Labrador, 7 German shepherd, 6 Pug and 2 Beagle) made on computed radiography system (Kodak) were used for measurements using in-built caliper. The total bone length from the greater trochanter to distal most medullary canal (cm), diameter of narrowest medullary canal / isthmus (mm), length of the bone fragment proximal (cm) and distal to the isthmus (cm), largest medullary canal diameter at proximal (mm) and distal (mm) diaphysis were recorded (Fig. 1). The mean of values for small, medium and large breed dogs were calculated and were used for designing.

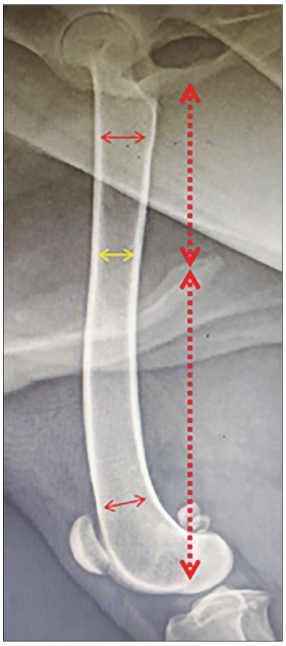

Fig. 1. Radiograph showing various measurements.

Objective 2

Preservation of cadaveric bones: A total of 17 long bones (8 femoral and 9 tibial) were collected from the anatomically normal dogs (≥1 year age and 15-30 kg bodyweight) that were euthanized due to reason(s) unrelated to hind limb disorders and whose cadavers were donated by the pet owners for teaching /research purpose. All bone specimens were isolated and were wrapped in the cotton gauze soaked in normal saline and inj. Gentamicin @ 10 mL/L solution and preserved at the –20ºC until biomechanical testing.

Preparation of bone-pin gap model constructs: The preserved bone specimens were thawed for 12 h at room temperature and were radiographed in lateral view. The medullary canals and total bone length of each bone was measured using inbuilt caliper of CR system. A distal (7 cm) transverse fracture was created using an orthopaedic wire and no bone segment was removed.

The pin size used was 60-70% of the narrowest medullary canal diameter for the ET and DT pins models while it was >80% for SS pin models. The pins were placed in a normograde manner with SS in 5 (2 femur, 3 tibia), ET in 6 (3 tibia, 3 femur) and DT in 6 (3 tibia and 3 femur) bones. While placing SS >80% diameter pin in the femur, one bone had a chip fracture/crack in the proximal fragment. For ET and DT models, paired femur and tibia bones were used. The medullary canal of the proximal fragment was reamed with the smallest to the largest diameter pin (0.5 mm less than that to be used for final fixation). The actual sized pin was placed keeping a gap of 10 mm at the fracture site to create a fracture gap model (Supplementary Fig. 1) simulating an unstable fracture configuration. The post procedure radiographs were obtained to determine the adequate placement and seating of the implant (Fig. 2). The positive profile threaded portion of the DT pin was found lodged at and above the isthmus of the bone.

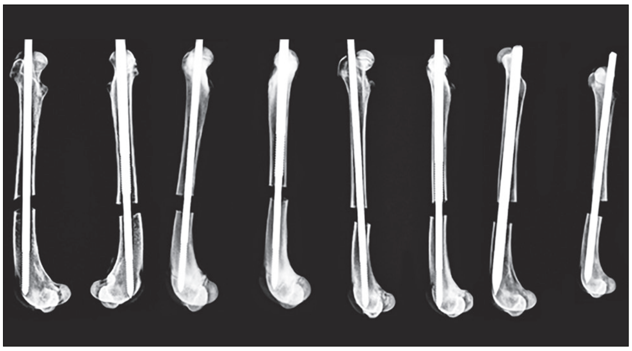

Fig. 2. Post-procedure radiographs of the bone-pin construct in femur fracture gap models.

Biomechanical testing of DT IM pins: The biomechanical stability of the indigenously designed DT IM pins were tested and compared with SS and ET pins on a fracture gap model. The compression test was performed with a universal (servo-hydraulic) testing machine (Model: WDW-S2.5, voltage: 220V/1PHS, power: 800W, Hz: 50Hz, China).

The pin-bone constructs were mounted on a servo-hydraulic machine (Supplementary Fig. 2), under axial loading with the head of femur/tibia in the compression and the condyles seated physiologically. The axial compression load was applied vertically at the 0.5 mm/min velocity rate. In each specimen, preload was kept at 0 N. The maximum load required to produce up to 5 mm displacement of the proximal fragment was recorded. Load verses displacement values were recorded in the form of load-displacement curve to calculate the axial holding of pin to bone strength. Displacement was measured by liner variable differential transformer in the testing machine. None of the constructs were loaded to failure in the axial compression.

Statistical analysis: The results were expressed as mean±standard deviation using Microsoft Excel 2010.

The data were compared for different pins using t- test and paired t-test for ET and DT. The level of significance was tested at $p<0.05$ or 0.01.

RESULTS AND DISCUSSION

Objective 1

The radiographic measurements of the healthy femur and tibia bones are shown in Supplementary Table 1.

Based on the large breed data, the DT pins were designed in a tapering fashion (Fig. 3) considering the isthmus in the proximal third region of the bone. The pin was smooth and thickest at the proximal end with first set of threads (positive profile) at a distance of 10 cm, which was designed so, to remain proximal to the isthmus of the bone (as proximal part was broader). These positive profile (0.75 mm on either side) threads were 3 cm long. The 5 cm central portion of the pin was made smooth as the core diameter of the proximal threaded portion. Distal to it, the negative profile threads (3 cm long) were made. The details of the indigenously designed DT pins (6 and 7 mm diameter) are shown in Table 1 and Fig. 3. The DT pin was designed considering the feasibility to place intramedullary in a normograde fashion, better implant stability and its removal following fracture union.

Objective 2

Evaluation of biomechanical stability of indigenously DT IM Pin: The IM pinning offers a mechanical advantage over other methods of fixation as implants are within the medullary canal near the neutral axis of the bone (Kerwin 2014). The indigenously designed DT pins were tested and analyzed for axial compression load on canine femur and tibia bones and compared with ET and SS pins.

Axial compression test: Among ET implant, the average load required for 2.5, 3.0, 3.5 and 4.0 mm displacement was significantly higher ($p<0.05$) for femoral as compared to the tibial bones (Table 2, Supplementary Fig. 3). Overall, the femoral bone models (irrespective of implant type) required higher compression load as compared to tibia for the same displacement inferring that tibial fractures require more stable fixation in comparison to femur. This can be correlated to the geometrical differences,

Table 1. Dimensions of indigenously designed double threaded intramedullary pin

Parameter		Double threaded pin specifications	
		6 mm × 4.5 mm	7 mm × 5.5 mm
Total length (cm)		21.0	21.0
Negative threaded portion (A)	Length (cm)	3.0	3.0
	Diameter (mm)	4.5	5.5
Distal smooth portion (B)	Length (cm)	5.0	5.0
	Diameter (mm)	4.5	5.5
Positive threaded portion (C)	Length (cm)	3.0	3.0
	Diameter (mm)	6.0	7.0
Proximal smooth portion (D)	Length (cm)	10.0	10.0
	Diameter (mm)	6.0	7.0

Fig. 3. Schematic diagram of designed double threaded pin.

between the femoral and tibial bones, i.e. tapering type tibial bone has marked variation in the medullary canal diameter at the proximal and distal ends including cortical thickness.

No statistical difference was observed between tibial and femoral bone models for DT and SS. However, in the overall groups of DT and SS, the DT implanted models required a significantly higher load for 2.5, 3.0, 3.5 and 4 mm compression compared to SS implanted bone models inferring that the DT pin configuration offers more stable fixation, irrespective of bone type (femur and tibia) in comparison to SS pins; besides, DT required higher compression load to get dislodged for the same displacement.

While comparing the tibial bone-implant models for 3 types of implants (Table 2), it was observed that the DT tibia always showed the lesser displacement at higher load but was statistically non-significant. For the femoral bones also, the findings were similar, where, the most of the time DT femur showed the same displacement at non-significantly higher load. The small sample size and individual variations between the cadaveric bones samples could be the reason for these non-significant differences between various bone-implant constructs; however, it suggests that DT implants are more stable for femoral and tibial fracture repair and can avoid compression of fragments up to a greater load.

For the SS implants in femur bone, it was observed that the SS pins took non-significantly more load up to 2 mm of displacement in comparison to ET pins but, got dislodged at 2.5 mm, while the ET pins dislodged at 4.5 mm. Similarly, between the DT and SS, the SS pins resisted non-significantly more load up to 1 mm displacement in comparison to DT femur; however, later its load started decreasing in comparison to DT. The SS pins used in the fracture gap models were thicker (>80%) which could have led to more resistance to compression load initially followed by loosening of implant at one point due to smooth surface. The DT pins had positive profile threads and thus had a

Table 2. Mean ± SD axial compression load (N) at various displacements on femur and tibia bone-implant constructs

Displacement/ compression (mm)	Axial compression load (N)								
	Femur ET (n=3)	Tibia ET (n=3)	ET overall (n=6)	Femur DT (n=3)	Tibia DT (n=3)	DT overall (n=6)	Femur SS (n=2)	Tibia SS (n=3)	SS overall (n=5)
0.5	88.37±97.36	86.68±69.75	87.52±75.75	70.11±41.27	141.58±81.53	105.85±69.81	150.19±76.83	62.18±40.36	97.38±67.93
1.0	193.97±150.18	124.45±152.66	159.21±140.69	194.55±49.16	218.57±148.56	206.56±99.84	253.78±132.17	63.15±40.52	139.40±126.85
1.5	301.15±158.65	138.13±173.62	219.64±173.49	364.15±63.09	308.41±187.65	336.28±128.88	340.93±148.08	64.38±39.96	175.00±170.95
2.0	409.73±157.45	124.51±153.74	267.12±209.23	529.11±122.78	400.37±212.66	464.74±170.57	419.90±144.39	65.08±39.83	207.01±209.22
2.5	542.26^{a}±176.17	124.77^{a}±153.44	333.52±272.25	599.40±268.87	488.75±277.46	544.07^{e}±251.76	301.02±127.73	65.33±39.55	159.60^{e}±146.72
3.0	640.53^{b}±180.94	124.87^{b}±153.34	382.70±319.80	654.84±410.48	543.54±328.25	599.18^{f}±337.95	334.94±125.70	65.42±39.44	173.23^{f}±174.03
3.5	733.21^{c}±193.60	124.99^{c}±152.20	429.10±367.91	717.69±519.13	541.84±326.77	629.76^{g}±399.73	371.44±227.32	65.47±39.38	187.86^{g}±204.40
4.0	789.80^{d}±207.62	124.96^{d}±153.23	457.38±399.05	766.76±604.01	540.47±324.53	653.62±451.02	410.48±282.53	65.48±39.37	203.48±237.57
4.5	689.68±395.40	124.97±153.22	407.33±409.38	787.26±639.48	517.87±315.53	652.56±474.52	390.66±254.50	65.51±39.33	195.57±220.64
5.0	647.09±540.64	125.18±152.98	333.95±408.03	783.71±633.33	523.13±325.44	653.42±472.42	390.66±254.50	65.51±39.33	195.57±220.64

Values with same superscript in the same row differ significantly from each other at $p<0.05$.

larger pin diameter (>80%) at the proximal end; therefore for the unbiased comparison, the SS pins of similarly higher diameter were used. Out of 17 bone models, one femur bone model with SS pin of >80% diameter had a chip fracture/crack in the proximal fragment. No such complication was observed with DT implants irrespective of bone types inferring superior configuration of the indigenously designed DT pins.

For SS implants in tibial bones, the ET and DT always recorded non-significantly higher load for the same displacement in comparison to SS tibia. Similarly, while comparing the ET and DT implants for femur bone, the ET showed slightly higher load at 0.5 mm displacement but later, the DT implanted femur recorded a higher load in comparison to ET for femur bones. For the tibial bones also, the DT load for each 0.5 mm displacement was non-significantly higher compared to other implants.

The biomechanical results indicated, that the DT implants provide better stability and resists higher axial compression load/mm of displacement for both femur and tibia bones in comparison to ET and SS. Though, the SS can be stable for femur bone in light weight dogs where the load will be less. Keller *et al.* (2019) found higher amount of lateral displacement under axial loading in centrally threaded pins due to its significantly highest breaking strength under cyclic loading conditions than smooth pins; which have a decreased holding power and tends to loosen faster under cyclic loading.

Mean±SD of maximum axial compression load, max displacement (mm) and average load (N)/mm of displacement on femur and tibia bone-implant constructs: The magnitude of the axial compression load/mm displacement was influenced by bone (femur versus tibia) and implant (SS, ET and DT) types. Most of the values remained non-significantly different in various groups which could be due to individual variations in the same type of bone and small sample size (limited availability of the cadaveric dog bones). (Table 3, Supplementary Fig. 4) However, to minimize the error in the biomechanical testing results, paired bones (femur or tibia) from the same dog cadaver were used, each for ET and DT pin. The maximum axial compression load, after which the implant started dislodging, was non-significantly highest for DT pins of femur and tibia followed by ET and SS. Among the bones, the femur bone with ET recorded significantly higher load in comparison to tibia with ET, which may be due to higher compressive strength of femur relative to tibia.

The average load required/mm compression of the fracture line was highest for the femur DT followed by SS and ET. However, for tibial bones the average load required /mm displacement/compression of the proximal fragment was highest for tibia DT followed by tibia ET and SS. This concludes that, for diaphyseal femoral fractures, the DT may provide maximum stability followed by SS and ET. However, for diaphyseal tibial fractures, the DT is maximum stable, followed by the ET and SS. The tibio-tarsus bone has 26% thicker cortex than humerus, which

Table 3. Mean ± SD of maximum axial compression load, max displacement (mm) and average load (N)/ mm of displacement on femur and tibia bone-implant constructs

Parameter	Femur ET (n=3)	Tibia ET (n=3)	ET overall (n=6)	Femur DT (n=3)	Tibia DT (n=3)	DT overall (n=6)	Femur SS (n=2)	Tibia SS (n=3)	SS overall (n=5)
Max axial compression load (N)	796.31±228.84*	178.69±153.23*	473.25±396.62	824.26±608.61	559.62±325.33	691.94±459.90	569.96±57.44	65.49±39.36	267.28±279.19
Max displacement (mm)	4.29±0.47	3.37±2.74	3.33±2.05	3.46±0.95	3.13±0.90	3.30±0.85	3.02±1.50	2.57±1.24	2.75 ±1.18
Average load (N/mm)	183.30±32.48	150.20±166.74	181.00±99.1	221.53±104.18	168.84±80.06	195.18±87.97	209.86±85.15	31.49±25.03	102.84±108.03

Values with same superscript in the same row differ significantly from each other at $p<0.05$.

leads to higher holding strength of tibia than humerus. The thinner cortex of the bone diminishes the influence of threaded pins (Degernes *et al.* 1998).

The study reports the first of its kind indigenously designed double threaded pin for canine long bone fracture fixation. The *ex vivo* biomechanical study proved superior retention of double threaded pin over the end threaded and simple Steinman pin. Further controlled clinical studies on the use of indigenously designed double threaded pin for the long bone fracture fixation in dogs are recommended.

ACKNOWLEDGEMENTS

The authors duly acknowledge the financial support provided by Science and Engineering Research Board (SERB), New Delhi (File no. CRG/2018/002997) dated 5.12.2018 and Guru Angad Dev Veterinary and Animal Sciences University for providing necessary facilities.

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