Tibial diaphyseal fractures managed surgically by interlocking intramedullary nailing: A prospective study

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Abstract

The tibia is by far the commonly fractured long bone in the human body, as it has got a poor soft tissue coverage and its medial surface is almost completely subcutaneous. Tibial diaphyseal fractures are treated surgically by various methods. In the last two decade intramedullary interlocking nailing has emerged as a gold standard in this treatment. The clinical and radiological outcomes have been good and complication rates are relatively low. We prospectively studied 35 cases of tibial diaphyseal fractures treated with intramedullary interlocking nail. Clinical and functional outcomes were assessed by Johner and Wruh’s criteria. As per the Johner and Wruh’s criteria our study established 25.58% of excellent, 48.57% of good and 17.14% of fair clinical and functional outcomes. Only 5.71% of our cases resulted in poor outcome.

Keywords: Tibial diaphyseal fractures, intramedullary interlocking nailing, Johner and Wruh’s criteria

1. Introduction

In view of the subcutaneous nature of the tibial bone, tibial fractures are frequently encountered as a result of high energy trauma. For closed tibial fractures both nailing and plating have reportedly giving similar favorable clinical and functional outcome results [1]. In open tibial fractures the optimum method for skeletal stabilization, in the available literature is controversial. Among the long bone fractures tibial fractures are the most common [2]. Intramedullary nailing has, in the last two decades, become the treatment of choice for displaced diaphyseal fractures of the tibia in adults. A commonly cited complication of this injury being treated by this method is a persistent anterior knee pain [3-23]. One distinct advantage in patients treated with interlocking nailing is their early return to weight bearing and work [4-16]. The aim of the present prospective study is to assess diaphyseal tibial fractures which are closed and open, but not beyond the Type II Gustilo Anderson classification, treated with interlocking intramedullary nails. The study shall further aim to deduce the average intervention time, duration of the surgical procedure, average blood loss, average time taken for radiological evidence of sound union and the final functional and clinical outcomes which shall be assessed by the Johner and Wruh’s criteria, at the end of 10 months.

2. Materials and Methods

This prospective study was conducted in Sree Balaji Medical College and Hospital, BIHER, Chromepet Chennai from March 2015 to December 2017 (34 months). The recruitment of patients stopped in February 2017, so that there shall be a minimum follow up period of 10 months.

2.1 Inclusion Criteria

1. Patients in the age group 21 to 45 years were included.
2. All closed fractures and type I and type II open Gustilo Anderson classification, irrespective of fracture pattern were included.
3. Only acute fractures of less than 2 weeks duration were included.
2.2 Exclusion criteria
1. We excluded patients aged less than 21 years of age and more than 45 years of age.
2. Grade III open Gustilo Andersons Fractures were excluded.
3. Fractures due to congenital anomalies and pathological fractures were excluded.

2.3 Implants and Instruments used
A complete set of IL-nails from 28-38cm length available in 7, 8, 9 mm diameter.
An Osteotome, Hammer and Periosteum elevator.
A diamond-tip bone awl.
A V-nail.
An aluminium tissue protector.
A nail-extractor.
Hand/Power drill and drill bits of 3.2mm.
Depth gauge, bone tap and 4.5 mm cortical screw set.
Hexagonal tipped screw drive, tourniquets.
Image intensifier television (IITV).
Flexible Reamer.
Guide wire.

2.4 Description of IL-Nail
A specially constructed IL-nail was used for the purpose in all cases. IL-nail is a hollow, metallic modified clover-leaf nail having a D-shaped platform at its proximal end (head) and a proximal locking hole. It has proximal bent of 20° in antero-posterior direction to compensate for the proximal Herzog's curve within the medullary canal. The nail has a slot along its whole length on the posterior direction which facilitates nail insertion. About 2.5cm above the tip of the nail is a distal locking hole in the antero-posterior direction. A suitable length of the nail is chosen by measuring from the tibial tuberosity to the base of the medial malleolus on the contralateral healthy side. The diameter of the nail is decided according to the size of the medullary canal on the X-ray or by reaming.

2.5 Pre-operative Protocol
All cases were operated within 14 days of the injury. After obtaining anesthetic fitness, patients were initiated on intravenous antibiotics (Ceftriaxone with Sulbactam 4.5g IV BD). Patients on blood thinners had their drugs stopped 3 days prior to surgery. Close intramedullary nailing was done without opening the fracture site and nailing was done with or without reaming.

2.6 Operative Technique
In the operation theatre, under appropriate anesthesia and under aseptic precaution, painting and draping was done. Then a tourniquet was applied and a cautery pad was placed under the posterior proximal part of the contralateral thigh. A 3" long incision was marked on the antero-medial aspect of the tibial tuberosity. The periosteum was incised along the skin incision.

The knee was flexed to more than 90°. A quadrangular flap of bone with its proximal base intact was made just medial to the tibial tuberosity in the anterior tibial cortex with the help of an osteotome. The lid of the bone so formed was inturned so as to form a sort of a hood for the head of the IL-nail underneath it.
Keeping the knee flexed, with the help of a curved awl, the window was tunneled to the medullary canal. A V-nail was used to further smoothen the passage. Reaming was done after inserting guide wire by the flexible reamer. The reaming was begun with an end cutting reamer and subsequently proceeded to a larger reamer diameter in increments of 5mm. The soft tissues were protected at the entry site during this process with a reamer sleeve or suitable retractors. It was important not to force the reamer while advancing and it’s advisable to intermittently pull it back and forth a little, in order to clear the debris from the medullary canal.

The IL nail was introduced over guide wire with its eye anteriorly and the slot kept posteriorly. The fracture was closely reduced under C-Arm guidance and the nail was negotiated into the distal fragment with the gentle taps of the hammer over the nail head, keeping the nail dead parallel to the axis of the limb. Impaction was done, by padded gentle strokes over the heel. In comminuted segmental fracture with a large butterfly fragments, joysticks (Schantz screw on a T-handle chuck) are placed into the proximal and distal fragments to negotiate the pathway for the guidewire. Alternatively, a large distractor was placed in the coronal plane which lies posterior to the tibia, either laterally or medially so that they do not obstruct the imaging of the locking screw while imaging. Percutaneous pointed reduction forceps were sometimes used in oblique or spiral fractures. Slightly bending the guidewire 10 to 15mm above its tip is helpful for two reasons- it helps in passing through the fracture site into the distal fragments as the rotation of the guidewire redirects its tip. Further, it also facilitates the proper positioning of the tip in the distal metaphysis.

Even though nail length was estimated pre-operatively but intra-operative measurement is more precise. For this a radiographic ruler was used. With the fracture reduced, the distance from the planned nail entry site to just above the ankle joint was measured. The nail diameter was large enough to provide sufficient strength and durability to both nail and locking screws. If a 10mm nail was supposed to be a used, reaming was done 0.5mm to 1mm greater than the nail diameter. This is because the medullary canal is not perfectly straight.
With adequate reduction and sufficient over-reaming, a cannulated nail was inserted over the guidewire either manually by hand or with gentle hammering. It is pertinent to ensure that the proximal end of the nail was sufficiently below the bone entry point in order to decrease the risk of anterior knee pain. The tip of the nail was placed in the center of the distal tibia approximately at the level of the physeal scar. Once the appropriate length of the nail was inserted, proximal locking screws are inserted first and then the insertion handle was removed. After this, the knee is extended and distal locking is performed under fluoroscopic guidance using the instrumentation jig or free hand under C-Arm guidance. An appropriate length of 4.5 mm cortical screw was used for locking. Typically, 2 distal locking screws were used for a diaphyseal fracture.

Fracture distraction interferes with healing and must be meticulously eliminated. Distraction was corrected by locking the nail distally and then “back slapping” the nail by strokes at the heel in which case the distal locking screws were inserted first.

After removal of the insertion handle and the connecting screw, an end cap was inserted to prevent ingrowth of bony tissue which would otherwise interfere with nail removal. Wound closure was done after repairing the patellar tendon and its para-tenon with interrupted sutures, if they had been incised. Skin and subcutaneous tissue was closed with vicryl. A soft sterile dressing was then applied in such a way that knee movement were not interfered with. Compression bandage was applied after tourniquet release.

### 2.7 Immediate post-op protocol
The limb was kept elevated at all times and active toe movements were encouraged from POD 1. The patient was observed for active toe and ankle movements. Pre-operative parenteral antibiotics were continued for 5 days and then changed to oral Linezolid 600 mg twice daily until sutures were removed. The first dressing was done on POD 3. If suture line was clean, sutures were removed on POD 12 under aseptic precaution. The compression bandage was removed intermittently and active knee and ankle mobilization were started from POD 3. Partial weight bearing with a walker was initiated from POD 5. Advice regarding full weight-bearing was given on the basis of pain the geometry of the fracture stability of the fracture fixation from 12th week onwards.
2.8 Follow-up and Evaluation
The patient was followed up at 4 weeks, 8 weeks, 12 weeks, 16 weeks, 20 weeks, 6 months and then at 10 months. Check X-rays are taken at every visit and the patient was assessed clinically and radiologically for evidence of fracture union. Pain, deformity, shortening and range of movement of knee, ankle and sub-talar joints and evidence of radiological union were noted. Any complications like screw breakage, nail bending, non-union, limp, anterior knee pain and infections were also noted. Appropriate treatment for complications was given. The functional outcome was tabulated as excellent, good, fair or poor using Johner and Wruh's criteria (Table 1).

Table 1: Johner and Wruh’s Criteria

| Criteria                          | Excellent | Good | Fair | Poor |
|----------------------------------|-----------|------|------|------|
| Nonunion/infection               | None      | None | None | Yes  |
| Neurovascular injury             | None      | Minimal | Moderate | Severe |
| Deformity                        | Varus/valgus | None | 2-5* | 6-10* | >10* |
|                                   | procurvatum | 0-5* | 6-10* | 11-20* | >20* |
|                                   | Rotation   | 0-5* | 6-10* | 11-20* | >20* |
|                                   | Shortening | 0-5 mm | 6-10 mm | 11-20 mm | >20 mm |
| Mobility                         | Knee      | Full | >80% | >75% | <75% |
|                                   | Ankle     | Full | >75% | >50% | <50% |
|                                   | Subtalar  | >75% | >50% | <50% |
|                                   | Pain      | None | Occasional | Moderate | Severe |
|                                   | Gait      | Normal | Normal | Mild limp | Significant |
| Activities                       | Strengthen | Possible | Limited | Severely limited | Impossible |
| Study results                    |           | 34 | 6 | 2 | 0 |

3. Results

Table 2: Mode of Injury

| Mode of Injury          | Male (n) | Female (n) | Total(n/% age) |
|-------------------------|----------|------------|----------------|
| RTA                     | 13       | 10         | 23 (65.70%)    |
| Fall from height        | 6        | 2          | 8 (22.86%)     |
| Fall into a well        | 0        | 1          | 1 (2.86%)      |
| Assault                 | 2        | 0          | 2 (5.72%)      |
| Fall from a Horse       | 1        | 0          | 1 (2.86%)      |
| Total                   | 22       | 13         | 35 (100%)      |

Table 3: Age and Sex Distribution

| Age group   | (n/% age distribution) | Sex(n) |
|-------------|------------------------|--------|
|             |                        | Male   | Female |
| 21-25       | 8 (22.86%)             | 6      | 2      |
| 26-30       | 11 (31.43%)            | 7      | 4      |
| 31-35       | 6 (17.14%)             | 3      | 3      |
| 36-40       | 6 (17.14%)             | 4      | 2      |
| 41-45       | 4 (11.43%)             | 2      | 2      |
| Total       | 35 (100%)              | 22 (62.85%) | 13 (37.15%) |

Table 4: Type of Fracture Pattern

| Type of Fracture          | (n/% age distribution) | Sex(n) |
|---------------------------|------------------------|--------|
|                           |                        | Male   | Female |
| Closed                    | 5 (14.28%)             | 1      | 4      |
| Gustillo Anderson Type I  | 9 (25.72%)             | 5      | 4      |
| Gustillo Anderson Type II | 21 (60.00%)            | 16     | 5      |
| Total                     | 35                     | 22 (62.85%) | 13 (37.15%) |

Table 5: Time taken for radiological evidence of union

| Period In weeks | Sex (n) | (n/% age distribution) |
|-----------------|---------|------------------------|
|                 | Male    | Female                |
| 14-15           | 3       | 1                      | 4 (11.43%) |
| 16-17           | 6       | 3                      | 9 (25.71%) |
| 18-19           | 7       | 4                      | 11 (31.43%) |
| 20-21           | 4       | 3                      | 7 (20.00%) |
| 21-22           | 2       | 2                      | 4 (11.43%) |
| Total           | 22      | 13                     | 35 (100%) |
We had 35 patients with diaphyseal fracture of tibia treated with closed intra medullary interlocking nailing. There were 62.85% (n=22) male and 37.15% (n=13) female. Minimum age of patients was 21 years and the maximum was 45 years in our study. Average age of patients under our study was 33 years. Majority of the patients came under the age group 26 to 30 years 31.43% (n=11) showed signs of radiological union between 14 to 22 weeks. Majority of the patients (80%) were begun on partial weight bearing between 8 weeks to 10 weeks (n=21) at an average of 8.2 weeks, whilst full weight bearing was initiated between 12 weeks to 14 weeks (11.43% n=7) of injury. Based upon the Johner Wruh’s criteria, we obtained excellent results in 25.58% (n=10) patients, good results in 48.57% (n=17) cases and fair results in 17.14% cases (n=6). We had poor results in 5.71% (n=2) cases, which were due to the complication of shortening of 2.6 cm in one case and valgus of 16 degrees in another. We had as minor complication, superficial infection in 5.71% (n=2) patients, proximal screw breakage in 2.86% (n=1) patient and anterior knee pain in 11.43% (n=4) patients forming a total of 20% (n=7) of patients. There were no patients with deep infection, distal screw breakage, operated leg pain and mal-union in our series. The mean duration of surgery was 82 minutes (range: 70 minutes to 95 minutes). The average blood loss was 75ml (range: 60ml to 90ml), achieved by using local and parenteral tranexamic acid.

### 4. Discussion

| Complications         | Sex (n)   | (n/% age distribution) |
|-----------------------|-----------|------------------------|
|                       | Male      | Female                |
|                       | (n/% age) |                        |
| Superficial Infection | 1         | 1                      | 2 (5.71%)               |
| Deep Infection        | 0         | 0                      | 0                       |
| Proximal Screw Breakage | 1        | 0                      | 1 (2.86%)               |
| Distal Screw breakage | 0         | 0                      | 0                       |
| Anterior Knee Pain    | 2         | 2                      | 4 (11.43%)              |
| Malunion              | 0         | 0                      | 0                       |
| Operated Leg Pain     | 0         | 0                      | 0                       |
| Total                 | 4         | 3                      | 7 (20%)                 |

Table 7b: Major complications (Having an impact on the final functional outcome)

### Table 7A: Minor complications (Not having any impact on the final functional outcome)

| Complications | Sex (n) | (n/% age) |
|---------------|---------|-----------|
|               | Male    | Female    |
| Shortening > 2cm | 1   | 0         | 1 (2.86%) |
| Valgus > 10 degrees | 0 | 1         | 1 (2.86%) |
| Total         | 1       | 1         | 2 (5.72%) |

### Table 6: Outcome analysis as based on the Johner and Wruh’s Criteria

| Period In weeks | Male | Female | (n/% age distribution) |
|-----------------|------|--------|------------------------|
| 14-15           | 3    | 1      | 4 (11.43%) |
| 16-17           | 6    | 3      | 9 (25.71%) |
| 18-19           | 7    | 4      | 11 (31.43%) |
| 20-21           | 4    | 3      | 7 (20.00%) |
| 21-22           | 2    | 2      | 4 (11.43%) |
| Total           | 22   | 13     | 35 (100%) |

Table 8: Comparison of various studies based on sex distribution

| STUDY                        | Sex            | Our Study | Kiran Kumar et al. [49] | Krishna Reddy et al. [50] | Omar Khaled et al. [51] | Ranganathan babu Kurupati et al. [48] | F.A Memon et al. [52] | Yogaraj M Rathwa et al. [53] |
|------------------------------|----------------|-----------|------------------------|--------------------------|------------------------|----------------------------------------|----------------------|-----------------------------|
| Male % age                   | 62.95          | 88.09     | 70                     | 55.15                    | 91                     | 85                                     | 84                   | 16                          |
| Female % age                 | 37.15          | 11.91     | 30                     | 44.85                    | 9                      | 15                                     | 16                   |                             |

Table 9: Comparison of various studies based on mean age group and average age

| Study                        | Mean age group (in years) | Average age (in years) |
|------------------------------|---------------------------|------------------------|
| Our study                    | 26-30 years               | 33 years               |
| Kiran Kumar et al. [49]      | 21-30 years               | 26.7 years             |
| Omer Khalid Farooq et al. [55] | 31-40 years            | 31.32 years            |
| Ranganathan babu Kurupati et al. [48] | 30-31 years       | 30.5 years             |
Fracture tibia is amongst the commonest long bone fracture. It is now appreciated that simple diaphyseal fractures react differently to plating and to nailing. In plating is employed, absolute stability must be achieved [37]. In contrast, multi-fragmentary fractures can be treated by splinting, providing relative stability either with intramedullary nail, external fixator or bridge plating. Also the fracture of tibia are the most common open fractures [38].

AO principles
- Fracture reduction and fixation to restore anatomical relationships.
- Fracture fixation providing absolute or relative stability.
- Preservation of blood supply to soft tissue and bone by gentle reduction and careful handling.
- Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

Tibial shaft fractures can affect the knee alignment, stability and strength. These fractures especially if open are associated with a high incidence of infection, delayed union, non-union and mal-union [39]. Direct trauma as seen in RTA, is by far the most common mechanism of injury [37].

IM nailing either by patellar tendon splitting or sparing approach, both had a similar incidence of anterior knee pain. In general, tibial shaft fractures are slow to heal. Intramedullary nail fixation remains the treatment of choice for unstable and displaced tibial shaft fractures in the adults. The goals of surgical treatment are to achieve osseous union and to restore length alignment and rotation of the fractured tibia [40]. IM nailing carries the advantage of minimal surgical dissection with appropriate preservation of blood supply to the fracture [41]. Moreover, the surgical implant offers appropriate biomechanical fracture stabilization and acts as a load sharing device, allowing for early post-operative mobilization.

Establishing an accurate starting point continues to play a crucial role for any IM nailing procedure [42]. We had closed the anterior edge of the tibial plateau just medial to the lateral tibial spine. We dissected just adjacent to the patellar tendon (para-tendinous approach). Nailing was always carried out in the semi-extended position, this helps to avoid apex anterior deformities. Reamed nailing allows for placement of larger sized nails, allowing for increased biomechanical stability and potentially improved fracture healing. The purpose of the inter-locking screws in the tibial shaft is to prevent shortening and mal-rotation. The construct allows for sufficient stability to allow for post-operative weight bearing [43].

Our study proves conclusively that good outcomes and reproducible results can be achieved with IM nail fixation of tibial shaft fracture. Anterior knee pain is a commonly reported complication in about 10 to 40% of the patients. Potentially contributing factors may include traumatic and iatrogenic damage to intra-articular structures, injury to infrapatellar branch of the saphenous nerve, thigh muscle weakness secondary to pain related neurovascular reflex inhibition, fat pad fibrosis leading to impingement, reactive patellar tendinitis, bending strain exerted by the nail on the proximal part of the tibial bone and proximal protrusion of the nail. Thus, the cause of the anterior knee pain is multifactorial. Thus, statistically locked reamed IM nails is a gold standard in the treatment of displaced tibial shaft fractures. Favorable union rates above 90% can be achieved by this modality.

In the recent years, surgeons have moved away from plates and external fixators in favour of intra-medullary nails in the treatment of both closed and open tibia diaphyseal fractures [59]. The pooled results from five studies that compare external fixators in favour of IMIL nails showed a reduction in the case of re-operation with nonreamed nails by over one third [60]. When compared with external fixation or casting, IMIL nails also offers the advantages of earlier knee motion, better patient mobility, faster return to work and decreased incidence of mal-uniions. Contraindications to nailing include tibial fractures in skeletally immature patients with open physes and in adult patients with very narrow or non-existing intramedullary canals (e.g. osteopetrosis). Tibia fractures result from high energy injury and often have large bone defects. This loss may occur at the time of primary injury on during subsequent surgical debriement. Mechanical stability

### Table 10: Comparison of various studies based on time taken for full weight bearing after fixation

| Study                  | Average Full weight bearing in weeks | Range in weeks |
|------------------------|--------------------------------------|----------------|
| Our study              | 13.6 weeks                           | 12-14 weeks    |
| Krishna Reddy et al. [56] | 8.5 weeks                            | 7-10 weeks     |
| Ranganathan babu Kurupati et al. [48] | 10 weeks                           | 8-12 weeks     |
| Naveen Chauhan et al. [50] | 18 weeks                           | 16-20 weeks    |

### Table 11: Comparison of various studies based on average time taken for attaining union

| Study-Union Time       | Average duration | Range in weeks |
|------------------------|------------------|----------------|
| Our study              | 18.2 weeks       | 14-22 weeks    |
| Ahmed Adnan Karaarslan et al. [54] | 22 weeks       | 17-27 weeks    |
| Ranganathan babu Kurupati et al. [48] | 17.36 weeks   | 14-28 weeks    |
| Naveen Chauhan et al. [50] | 20 weeks       | 16-26 weeks    |
| Atine Ekland. [58]     | 16 weeks         | 12-22 weeks    |
| Court Brown et al. [4] | 16.7 weeks       | 17-25 weeks    |

### Table 12: Comparison of various studies based on commonly seen complications

| Complication             | Our study % age | Kiran Kumar et al; % age [49] | Krishna Reddy et al; % age [46] | Ranganathan babu Kurupati et al; % age [48] | Naveen Chauhan et al; % age [50] | Yogaraj M Rathwa et al. % age [82] | Steinberg E.L. et al. % age [51] | Gregory P et al.; % age [18] |
|--------------------------|-----------------|-------------------------------|-------------------------------|--------------------------------------|-------------------------------|----------------------------------|-------------------------------|-----------------------------|
| Superficial infection    | 5.71            | 7.14                          | 10                           | 6.66                                 | 12.56                         | 3.7                              | 7.7                           | 3.97                        |
| Valgus                   | 2.86            | 6.54                          | 3.6                          | 8.99                                 | 10                            | 4.6                              | 7.66                         | 3.96                        |
| Shortening               | 2.86            | 4.22                          | 3.2                          | 3.77                                 | 2.4                           | 3.42                             | 2.76                         | 2.7                         |
| Anterior knee Pain       | 11.43           | 7.14                          | 24                           | 26                                   | 10                            | 28                               | 7.89                         | 8.99                        |
of the tibia must be restored at the time of initial treatment. The current preferred method of stabilization for open tibial fractures is a statically locked IMIL nail [61]. The IMIL nail allows for stability in the face of large bone defects and can be inserted into the tibia with minimal insult to the surrounding soft tissue. However, studies suggested that up to 66% of the cortex in the mid-diaphysis of the tibia are supplied by intramedullary branches of the nutrient artery to the tibia [62]. This had led to a considerable debate regarding the reaming of the canal before insertion of the intramedullary nail. Agreed, that reaming allows for the insertion of a larger intramedullary nail and thereby improves stability, whereas undreamed nailing may spare damage to the intramedullary blood supply. Clinical research has not found a significant difference in fracture healing between the reamed and undreamed IMIL for tibial fracture [63, 64].

5. Conclusion
Tibial diaphyseal fractures are commonly seen in the physically active young people and are most commonly seen in males as a result of road traffic accidents. Interlocking nailing helps to control the length, alignment and rotation preserving periosteal blood supply, allowing callus formation and thus lowering infection rates, non-union and mal-union and can be used in various fracture patterns. Patients are mobilized from the first post-operative day and allowed to resume work early reducing the morbidity and boosting the morale of the patient. Interlocking intramedullary nailing can be regarded as gold standard for diaphyseal fractures of tibia.

Case Illustration
Case 1

![Fig 14 a](image1)
![Fig 14 b](image2)
![Fig 14 c](image3)
![Fig 14 d](image4)
![Fig 14 e](image5)

Fig 14 a: Pre-op.  Fig 14 b: Immediate Post-op.  Fig 14 c: 6 Months follow-up.

Clinical photograph at 6 months follow up showing full ROM at ankle and knee.

Case 2

![Fig 15 a](image6)
![Fig 15 b](image7)
![Fig 15 c](image8)

Fig 15a: Pre-op.  Fig 15b: Immediate Post-op.  Fig 15c: 6 Months follow-up.
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