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A Biomechanical Comparison of Locking Compression Plate Constructs with Plugs/Screws in Osteoporotic Bone Model

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A Biomechanical Comparison of Locking Compression Plate Constructs with Plugs/Screws in Osteoporotic Bone Model

A thesis submitted in partial fulfillment
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BY

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I HEREBY RECOMMEND THAT THE THESIS PREPARED UNDER MY SUPERVISION BY Krishna Parashar Desai ENTITLED A Biomechanical Comparison of Locking Compression Plate Constructs with Plugs/Screws in Osteoporotic Bone Model BE ACCEPTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF Master of Science in Engineering.

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ABSTRACT

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Locking compression plates are proven to be safe for use in open reduction and internal fixation (ORIF) especially in osteoporotic bones. Because of various combinations of holes, the system provides more options for clinicians to use either locking screws or non-locking screws. This clinical research introduces screw like plugs which can be used along with the screws in case of locking compression plates. Experimental work was performed to determine the effectiveness of the plugs. The results showed that there is not a significant difference between the groups which used plugs and did not use the plugs, both in case of axial and torsion test conditions. This study demonstrates the initial work performed on the plugs and further studies are required to examine the effectiveness of constructs. If proven, this technique will contribute towards the treatment of the fracture using Locking Compression Plates and also it will be helpful in designing better locking compression plates with lower stiffness and increased load bearing capability.

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Finally, I would like to thank almighty for the courage and endurance to make this possible.

1

Introduction

There are many medical instrumentation areas which use invasive technology and one of the most common and widely used is, fracture fixation devices. According to International Osteoporotic Foundation, in North America alone, around 40% of US white women and 13% of US white men, aged 50 years will experience at least one clinically apparent fragility fracture in their lifetime. In 2005 in the USA, there were predicted over 2 million fractures costing $17 billion [20]. Also, the most common disease related to bone being Osteoporosis among the people in this age, fixation of these fractures requires more careful consideration and advanced technology, as well as methods. Thus, there is a substantial requirement of new and better medical devices for fracture fixation and continuous research to improve the existing ones.

The process of bone or fracture healing is a complex physiologic process which restores the tissue to its original physical and mechanical properties. It is also influenced by a variety of systemic and local factors. Fracture healing in general occurs in three distinct yet overlapping stages. These are reactive phase, reparative phase and remodeling phase.

1. Reactive Phase

Reactive phase can be divided into fracture and inflammatory phase and granulation tissue formation phases. Immediately after an injury occurs, during the fracture and inflammatory phase, blood cells within the damage tissue start to clot around the injured area and stop the blood from bleeding. During the granulation tissue formation phase, fibroblast starts to infiltrate near the injury area and they form a loose aggregate of cells with capillary sprouts, known as granulation tissue. **Figure 1.1** (a) and (b) show fracture and inflammatory phase and granulation tissue formation phases respectively.

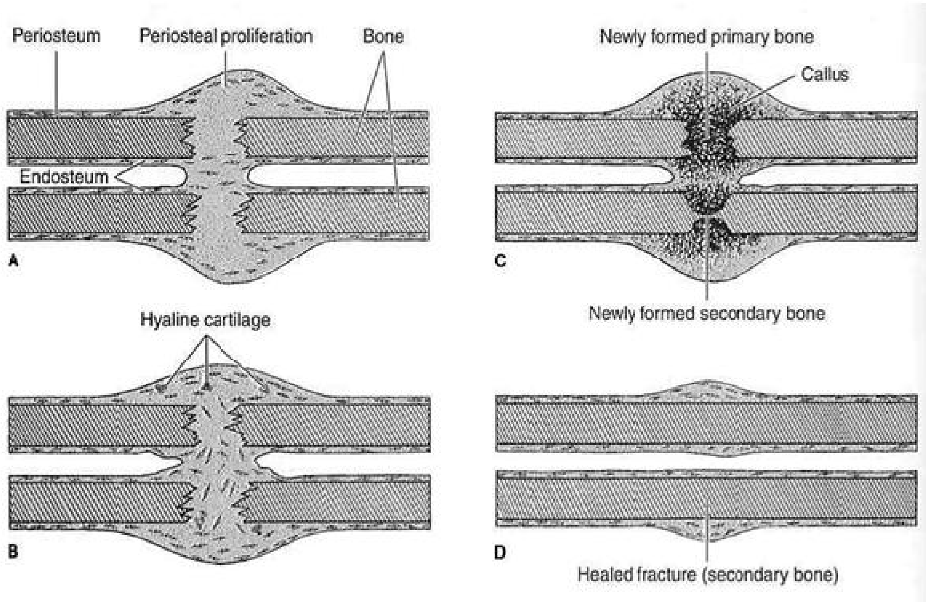


Figure 1.1 Bone Healing Process: (a) Fracture inflammatory stage (b) Granulation tissue formation (c) Reparative phase (d) Remodeling phase [12]

2. Reparative Phase

Reparative phase can be subdivided into callus formation phase and lamellar bone deposition phase. While the granulation tissues are forming, the periosteum starts to replicate. The periosteaum cells proximal to the fracture gap develops into chondroblasts whereas, periosteum cells distal to the fracture develops into osteoblasts and form woven bone. This tissue growth develops new form of fracture bone known as the “fracture callus” and this indicates the end of the callus formation phases. **Figure 1.1** (c) shows callus formation.

Following the phase above; the bony substitution and hyaline cartilage passes through the process known as endochondral ossification and form the lamellar bone. Osteoblasts form the new lamellar bone upon the recently exposed surface of mineralized matrix and start to form trabacular bone which eventually restores the original bone strength. **Figure 1.1 (c)** shows lamellar bone formation. The first sign of cartilage formation is observed on day 15 in humans [31] and it typically takes six weeks to 3 months to complete the entire process.

3. Remodeling Phase

During this phase, the weak trabacular bone is restored to its original shape, structure and mechanical strength. Shallow resorption pits known as "Howship's Lacuna" created by osteoclasts, resorb the trabacular bone and eventually callus is remodeled. **Figure 1.1** (d) shows remodeling phase.

There are many biological and mechanical factors which can either accelerate or hinder the progress of fracture healing. These socio-economical and physiological factors include age, severity of trauma, geometry and location of the fracture, nutritional status and hormonal milieu [6]. Depending on these factors, the need for fracture fixation device (i.e. external, internal or no fixation) is identified. Also, the type of healing varies depending on the method of treatment. This allows us to divide fracture healing process in two broad phases.

1. Primary Healing

Primary healing or direct bone healing, involves direct attempt by the cortex to reestablish itself once it has become interrupted [29]. It does not generally use any biomechanical fixation devices and it takes place when two fracture segments are properly positioned in order to rigidly oppose each other under compression and creates a mechanical environment with minimal inter-fragmentary motion. It is a sequential healing process which starts with the gap healing, while contact healing being the later stage [2].

2. Secondary healing

Secondary healing involves responses in the periosteum and external soft tissues with the subsequent formation of callus. It generally involves the use of either an internal or external fixation devices [3, 4]. These devices include plates, screws, wires, pins, intramedullary nails or rods, bone grafts etc. The majority of fractures heal by secondary fracture healing [29].

Thus, it is very important to control inter-fragmentary motions in order to achieve successful fracture fixation. To achieve this, it is important to understand the relationship between inter-fragmentary movement, bony loading and fixation stiffness.

The biological process of fracture healing involves the development of tissues at the fracture site that reinforces and eventually welds the bone fragments together. This tissue is called callus [30]. Callus can also be a number of different tissue types that may appear during the healing process. In a normal bone healing process, external callus formation is an early stage and also the amount of callus formed, depends on the treatment option used to cure the fracture. In some cases, it is also possible to bypass the callus formation. This can be achieved by fixation devices, usually employing internal fracture plates. In this case, it provides direct bony connection across the fracture site and the healing process can be very rapid. On the other side, it comes with the disadvantages such as risk of infection, loss of bone tissue under the plate and very precise fragment positioning to allow primary healing. **Figure 1.2** shows the spectrum of possible treatment techniques for fracture in different scenarios in terms of desired callus formation and fixator stiffness.

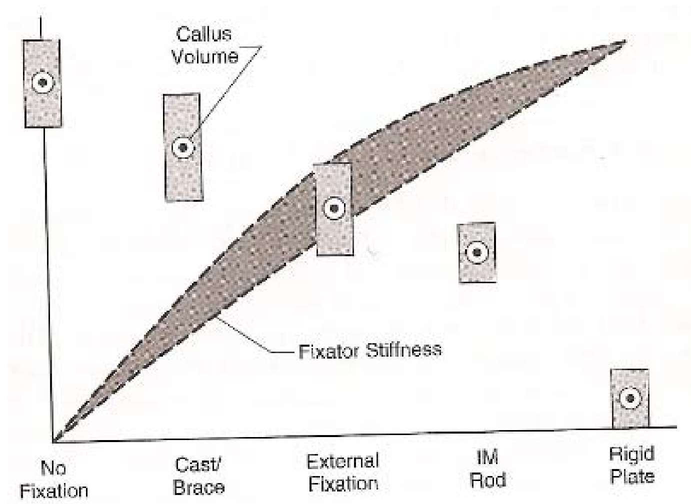


Figure 1.2 Callus volume and stiffness of various fixators [30]

As shown in the graph, “no fixation” and “rigid plates” being at the two extremes of the curve, shows the lowest and highest callus volume formation. Thus, depending on the choice of treatment, one can control the callus volume formation and also the fixator stiffness and thereby inter-fragmentary motion [30].

The presented research work focuses on one of these types of devices, which has received increased attention due to its effectiveness and success in fracture fixation [24, 25, 29]. Locking compression plates, due to its design and combination hole system, has proven to overcome the problems such as axial and angular stability of the construct, vascular damage and screw toggling. Many studies have been conducted on locking compression plates and experimental work also has been performed [11, 21, 22]. But due to the combination hole system, it is difficult to determine the perfect combination of different screws suitable for a particular application. In this study, new screw like plugs are introduced, which has the same physical properties as screws but without the screw length. These plugs are used in combination with locking and non-locking screws and biomechanical evaluation is performed to determine their effectiveness. Synthetic bone models were used to simulate osteoporotic femur bones. Axial and torsion tests were performed to evaluate the behavior in different loading conditions. Finally, statistical analysis was performed on the results and conclusions were drawn.

2

Background

In case of complex or multi-fragmentary fractures, where external fixation fails to provide support, use of internal fixation devices becomes necessary for bone healing. Internal fixation devices share the load with the bone and support it until it is fully healed or can be kept during the entire life time of the recipient. Today, there are many types of internal fixation devices available and one can be used depending on the application. Among all these devices, plates have been widely used as a bridging device for long bone fractures. In early days, the main goal of these devices was to achieve the stable fixation by mean of fracture compression. Non-locked plate osteosynthesis depends on the friction generated between the plate and the bone. In this type of osteosynthesis, screws are advanced in to the bone along a drilled and threaded pilot hole. As the screw head forces the plate onto the bone, potential energy converted to friction between the plate and the bone. This friction creates a load transfer path from the bone to the plate, across the fracture area and back to the bone again. As long as the frictional force exceeds the applied load, the construct remains stable. If the applied load exceeds the frictional force, it causes the screws to begin to toggle. Construct instability starts with screw toggling. [10] Compression plating technique had many disadvantages such as, vascular damage of the soft tissues, pre-contouring of the plate to match the anatomy of the bone and screw toggling. Gradual development in plating techniques led towards overcoming all these shortcomings of conventional plating technique and incorporating the most advanced technologies in fracture fixation in to a single internal fixation device, which is “Locking Compression Plate”.

2.1 Locking Compression Plate

Locking Compression Plate (LCP) is a result of the multilateral collaboration of clinicians, researchers, developers and industry. Locking compression plate has a combination hole system (locking and non locking) which can accommodate both locking and non-locking screws. According to AO (Arbeitsgemeinschaft Osteosunthesetragen – an association for the study of internal fixation) principle, any fracture fixation technique should fulfill following four conditions in order to be considered as a successful fixation device. These conditions include: anatomic reduction, stable fixation, preservation of blood supply and early mobilization. Locking compression plate follows all of these principles as shown in the **Figure 2.1**.

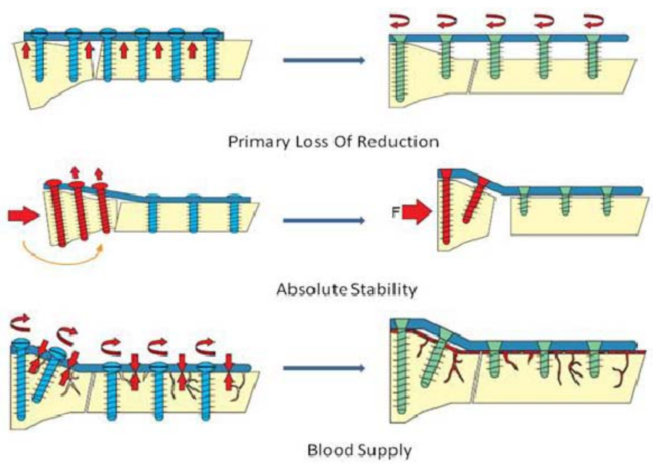


Figure 2.1 Locking compression plate fulfilling AO principles [12]

1. Anatomic reduction

Fixation device should not affect the anatomic structure of the bone by creating unnecessary loads or friction and also help progress the fracture healing by osteosynthesis.

2. Stable fixation

While attached to the bone, fixation should provide both angular stability and axial stability against external loads and movements.

3. Preservation of blood supply

Plate to bone contact area should be kept minimal in order not to interrupt the blood supply to the tissue underneath the plate.

4. Early mobilization

It must create required local mechanical environment to regain the original bone structure as early as possible without the possible inflammation or non-union.

Locking compression plates allow screws to be inserted perpendicular to the plate axis and thus it transmits the axial load over the length of the plate. This minimizes screw toggling and provides angular stability. Also, it is a point contact fixation system and thus it does not compress the plate to the bone and preserves the blood supply. Fixed angle construct and hybrid hole technique help in early callus formation and creates an environment suitable for bone healing and early mobilization.

2.2 Locking Plate Technology and Osteoporotic Bone

The fracture healing process is different in the case of osteoporotic bone compared to the normal bone but the mechanism of fracture healing in osteoporotic bone is not yet clearly identified [6]. Moreover, locking compression plate does not rely on the holding power of the screw for construct stability, providing successful fixation of an osteoporotic bone.

Conventional plating has a high failure rate in osteoporotic bone, classically seen with sequential screw loosening and migration. The thinner cortical bone in elderly also offers low resistance to pull out and toggle even if initial fixation is obtained. Locked plates as the screws are locked in to plate, cannot fail at the individual screw-bone interface level as all the screws have to pull out together with the plate. One more advantage is the smaller pitch of the screws which allows more threads to grasp the inner cortices [16].

Figure 2.2 shows the boundaries where standard and locking compression plates are beneficial. Also the graph depicts change in load to failure with respect to the bone mineral density (BMD). Locking compression plate shows significantly high load at failure compared to standard plating technique for lower bone mineral densities. For higher BMD values there is not a significant difference in load to failure values, in fact these values are lower for LCP compared to standard plates. This shows that it is not cost effective to use LCP over standard plate for normal bone. But it is extremely advantageous for osteoporotic fractures.

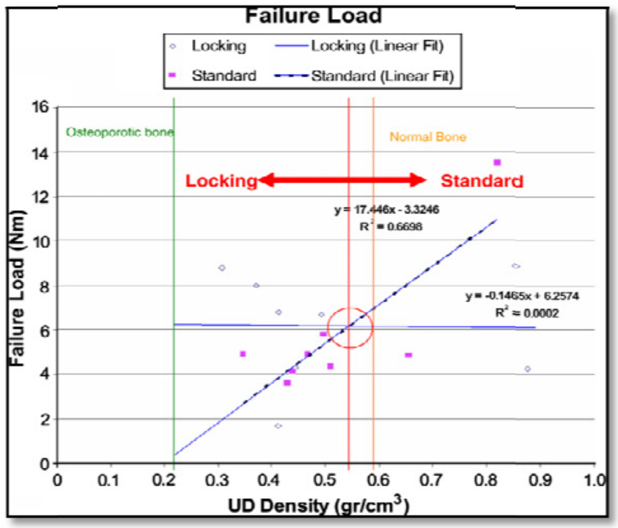


Figure 2.2 Dependency of load to failure on bone mineral density for standard plates and locking compression plates [13]

There is a point in the graph where two lines intersect (red line); this point which is close to the line depicting BMD for healthy bone is the transition point. This means when a person's BMD lies above 0.5 gr/cm^3 (right of the red line), they may be more suited for a standard plate. However, when the patient has a BMD which lies below 0.5 gr/cm^3 (left of the dividing line), the benefit would outweigh the cost and the use of an LCP is recommended. LCPs are not failsafe [16] and are unlikely to be the only solution for osteoporotic fracture management but they certainly offer better therapeutic option than any other extramedullary techniques [16].

Studies show that in majority of the cases where locking compression plates have failed, the underlying problem was the application and practice rather than the technology itself [10]. Most of these failures can be prevented with careful planning, application of the principles and knowledge of the indications and the limitations of the implants and the techniques [16]. There have been many studies conducted and an experimental work has been performed on locking compression plate, which will be discussed in more detail in the next chapter.

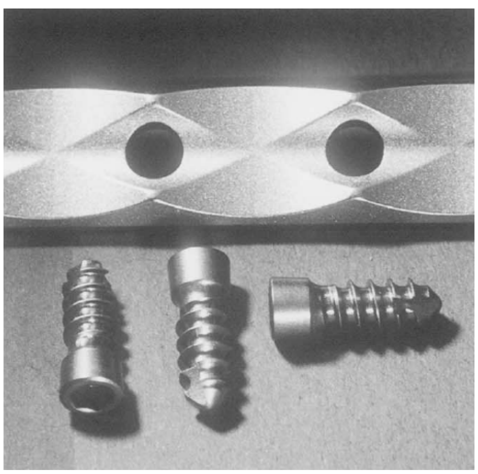
3

Locking Compression Plate

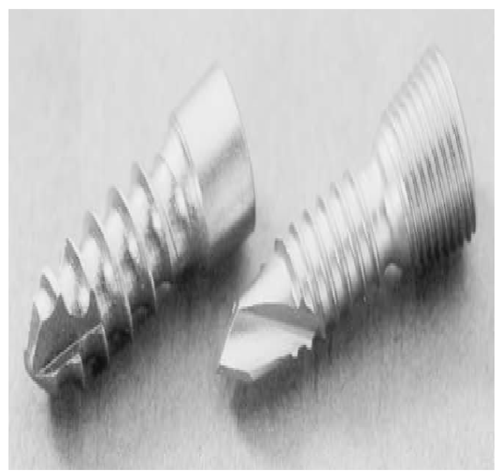
3.1 Evolution of LCP

Among all the types of internal fixation devices, plates can be used in conjunction with screws to cure large bone fractures. Evolution of plate technology started about 110 years ago but initial designs failed due to different reasons such as corrosion and screw sliding between two long slots etc. In 1949, Danis designed the plate that he called ‘Coapteur’ which influenced all subsequent plate designs. It was designed to provide fixation with compression [7]. Based on this compression technique, Schenk Willengegger developed the Dynamic Compression Plate (DCP). Even though DCP proved to be a better alternative to any of the previous plate designs, it required many improvements. DCP did not provide enough rigidity and also, one of the major problems with this type of technique was preservation of blood supply. In order to overcome the problem with the interrupted blood supply, PC-Fix plates were designed. These plates, because of its design, allowed only points of the plate to be in contact with bone and thus helped reduce vascular damage [8, 9].

Later on, so called locked internal fixators (PC fix) were developed which consisted of plate and screw systems where the screws are locked in the plate. This minimized the compressive forces exerted by the plate on to the bone [9]. The contact area was reduced down to point contact as shown in **Figure 3.1.**



(a)



(b)

Figure 3.1 (a) Undersurface of a PC-Fix plate with point-shaped elevations (b) Left: First generation PC-Fix screw; Right: Second generation PC-Fix screw [9]

After PC-Fix, PC-Fix2 was developed which also provided axial stability of the screws along with the angular stability. This was achieved by machining a conical thread in both the screw head and the plate hole. Additional improvement was achieved by creating a new generation of PC-Fix screws with self-drilling and self-tapping tip as shown in **Figure 3.1**. This can be helpful as screw track in the bone is no longer needed to be prepared with drill or tap. With PC-fix device, screws could only be inserted perpendicular to the plate which made it difficult to keep the bone fragments together when away from the plate. Thus, it failed to fully achieve stable fixation and anatomic reduction.

In 1990, a group of doctors from Davos of Switzerland developed the Locking Compression Plate with combined concept of DCP, PC-Fix and LISS (Less Invasive Stabilization System) plate [8, 9]. The locking head screw is captured in the threaded part of the combination hole through more than 200 degrees. This provided angular as well as axial stability of the screw in the plate.

3.2 Locking Plate Technology

Locking compression plate differs from conventional plating in a way that it has a combination hole which can accommodate two different types of screws. One is the conventional non-locking screw and another is the locking screw. Depending on the application, there can be numerous combinations of locked and non-locked screws; those can be used for better fixation and fracture healing. **Figure 3.2** shows the locking compression plate with its combination screw hole system.

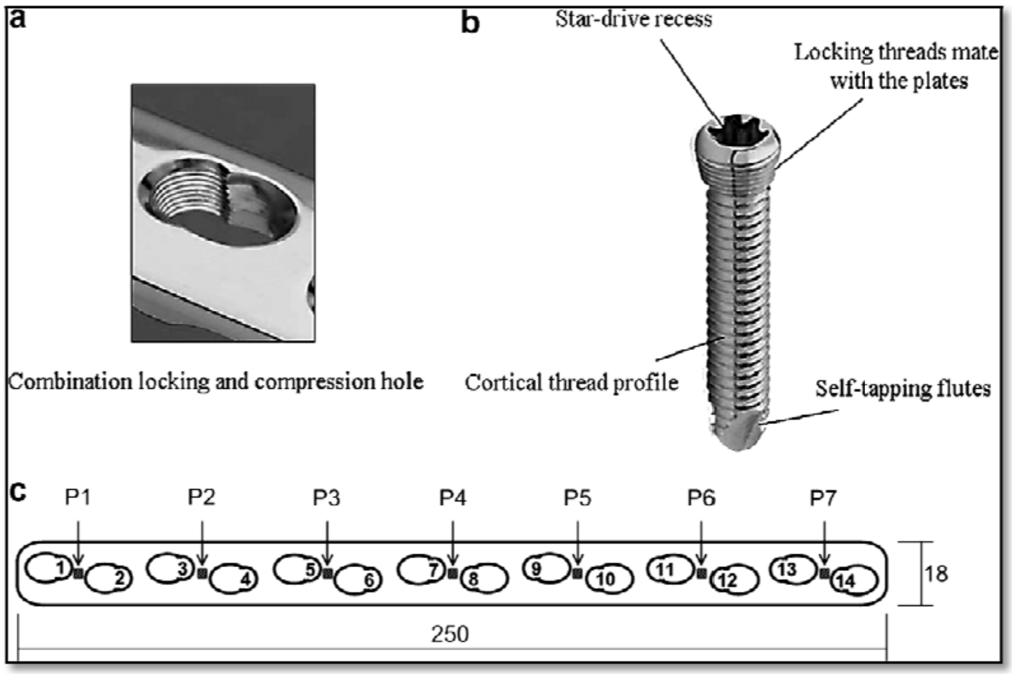


Figure 3.2 (a) Combination locking and compression Hole (b) Locking head screw [11] (c) Locking compression plate (dimension in mm) [11]

Thus, locking compression plate can be applied as conventional, locking or hybrid plate. A combination of both screw types offers the possibility to achieve a synergy of both internal fixation techniques [9]. Four types of screws may be inserted on LCP, standard cancellous screw, standard cortical screw, self-drilling screw and self-tapping screw [13].

Locking head screws provide more angular stability. Also, conventional screws function by pressing the plate to the bone and creating friction at the interface of plate and bone while locking head screws do not press the plate towards the bone. Screws of conventional plate are subject to minimum bending load while locking head screw transfers more bending load.

In a long term, after the healing has occurred because of plate fixation, the bone becomes capable of taking entire load itself, but must share the load with the attached plate. At this time, if the plate is still carrying the substantial part of the load, less bone tissue is needed to carry the remaining load than when it carried the entire load. This might change density and geometry of the bone due to stress shielding of the device [30].

D = device, B = bone

r_D = radius of bone, r_m = radius of rod

ρ_A = ratio of axial stiffness of the device to bone

$$R_A = E_D * A_D / E_B * A_B$$

$$\rho_A = [(E_D/E_B) * (\beta^2 / 1-\beta^2)]$$

Where,

$A_D = \pi \, r_m^2$

$A_B = \pi\,(r_D^{2} - r_m^{2})$

$\beta = r_m / r_D$

Now if $\beta \rightarrow 0$, $r_m = 0$, $\rho_A = 0$

If , $\beta \rightarrow 1$, $r_m = r_D$, $\rho_A =$ infinity

For stiffness of plate to match the stiffness of bone,

$\rho_A = 1$

Thus, $E_D\,\beta^2 = E_B\,(1-\beta^2)$

3.3 Application of Locking Compression Plate

There have been studies conducted to determine the effectiveness of locking compression plate in order to cure different types of fractures [23, 24, 25]. In one of the studies, 30 patients (26 males, 4 females with the mean age of 34) were implanted with locking compression plates for the treatment of diaphyseal comminuted fractures of forearm bones. A 3.5 mm stainless steel LCP was used for internal fixation. As a result of it, all the fractures were united with mean union time 12.6 weeks. Only one case experienced delayed union while not a single case had non-union, implying that LCP is effective in the treatment of comminuted or complex forearm fractures [23].

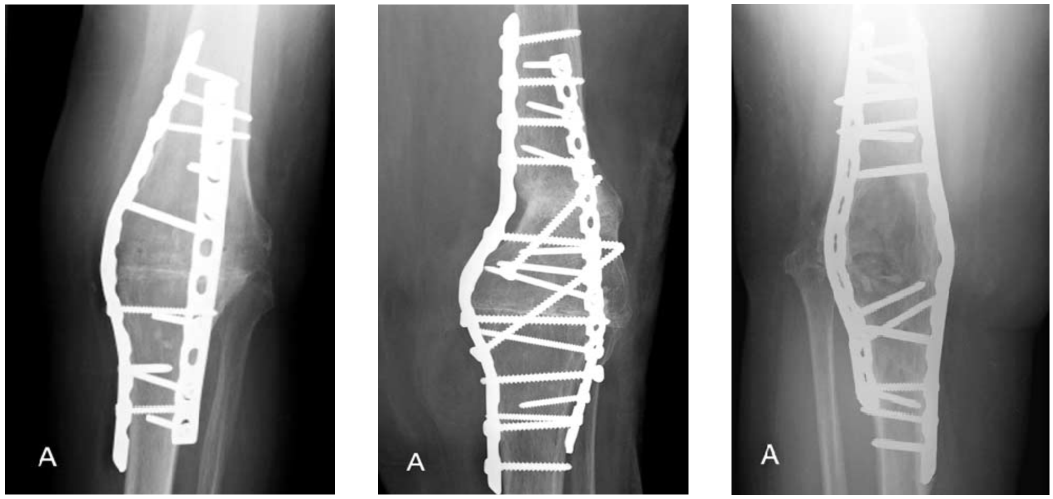
Figure 3.3 shows different bone healing stages after surgery was performed.

(a) (b)

(c) (d)

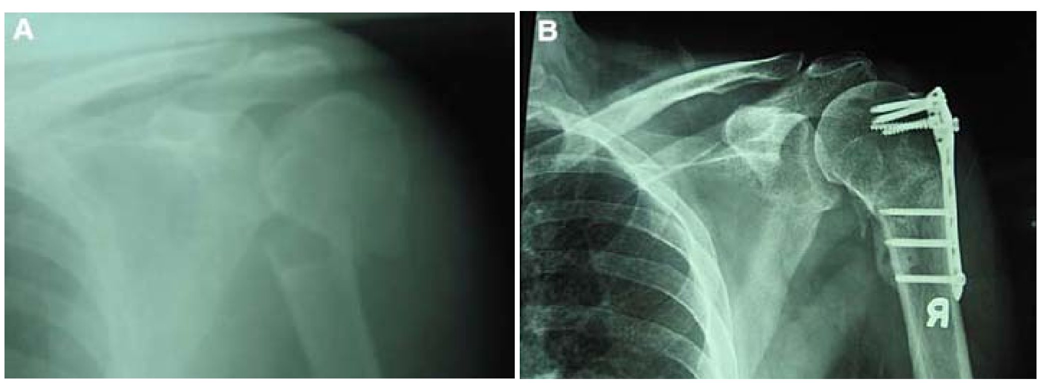
Figure 3.3 Radiographs of a 44 year old man showing (a) Simple Fracture of Both radius and ulna (b) Immediate post operative radiographs (c) Callus formation at 8 weeks (d) Union at 16 weeks [23]

In another scenario, dual locking compression plates were used for knee fusion [24]. Authors described three cases of infected total knee arthroplasties or total knee replacement treated with knee fusion using locking compression plates. All three patients were able to achieve improved functional outcomes and solid arthrodesis. LCP served a dual purpose of locking in to one fragment by using locking screws and achieving compression in the other fragment and thereby enhancing healing of an arthrodesis. Also, it demonstrated better result as a load bearing device under cyclic loading and proved to be an ideal implant for knee fusion [24]. **Figure 3.4** shows the use of dual locking compression plate for the treatment of total knee fusion.



(a) (b) (c)

Figure 3.4 Anterior-posterior radiographs of (a) case 1 (b) case 2 (c) case 3 [24]



(a) (b)

Figure 3.5 (a) fracture in a patient with grade 2 osteoporosis (b) Anteroposterior radiograph of same patient 12 months postoperatively [25]

One of the other most common fractures is the proximal humeral fracture. It is the third most common in the elderly patients [26]. In one of the studies, locking proximal humeral plates (LPHP) were used to treat 25 patients (mean age of 62 years) having proximal humeral comminuted fractures with osteoporosis. A proximal fragment being too small, it is difficult to accommodate minimum of three screws which leads to loosening of screws and loss of reduction with conventional implants. At the end of the study, all fractures united with the average union time of 18 weeks. Even though, there were cases of varus malalignment in two patients, subacromial impingement in another two patients and loosening of implant in one patient, all the fractures reunited without the need of refixation. Here, LPHP offered the advantage of locking head screws, which enter the humeral head at different angles in order to maximize purchase [25]. **Figure 3.5** shows the preoperative and postoperative radiograph of one of the patients.

Thus, by identifying a perfect combination of screws and application methods of them, locking compression plate can be beneficial for the treatment different and almost any types of fractures.

3.4 Biomechanics of Locking Compression Plate

Locking compression plate allows the use of both locking and non-locking screws, which influences its behavior in different scenarios, depending on the choice of screws and application method. Whenever the non-locking screws are used alone, locking compression plate acts as a conventional compression plate. In this case, torque on each screw plays a major role. As shown in **Figure 3.6**, force F1 is generated by tightening screw and compressive force F2 is generated on the bone. Due to these two forces, friction force F3 is generated between bone and plate which leads to stable plate fixation. Plate and screw remain stable until axial force F4 can't exceed friction force F3. The friction force F3 depends on sum of torques on each of the screws. So the axial load F4 is proportional to the sum of torques in each screw. As axial load increases, torque in screws start decreasing, causing screw to toggle and making the fixation unstable [14].

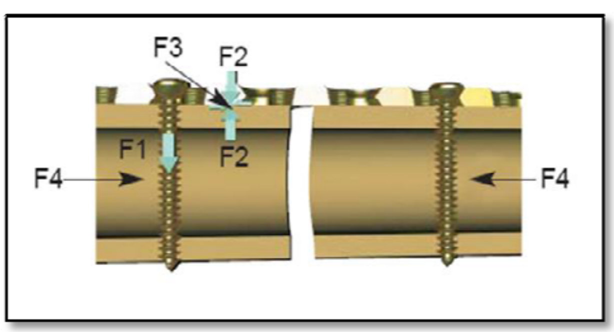


Figure 3.6 Biomechanics of Locking Compression Plate [15]

Where,

F1 = Force to tighten screw in to bone

F2 = Reaction force developed due to force F1

F3 = Friction force between plate and bone due to F2

F4 = Axial load

The pull out strength of a single bone screw in the case of locking compression plate can be given by,

$$F = L * C * S * G$$

Where, F = Pull out force

L = Effective length or length of engagement of the screw

C = Circumference of the screw

S = Shear strength of the bone

G = Geometric parameter (<1)

When locking compression plate is used with the locking screws, it does not compress the plate to the surface of the bone and thus blood supply to the soft tissue is not altered. When used as a hybrid plate, with both locking and non-locking screws, LCP provides compression and stability at the same time. Even though preservation of blood supply is an important factor in fracture healing, there has to be a tradeoff between preserving the biology of the bone and maintaining the stability of the bone-plate construct. Biomechanical stability of the implant also depends upon the distance between the plate and the bone. A study was performed to investigate how the stability of fracture fixation with a non-contact locking plate is affected by increasing the distance between the plate and the bone as compared with the DCP fixation [21]. **Figure 3.7** shows the sample specimens used in the study.

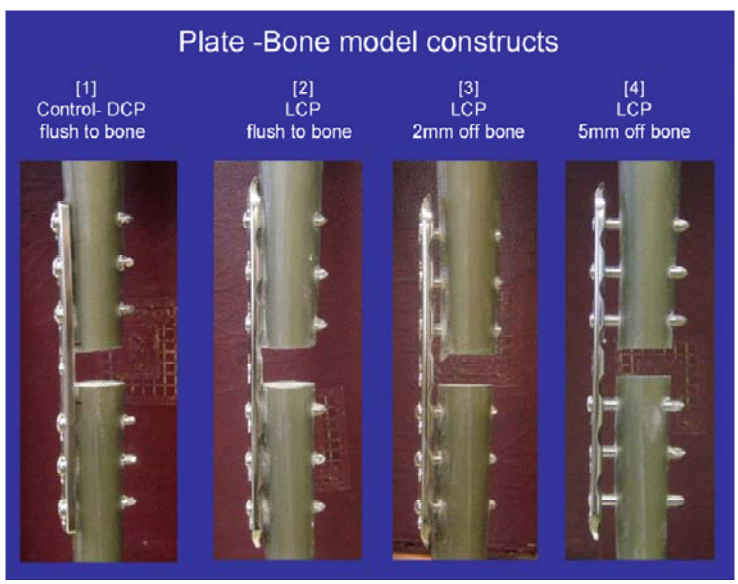


Figure 3.7 Specimen used in the study [21]

Forty eight mechanical testing experiments were conducted on humerus sawbones. The specimens underwent axial and torsion tests, under static and dynamic loading conditions. The results showed that it required higher mean load to fail LCP compared to DCP but as the distance between bone-plate increased in case of LCP, the load required to fail the specimen decreased. Also, during static torsion test, LCP fixed at 5mm showed increased rotational deformity for any given torque applied [21].

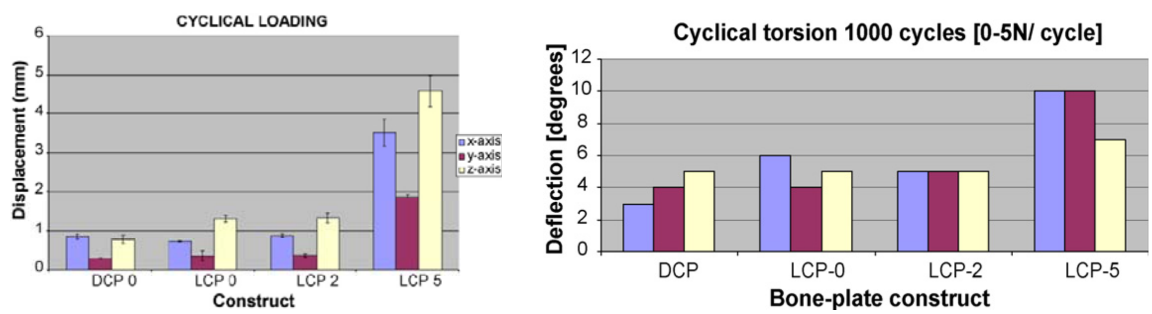


Figure 3.8 Results for Cyclic axial and torsion loading conditions [21]

The results for cyclic axial and torsion loading conditions are shown in the **figure 3.8**. As seen here, the LCP fixed at 5mm showed significant displacement or deflection over any other type of constructs. Thus, we can conclude that LCP behaves in a mechanically similar manner when flushed to the bone or at 2mm distance from the bone. Whereas, placing it at 5mm distance away from the bone, significantly reduces the axial stiffness and torsion rigidity [21].

Stability of locking compression plate does not rely on friction force between the plate and the bone interface as in the case of conventional plate. Also, the strength of locking compression plate is equivalent to the sum of all bone-screw interfaces. This friction force at bone-screw interface develops a shear stress which can be determined by using following equation [33].

$$\tau_{fail} = \frac{P}{As} = \frac{P\ .\ Sut,bone}{2\ .\ At\ .\ Sut,screw}$$

Where,

P = Failure load = Load required to fail the specimen

A_s = Shear stress area = Sum of all screw areas in contact with the bone

A_t = Tensile stress area

S*ut,screw* = Ultimate strength of screw

S*ut,bone* = Ultimate strength of bone

τ_{fail} = Shear stress at failure

Thus, we can conclude that, shear stress at the bone-screw interface and the eventual failure of the construct depends on the failure load and ultimate strengths of screw and bone. Also, the tensile stress area and shear stress areas can be calculated using following equations [33].

$$\text{Tensile stress area, } A_{t,screw} = \frac{\pi}{4}\,(\,D - 0.938194\,.\,p\,)^2$$

$$\text{Shear stress area, } A_s = \frac{2\,.\,At\,.\,Sut,screw}{Sut,bone}$$

Where,

p = pitch of the screw

Thus, as the length of engagement of screws or shear stress area increases shear to failure decreases. But looking at equation for pull out strength of the screw, when shear stress area increases, shear strength of the bone reduces and this again reduces the pull out strength of the screws.

3.5 Disadvantages/Failures of Locking Compression Plate

Studies show that in majority of the cases where locking compression plates have failed, the underlying problem was the application and practice rather than the technology itself [10]. Locking compression plate provides improved stability and preserves blood supply over conventional plating system. As described earlier, it also fulfils all AO principles, to be considered as a successful fracture fixation device. But due to complexity of the design and combination hole system, selection of screws and method of application depending on application becomes difficult. This has led to failures of LCP in few cases [10, 17, 18]. Some of the examples of disadvantages/failures of LCP will be discussed in this section.

Figure 3.9 Failure of locking plate fixation due to improper angle of screw insertion [10]

Locking plates are very sensitive to screw insertion angle. Locking head screws are designed to thread into the locking hole at a fixed angle. If there is a variation in this angle of insertion, it can result in to cross threading the head as shown in **Figure 3.9**. A 26% reduction in the bending load to failure was observed with a 5^{o} deviation from the correct angle of insertion. A 10^{o} deviation decreases load to failure to less than a third of the correctly executed construct [10]. Also, careful technique is required to ensure that the screw is perfectly lined up with the axis of the screw threads in the plate.

LCP does not need to rely on screw threads to generate compression or friction between the plate and the bone [17]. Therefore, pull out strength is lower in a locking screw compared to a standard screw because of decreased thread-bone interface which makes LCP more susceptible to failure when the screws are loaded purely in an axial direction, which is rare in clinical practice [17]. Four cases have been reported where LCP had failed due to axial pull-out while applied to the superior aspect of the clavicle [17].

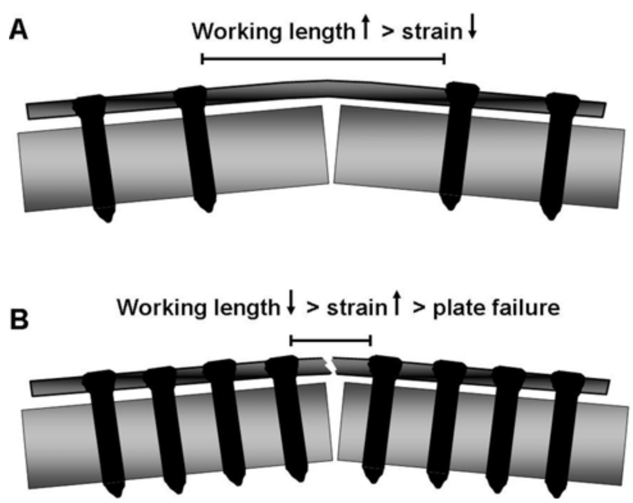


Figure 3.10 Relationship between working length and strain at the fracture level for locked internal fixator [18]

There are many factors which decide the success of the fracture treatment using LCP. Some of them are,

1. Fracture type

2. Plate length & plate working length

3. Screw type and placement

4. Clearance

There are many reported cases in which the failures have occurred due to improper selection for one these factors. For example as shown in **Figure 3.10**, if the plate working length is long that means three or four plate holes are left empty near fracture site, the stress and strain concentration decreases on the plate. If the plate working length is short then, it causes stress and strain concentration points near fracture and ultimately it breaks under axial and torsion loading [18]

In another scenario, nine patients, older than 65 years of age who underwent internal fixation with locking compression plate, had early failure within 4 weeks postoperatively [28]. All failure had occurred due to back out of the plate-screw constructs from the humeral head, leading to varus displacement in eight patients and plate breakage in one. This shows possible failure of the LCP and complications in fracture patterns with missing medial support and also an example of the technical errors during surgery. After revision surgery, which provided tension band wiring to the tuberosities, adequate medial support when the screw did not reach subchondral bone in the head and the bone graft applied in the medial comminution, successful union was achieved in six patients [28].

Thus, combination of conventional plating technique with a locking plate technology also brings with it the risk of improper handling, but correct use of it will offer optimal benefit to the fracture treatment, especially for osteoporotic bones. Further laboratory investigation is required in order to determine when each method should be used alone or in combination with one another and also how other parameters which affect success of LCP, interact with each other, to achieve optimal fracture treatment [12].

4

Biomechanical Experiments

Biomechanical evaluation was performed on synthetic femur bone models with locking compression plates, in order to determine the effectiveness of using plugs, in combination with locking and non-locking screws.

4.1 Experimental Set-up

4.1.1 Materials

Synthetic bone models were used to simulate the actual cadaveric femur bones. These bone models have cortical bone made of a mixture of short glass fibers and epoxy resin pressure injected around a foam core, while cancellous core is made up of solid rigid polyurethane foam. **Table 4.1** shows the typical properties of the simulated bone models.

Table 4.1 Typical properties of composite bones

Simulated Cortical Bone (Short fiber filled epoxy)

	TENSILE		COMPRESSIVE	
DENSITY	STRENGTH	MODULUS	STRENGTH	MODULUS
g/cc	MPa	GPa	MPa	GPa
1.64	106	16.0	157	16.7

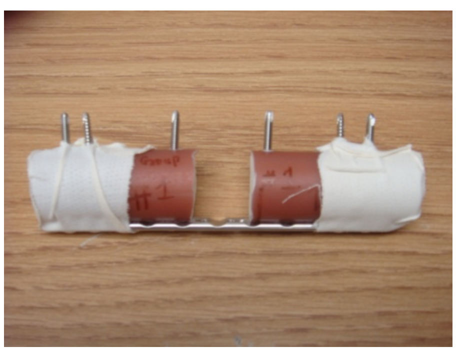
Material property data based on ASTM D-638 and D-695

Simulated Cancellous Bone (Rigid polyurethane bone)

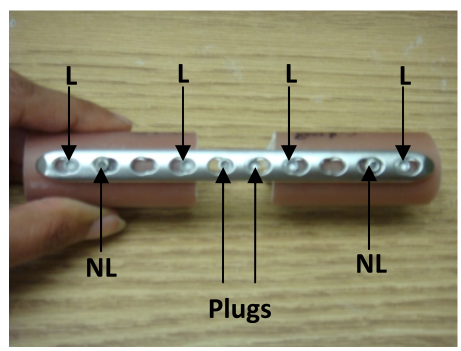
		COMPRESSIVE	
	DENSITY	STRENGTH	MODULUS
	g/cc	MPa	MPa
SOLID	0.27	6.0	155
CELLULAR	0.32	5.4	137

Material property data based on ASTM D-1621

Samples were made using the same surgical techniques which are used in actual surgeries. An example of the sample is shown in the **Figure 4.1**.



(a)



(b)

Figure 4.1 (a) Femur construct for experiments (b) 10 – hole locking compression plate with locking and non-locking screws

* L – Locking screw NL – Non locking screw

Locking compression plates, which were used in this study, were 10-hole large fragment locking compression plates from Synthes. The locking plugs were made out of the same material as screws and **Figure 4.2** shows these plugs used in the study.

Figure 4.2 Locking plugs used in the study

4.1.2 Biomechanical Testing Machine

All the experiments were performed at Miami Valley Hospital, Dayton, Ohio. The tests were performed on an EnduraTec Smart Test Series from BOSE as shown in the **Figure 4.3**.

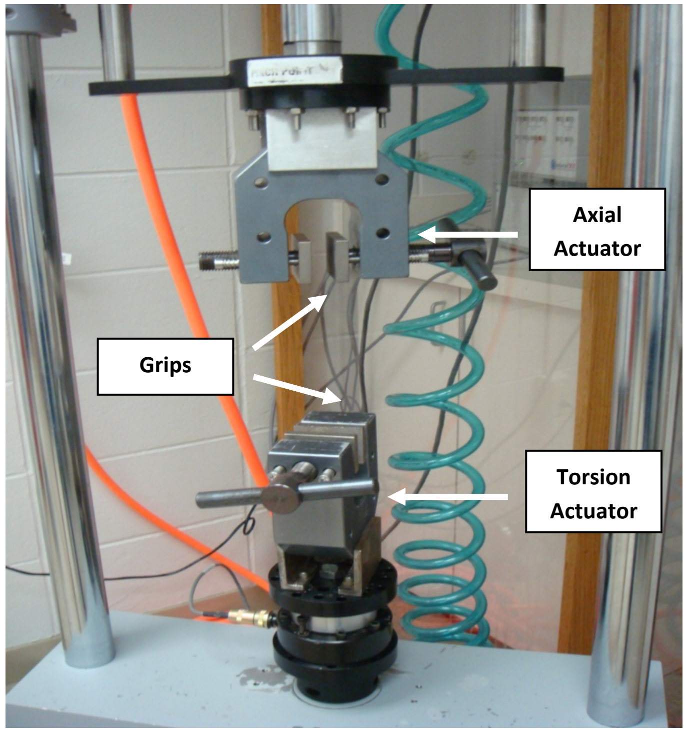


Figure 4.3 EnduraTec Smart Test Series machine from BOSE used for experiments

The machine uses software control system called "Wintest", which allows time control, integrated data control and multi-channel control. The top actuator which is an axial actuator follows axial command, while bottom or torsion actuator follows torsion command. Specimen can be held firmly by using the grips shown in the **Figure 4.3**.

The specimen was placed between the grips such that the bottom surface of the top actuator touches the top surface of the specimen. Also, the tape was used on each ends of the specimen to avoid any kind of slipping while gripping it between the grips. The final set-up of the experiment is shown in the **Figure 4.4**.

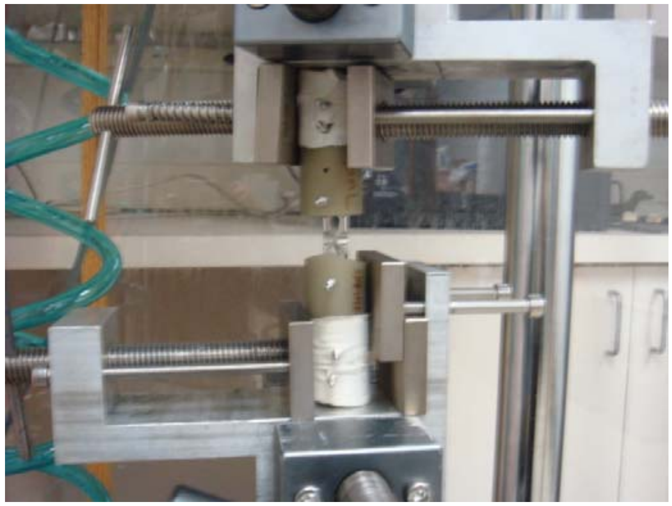


Figure 4.4 Final experimental set up

4.2 Method

Total 24 specimens were tested under axial and torsion loading conditions. **Table 4.2** shows the division of all the specimens in different groups on the basis of testing condition and presence or absence of plugs.

Group		Type of Test	No. of Specimens
Group # 1	Normal	Axial	6

	Control		6
Group # 2	Normal	Torsion	6
	Control		6

Table 4.2 Femur constructs divided into 4 groups

Here, “Normal” group refers to the specimens without the plugs near the fracture gap and “Control” group refers to the ones with the plugs near the fracture gap. For all the specimens, placements of locking and non-locking screws were the same. Screws in plate holes 1, 4, 7, 10 were locking head screws while non-locking screws were used in holes 2 and 9. As locking screws provide more axial and angular stability, they are placed where there is high stress concentration (near osteotomy site and at the two ends). Also, non-locking screws being less expensive compared to locking screws, they were used in the areas which has comparatively lower stress concentration. There were no screws placed at position 3 and 8 while plugs were used in 5 and 6 in case of “Control” group as shown in **Figure 4.5**.

Also, the transverse fracture site was created in a cylindrical shaft of approximately 2cm (20 mm) length while total length of the cylinder was in the range of 12 cm to 13 cm.

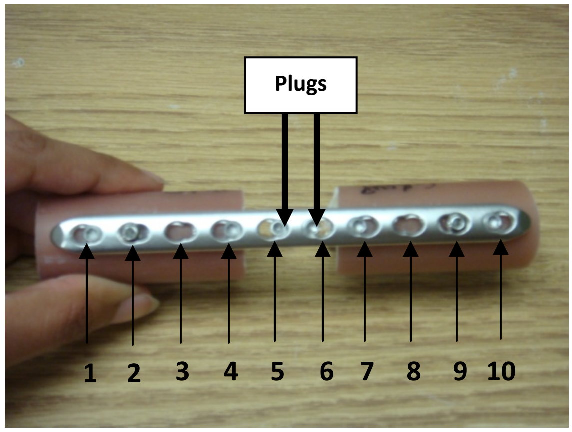


Figure 4.5 Femur construct in a "Control" group

After the specimen was set up in the machine, all the test parameters were set in the system using software called "Wintest". Normal and control group specimens were tested under the same testing conditions for both axial and torsion tests. Test parameters for both axial and torsion tests were as shown in **Table 4.3**.

<table>
<tr><td colspan="2">Type of test</td><td>Testing Parameters</td></tr>
<tr><td rowspan="2">Axial</td><td>Cyclic Test
(Load Controlled)</td><td>Load: -50 N to -350 N (Sin wave)
No. of cycles: 30,000
Frequency: 2 Hz</td></tr>
<tr><td>Load to Failure
(Displacement Controlled)</td><td>Continuously increasing load at
displacement rate of 0.03 mm/sec</td></tr>
<tr><td>Torsion</td><td>Cyclic Test</td><td>Torque: -3 Nm to +3 Nm</td></tr>
</table>

	(Torque Controlled)	No. of cycles: 30,000 Frequency: 2 Hz
	Torque to Failure (Rotation Controlled)	Continuously increasing torque at rotation rate of 0.5 deg/sec

Table 4.3 Testing condition/parameters for axial and torsion test

Each specimen underwent first cyclic loading and then it was loaded to failure. Cyclic loading was performed to simulate the normal walking conditions and load to failure simulated the accidental scenario when failure of the construct occurs. The fatigue test was carried out for 30,000 cycles which simulated 14 to 15 days of walking for a person with fractured femur.

Finally after the test was complete, results were stored as displacement and load values for axial tests and as rotation and torque values for torsion test, over the entire test period.

5

Results

Experimental data was collected while the tests were running using a “Wintest” program. One scan of data points was taken at every 50 cycles having 220 points in each scan. Thus, the data points were collected at approximately less than a quarter of a cycles time period for each cycle. The large data set was reduced to extract only the information of interest. Following sections describe the results for both axial and torsion tests in detail.

5.1 Stiffness Calculation

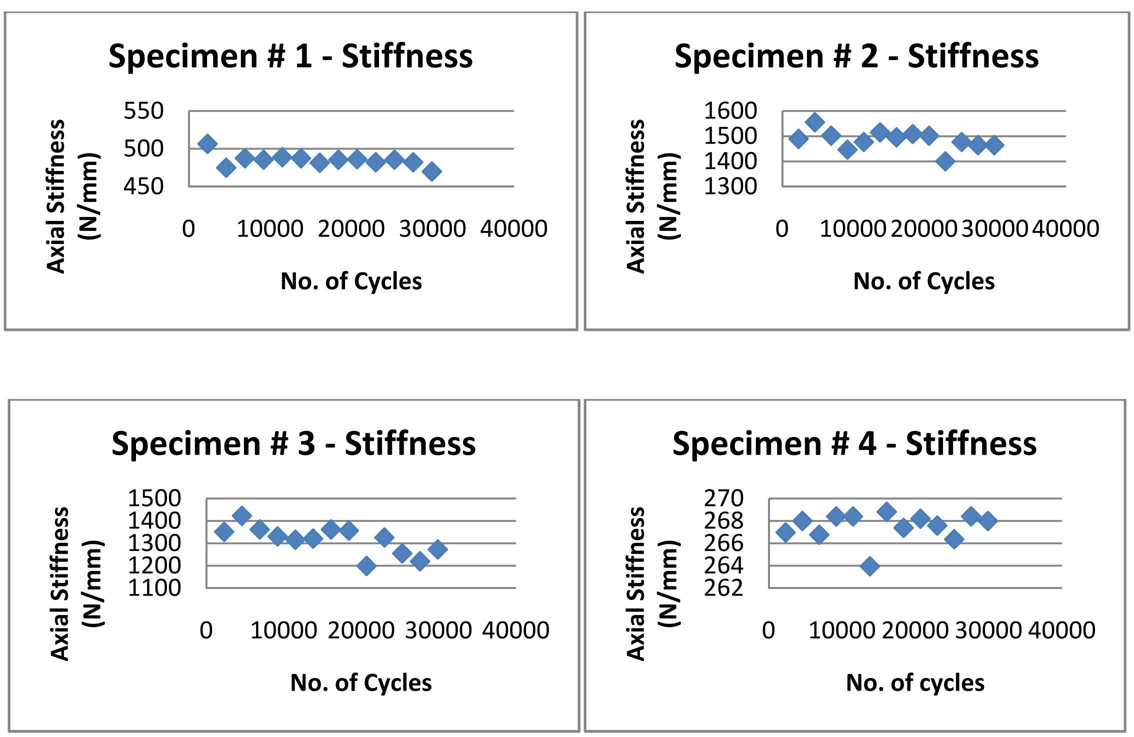
All specimens went through cyclic test either in axial or torsion loading. Using the cyclic loading test data, stiffness was calculated for each specimen. A general expression for calculating stiffness is,

$$\text{Stiffness} = \frac{\text{Constant Load}}{\text{Total displacement due to load}}$$

Here, "Constant load" can be either axial load (in the case of axial test) or torque (in the case of torsion test). To determine total displacement, initial and final positions of the grips were recorded. In case of axial test, axial displacement (mm) was recorded whereas, in the case of torsion test, rotational displacement was measured.

5.1.1 Axial Stiffness

For each specimen in group 1, axial stiffness was calculated at every 2500 cycles and an average of those was determined. Dynamic axial stiffness for each specimen is shown in the **Figure 5.1**.



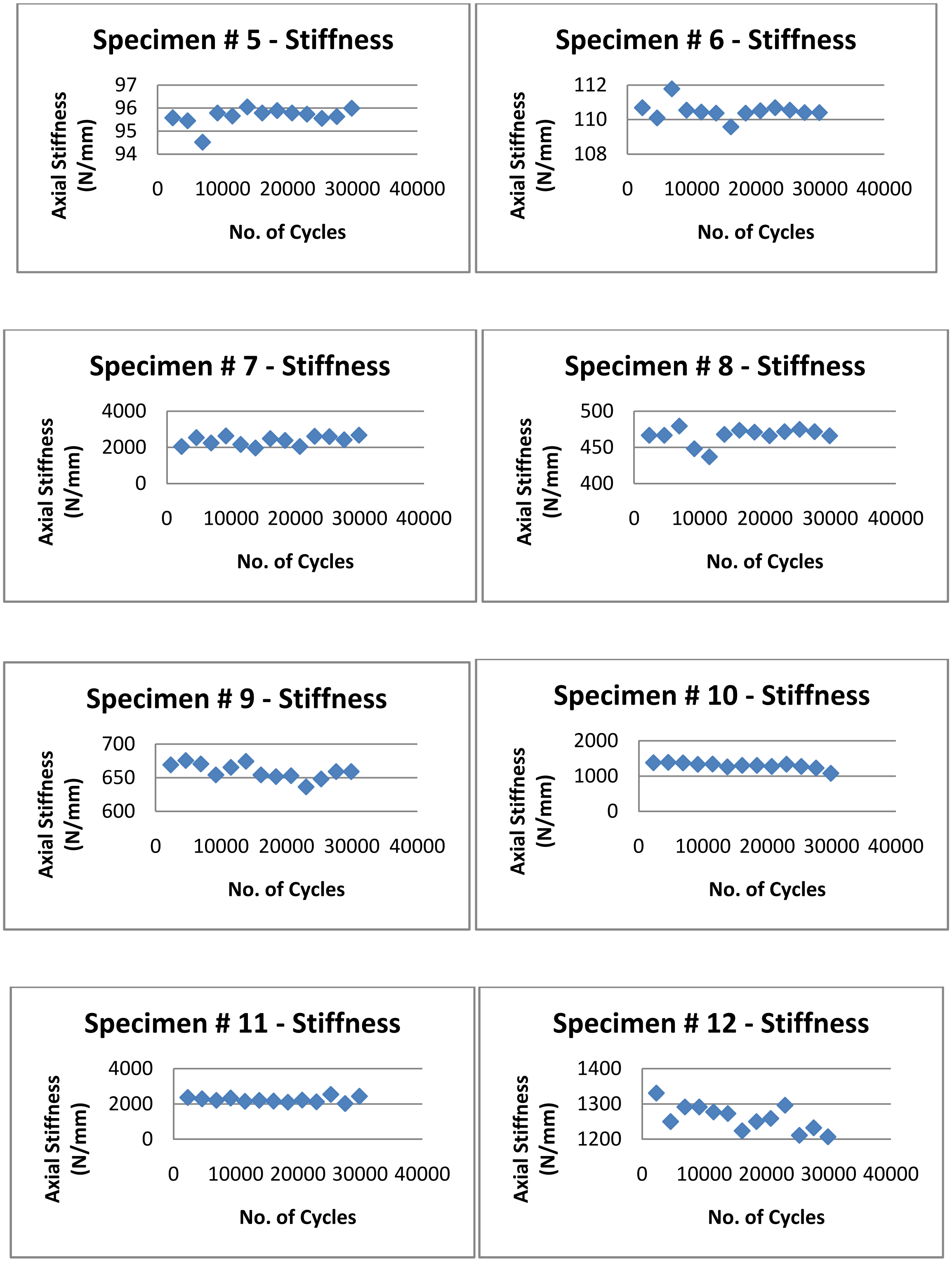


Figure 5.1 Graphs showing Dynamic Axial Stiffness of "Normal" and "Control" groups

Average of all the data points for each specimen was determined and average stiffness was calculated at -350 N. **Table 5.1** and **Table 5.2** show the results for the average axial stiffness of group 1.

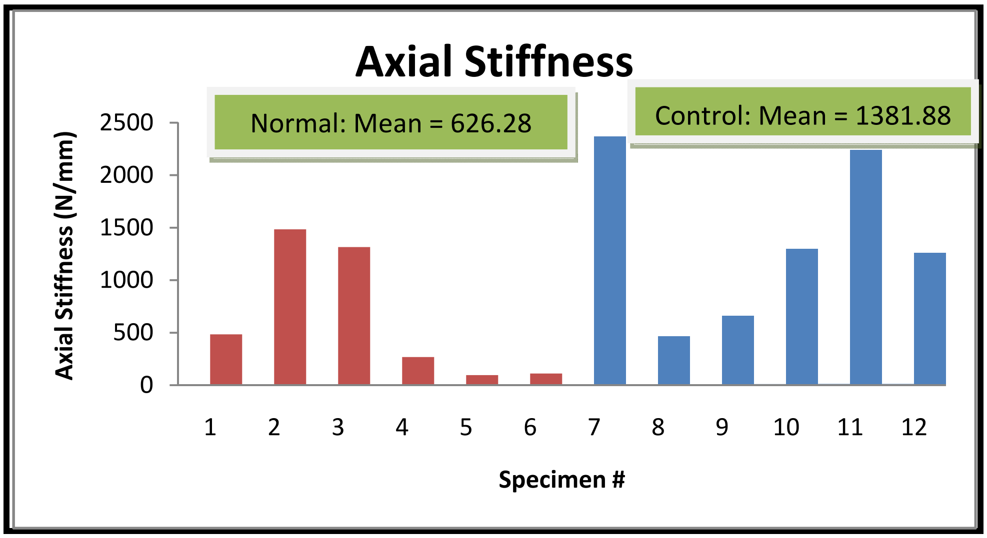
Specimen Number	Axial Stiffness (N/mm)
1	484.85
2	1484.42
3	1314.84
4	267.48
5	95.65
6	110.49

Table 5.1 Axial stiffness for Group 1 – Normal

Specimen Number	Axial Stiffness (N/mm)
7	2368.08
8	466.22
9	659.32
10	1296.824
11	2239.856

12	1261.0265

Table 5.2 Axial stiffness for Group 1 – Control



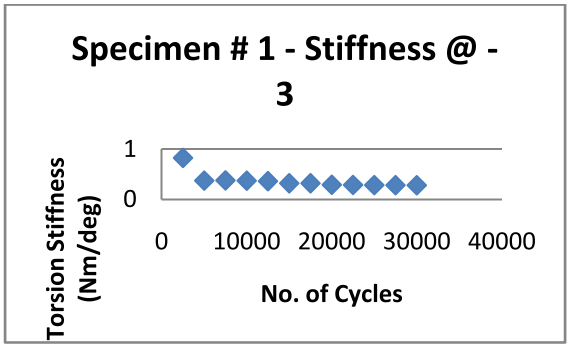
* Specimen# 1-6: Normal, Specimen# 7-12: Control

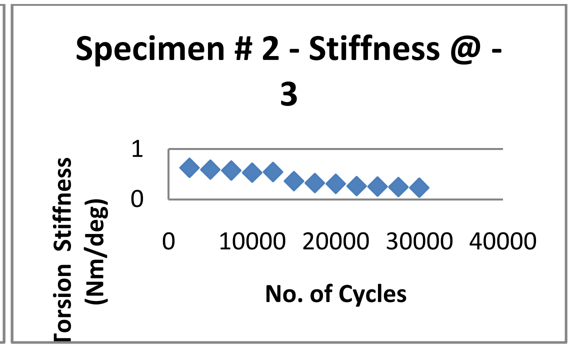
Figure 5.2 A graph of axial stiffness of “Normal” and “Control” groups

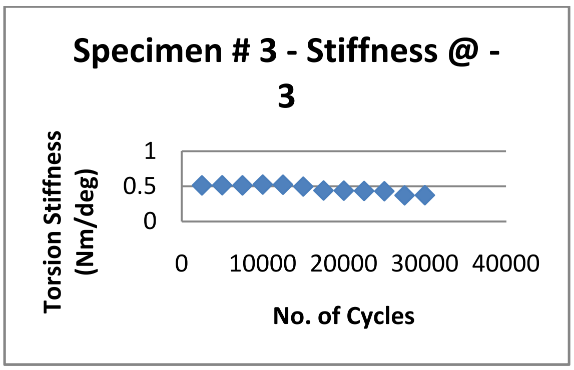
5.1.2 Torsion Stiffness

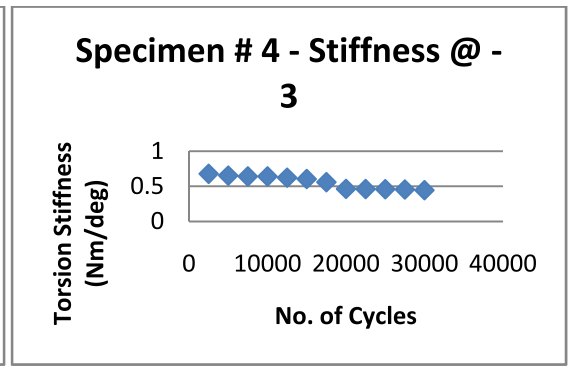
For each specimen in group 2, torsion stiffness was calculated at every 2300 cycles and an average of those was determined. **Figure 5.3** and **Figure**

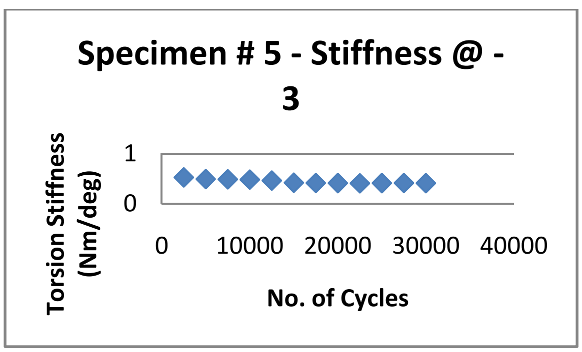
5.4 shows plots of dynamic torsion stiffness calculated at both -3 Nm and +3 Nm respectively, for all specimens.

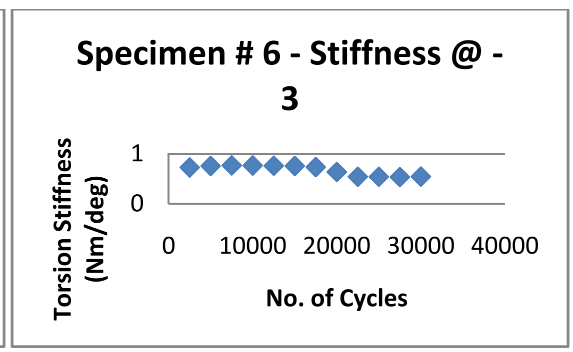












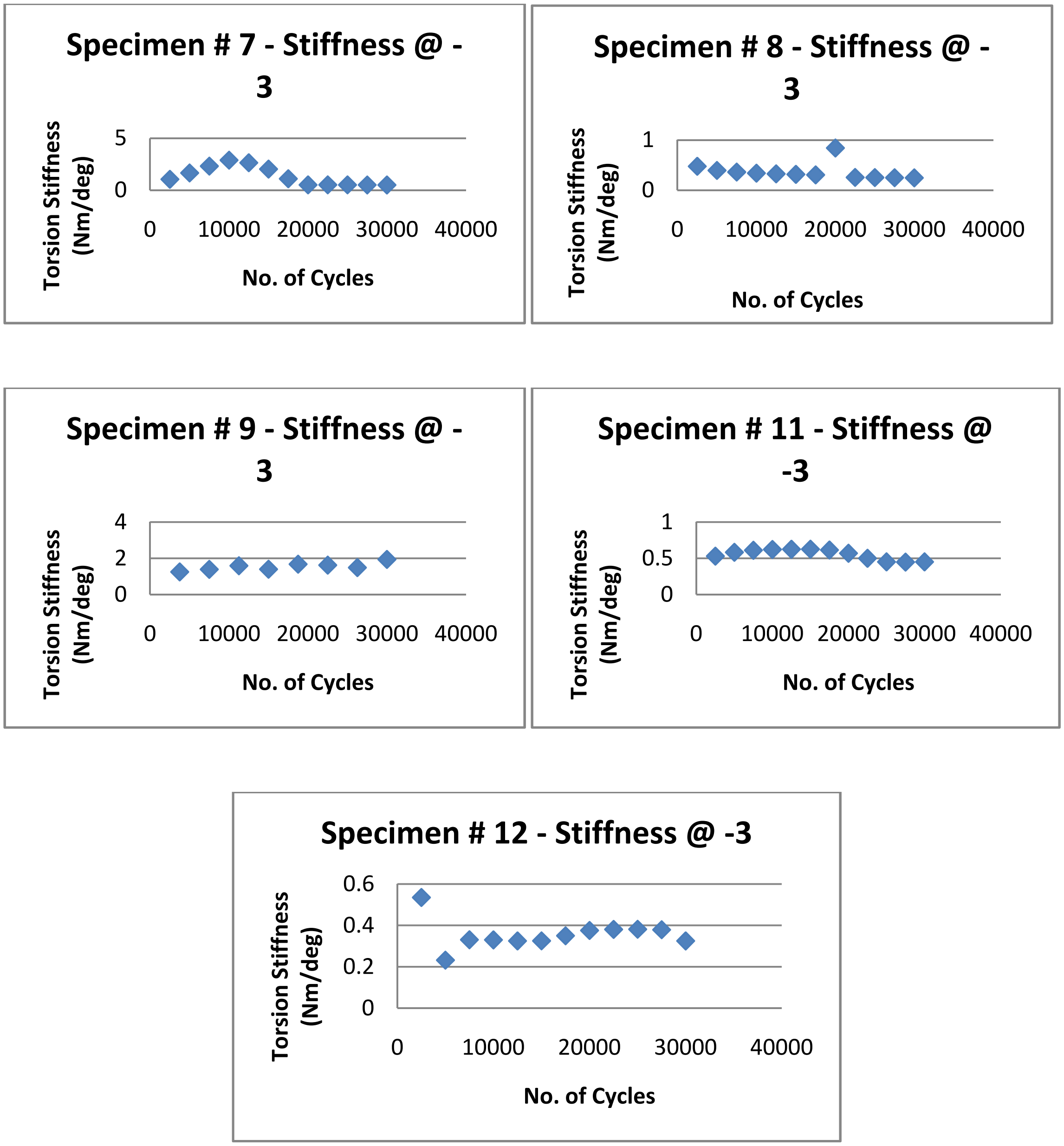
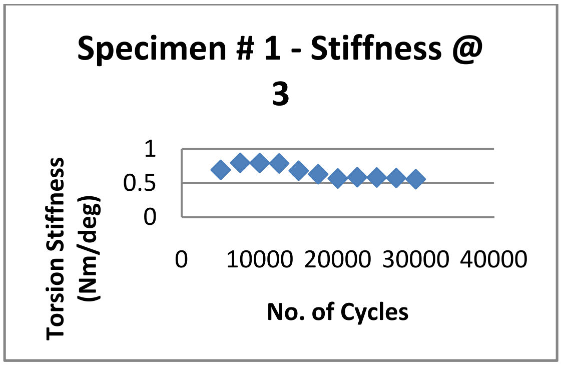
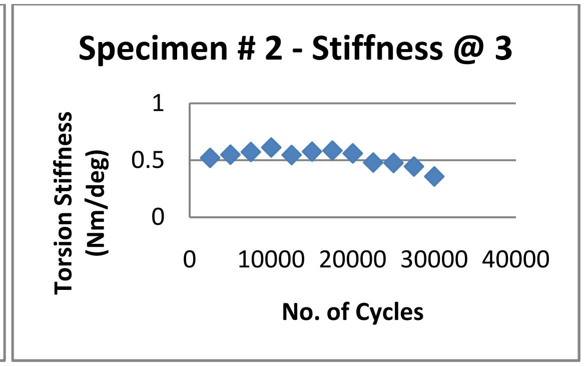
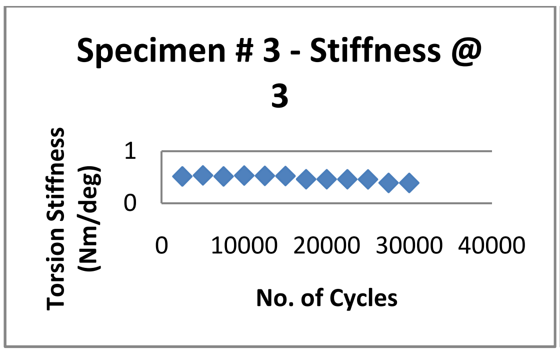


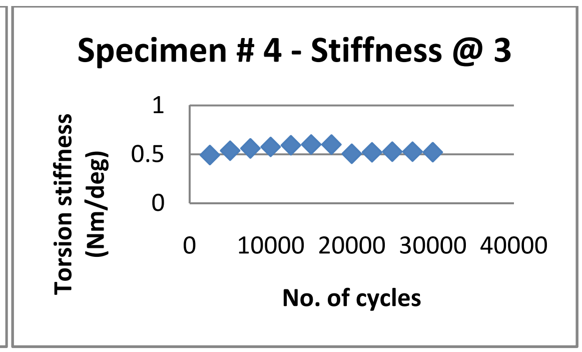
Figure 5.3 Graphs showing Dynamic Torsion Stiffness at -3 Nm of

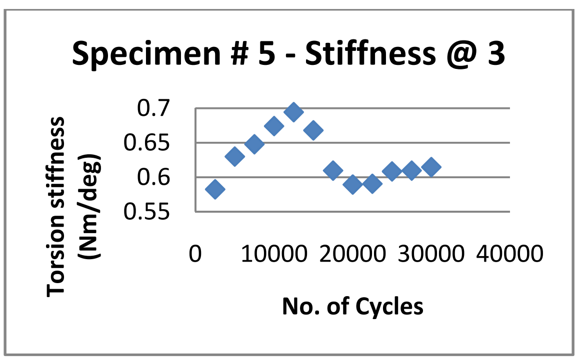
“Normal” and “Control” groups

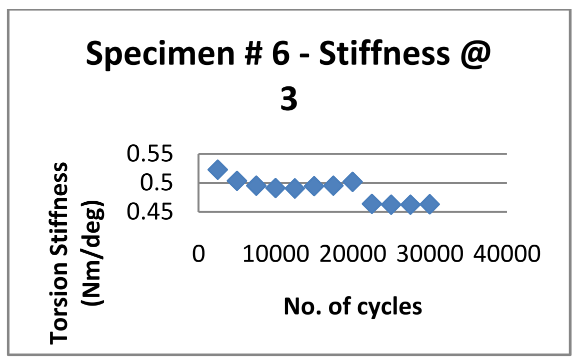

Specimen # 1 - Stiffness @ 3
Torsion Stiffness (Nm/deg)
1
0.5
0
0 10000 20000 30000 40000
No. of Cycles

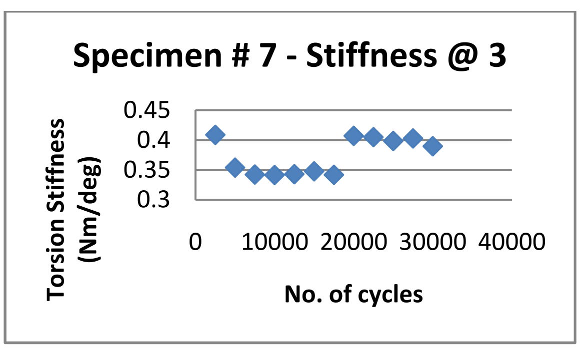

Specimen # 2 - Stiffness @ 3
Torsion Stiffness (Nm/deg)
1
0.5
0
0 10000 20000 30000 40000
No. of Cycles

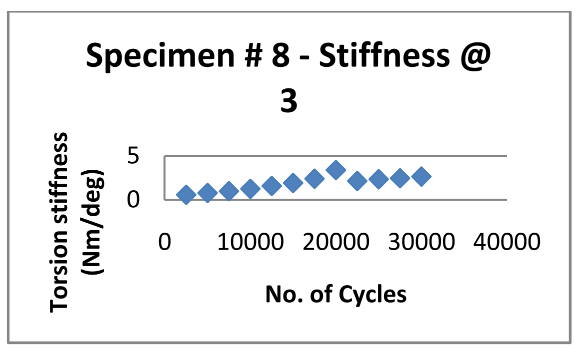

Specimen # 3 - Stiffness @ 3
Torsion Stiffness (Nm/deg)
1
0
0 10000 20000 30000 40000
No. of Cycles

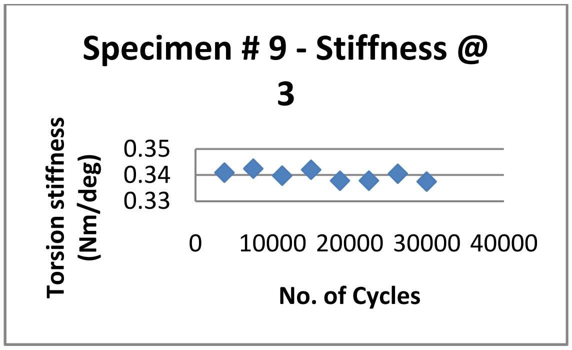

Specimen # 4 - Stiffness @ 3
Torsion stiffness (Nm/deg)
1
0.5
0
0 10000 20000 30000 40000
No. of cycles

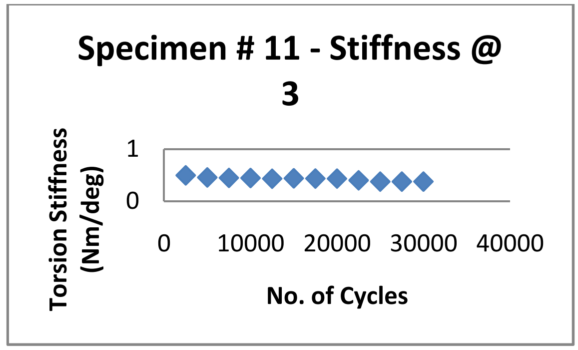

Specimen # 5 - Stiffness @ 3
Torsion stiffness (Nm/deg)
0.7
0.65
0.6
0.55
0 10000 20000 30000 40000
No. of Cycles


Specimen # 6 - Stiffness @ 3
Torsion Stiffness (Nm/deg)
0.55
0.5
0.45
0 10000 20000 30000 40000
No. of cycles


Specimen # 7 - Stiffness @ 3
Torsion Stiffness (Nm/deg)
0.45
0.4
0.35
0.3
0 10000 20000 30000 40000
No. of cycles


Specimen # 8 - Stiffness @ 3
Torsion stiffness (Nm/deg)
5
0
0 10000 20000 30000 40000
No. of Cycles





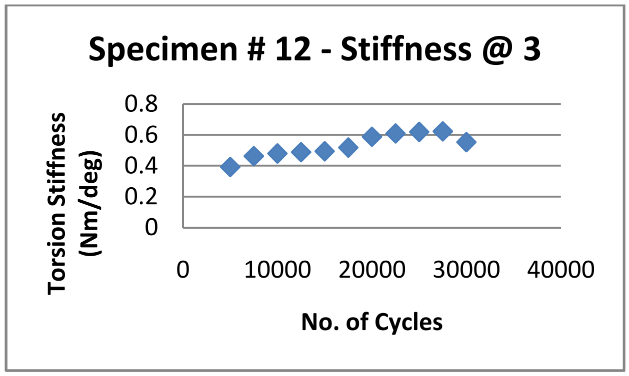


Figure 5.4 Graphs showing Dynamic Torsion Stiffness at +3 Nm of "Normal" and "Control" groups

Table 5.3 and **Table 5.4** show the results for the torsion stiffness of group 2.

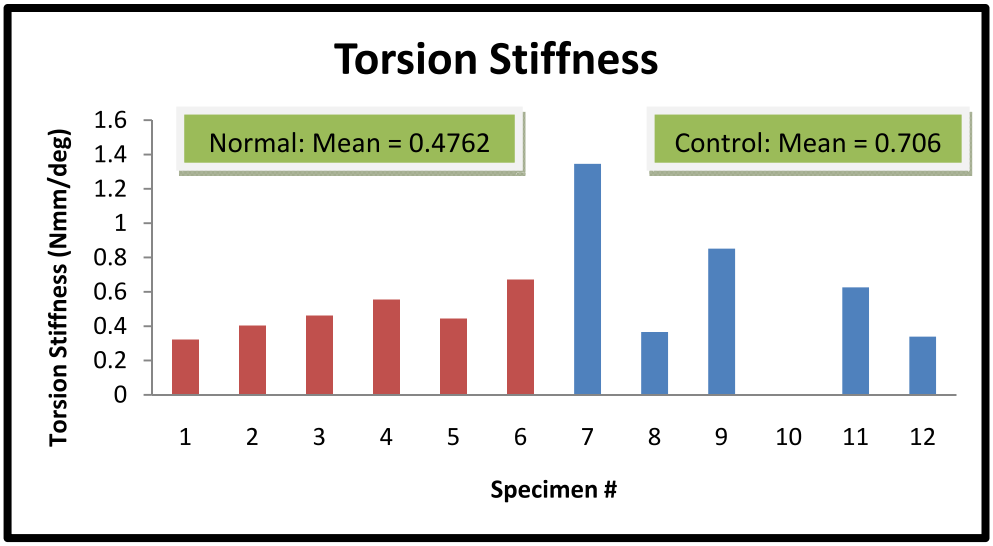
Specimen Number	Torsion Stiffness (Nm/deg) at -3 Nm	Torsion Stiffness (Nm/deg) at +3 Nm
1	0.32145	0.65849
2	0.40465	0.52327
3	0.46239	0.48076

4	0.55527	0.54693
5	0.44396	0.62663
6	0.66957	0.48703

Table 5.3 Torsion stiffness for Group 2 – Normal

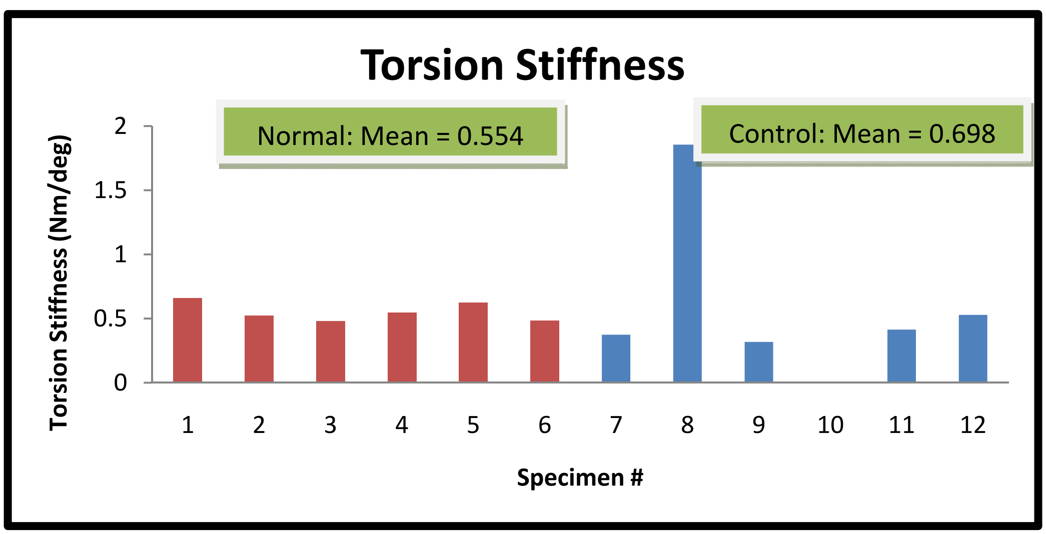
Specimen Number	Torsion Stiffness (Nm/deg) at -3 Nm	Torsion Stiffness (Nm/deg) at +3 Nm
7	1.346	0.37376
8	0.36636	1.85567
9	0.85197	0.31771
10	-	-
11	0.6266	0.41431
12	0.33921	0.52911

Table 5.4 Torsion stiffness for Group 2 – Control



* Specimen# 1-6: Normal, Specimen# 7-12: Control

Figure 5.5 A graph of torsion stiffness at -3Nm of “Normal” and “Control” groups



* Specimen# 1-6: Normal, Specimen# 7-12: Control

Figure 5.6 A graph of torsion stiffness at +3Nm of “Normal” and “Control” groups

Here, specimen number 10 in torsion test failed during fatigue test after 28292 cycles.

5.2 Load/Torque to Failure

Each specimen went through load/torque to failure test after fatigue testing. Continuously increasing load was applied in case of the axial test and same way, increasing torque was applied in case of torsion test. Testing parameters are shown in **Table 3**.

5.2.1 Load to Failure

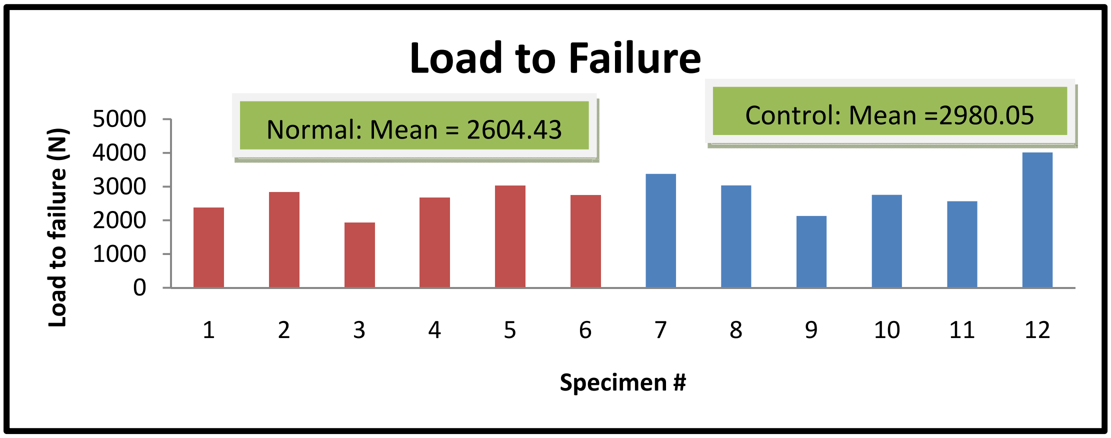
For axial test, as the construct undergoes increasing compressive loads, at one point, the failure occurs. As a result of this, the specimen breaks and after this point onwards, it requires less load to apply the same amount of compression. Because of this, after the failure occurs, the value of load drops down and this maximum value of load is considered as a load to failure. **Table 5.5** and **Table 5.6** show these values for normal and control groups in axial loading.

Specimen Number	Load (Compressive) to Failure (N)
1	2375.7
2	2846.6
3	1942.7
4	2675.2
5	3034
6	2752.4

Table 5.5 Load to failure for Group 1 – Normal

Specimen Number	Load (Compressive) to Failure (N)
7	3376.5
8	3035.2
9	2130.9
10	2756.5
11	2567.6
12	4013.6

Table 5.6 Load to failure for Group 1 – Control



* Specimen# 1-6: Normal, Specimen# 7-12: Control

Figure 5.7 A graph of load to failure for “Normal” and “Control” groups

5.2.2 Torque to Failure

In case of torsion test, it is difficult to determine the point at which the failure occurred due to the nature of torque curve during the test. Thus, the torque at failure was considered as 10% low from the maximum value of the torque during the entire test. **Table 5.7** and **Table 5.8** show the values of torque to failure for both normal and control groups.

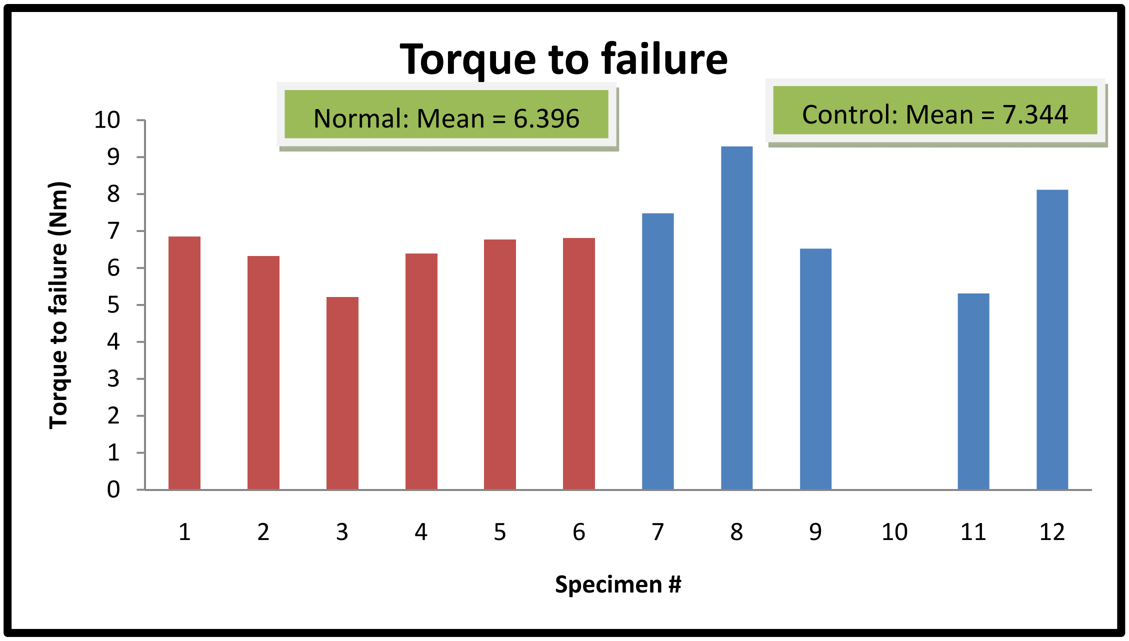
Specimen Number	Torque to failure (Nm)
1	6.858
2	6.327

3	5.211
4	6.399
5	6.768
6	6.813

Table 5.7 Torque to failure for Group 2 – Normal

Specimen Number	Torque to failure (Nm)
7	7.479
8	9.288
9	6.525
10	-
11	5.31
12	8.118

Table 5.8 Torque to failure for Group 2 – Control



* Specimen# 1-6: Normal, Specimen# 7-12: Control

Figure 5.8 A graph of torque to failure for “Normal” and “Control” groups

Here, specimen 10 failed during the fatigue test and thus, could not go through the torque to failure test.

5.3 Loosening Torque

Loosening torque is the difference between the initial value of torque on each screw and the final value of torque. Loosening torque was measured only in case of group 2. **Table 5.9** shows the initial values of torque on each screw.

Specimen #		Plate Hole #									
		1 L	2 NL	3	4 L	5	6	7 L	8	9 NL	10 L
Normal	1	4.698	3.159	None	4.168	None	None	5.189	None	2.961	4.832
	2	-	-	None	-	None	None	-	None	-	-
	3	-	-	None	-	None	None	-	None	-	-
	4	0.783	0.63	None	0.83	None	None	0.814	None	0.657	0.812
	5	3.989	1.72	None	3.792	None	None	3.307	None	1.724	4.044
	6	4.148	1.96	None	4.578	None	None	4.344	None	1.573	4.423
Control	7	4.12	3.045	None	4.266	Plug	Plug	4.014	None	2.306	4.061
	8	4.374	2.385	None	4.712	Plug	Plug	4.492	None	2.304	4.34
	9	4.975	2.467	None	4.651	Plug	Plug	4.847	None	2.701	4.277
	10	4.409	2.338	None	4.844	Plug	Plug	4.696	None	3.291	4.283
	11	4.156	2.851	None	4.877	Plug	Plug	4.643	None	2.67	4.193
	12	4.209	2.53	None	4.537	Plug	Plug	4.411	None	2.697	4.401

* L – Locking Screw, NL – Non-locking Screw, '-' – Information is not available

Table 5.9 Initial torque for each screw in Normal and Control groups

Following **Table 5.10** shows the loosening torque for the respective screws.

Specimen #			Plate Hole #									
			1 L	2 NL	3	4 L	5	6	7 L	8	9 NL	10 L
	Normal	1	2.051	2.68	None	Broken	None	None	Broken	None	1.517	1.257
		2	-	-	None	Broken	None	None	-	None	-	-
		3	-	-	None	Broken	None	None	Broken	None	-	-
		4	0.026	0.18	None	Broken	None	None	Broken	None	Broken	-
		5	0.823	1.095	None	1.606	None	None	Broken	None	1.389	0.31
		6	0.925	1.293	None	2.705	None	None	Broken	None	1.256	3.11
	Control	7	3.085	2.212	None	Broken	Plug	Plug	Broken	None	2.1	1.53
		8	1.496	1.686	None	Broken	Plug	Plug	4.027	None	1.508	2.97
		9	1.968	2.467	None	Broken	Plug	Plug	Broken	None	2.261	1.29
		10	1.32	1.777	None	Broken	Plug	Plug	Broken	None	Broken	Broken
		11	2.114	1.883	None	Broken	Plug	Plug	Broken	None	1.714	1.97
		12	2.318	1.912	None	Broken	Plug	Plug	1.092	None	1.88	3.71

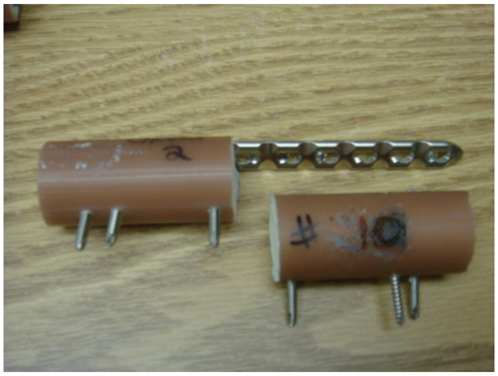
* L – Locking Screw, NL – Non-locking Screw, '-' – Information is not available

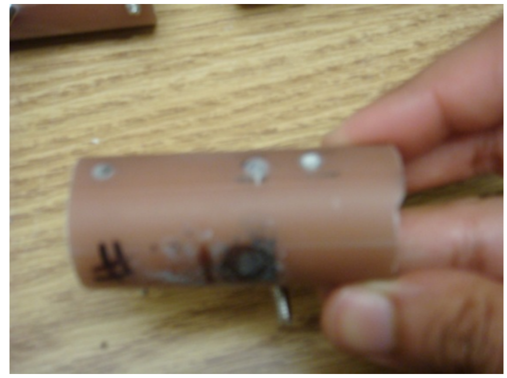
Table 5.10 Loosening Torque for each screw in Normal and Control groups

As seen in the **Table 5.10**, screws 4 and 7 are broken in most cases. Plate holes 5 and 6 were left open in case of normal and filled with plugs in case control group.

5.4 Failures during the tests

All the specimens in axial and torsion tests survived the cyclic loading tests except from one specimen in torsion test. Specimen 10 in torsion test failed during the cyclic loading after 28292 cycles. **Figure 5.9** shows the type of failure occurred. As seen in it, all the screws on one side of the osteotomy gap were broken at bone-plate interface, which made the piece of bone on that side completely fall apart.

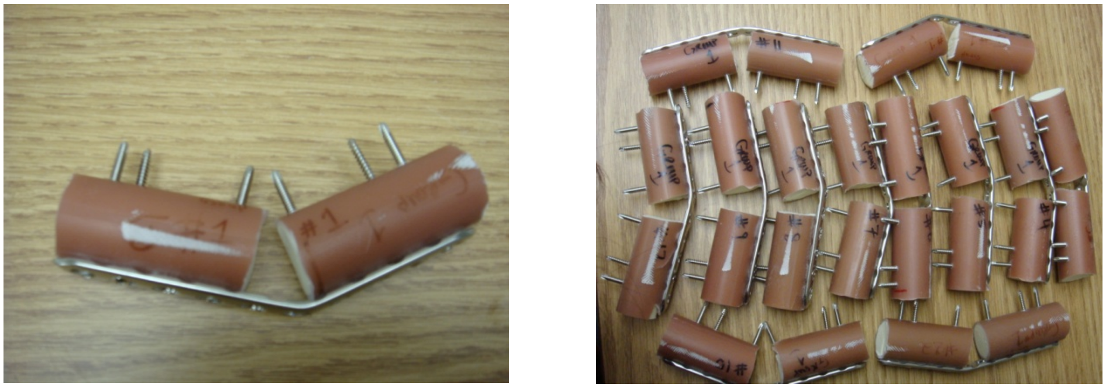




(a) (b)

Figure 5.9 (a) Failure of specimen#10 (b) Screws broken at bone-plate interface

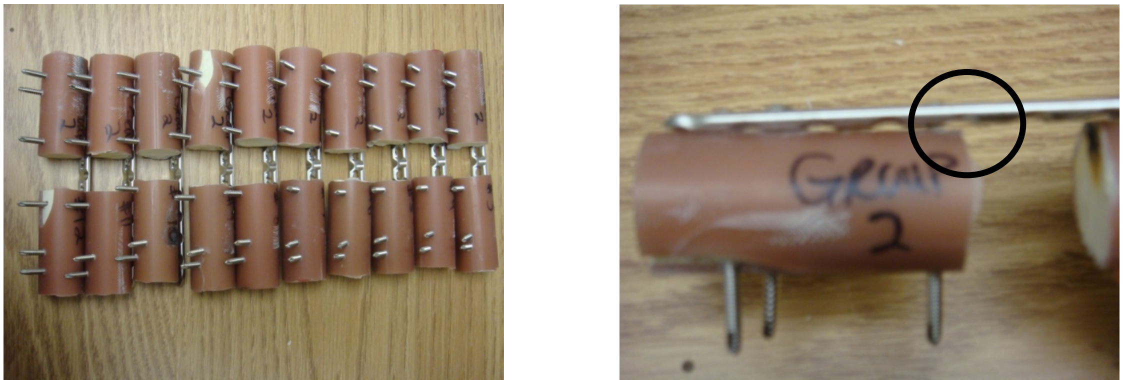
In load/torque to failure test, each specimen was loaded with continuously increasing load /torque until it failed. In case of axial loading, all the specimens were bent due to compressive load. **Figure 5.10** shows an example of failure occurred in an axial test.



(a) (b)

Figure 5.10 (a) An example of a failure in load to failure test (b) Group 1 after undergoing load to failure test

In torsion test, there was no obvious physical damage to the constructs. But by closely examining and determining loosening of the screws, screw 4 and 7 were found broken at bone-plate interface in most of the specimens. **Figure 5.11** shows an example of the failure occurred in torque to failure test.



(a) (b)

Figure 5.11 (a) Group 2 after undergoing torque to failure test (b) Broken screw near osteotomy gap at bone-plate interface

6

Discussion

Statistical evaluation was performed on stiffness and load/torque to failure data. The data not being normally distributed, non-parametric test was used. Non-parametric, Mann-Whitney test was performed on both stiffness and load to failure data for axial and torsion tests. Here, the goal was to determine if there is a significant difference between normal and control groups for each data set. The **Table 6.1** shows the results of Mann-Whitney test performed on two parameters per group and also the **Table 6.2** shows the respective p-values for each one.

	Group	N	Mean Rank	Sum of Ranks
Axial Stiffness	Normal	6	5	30
	Control	6	8	48
	Total	12		

Load to Failure	Normal	6	5.33	32
	Control	6	7.67	46
	Total	12		
Torsion Stiffness at -3 Nm	Normal	6	5.33	32
	Control	5	6.80	34
	Total	11		
Torsion Stiffness At +3 Nm	Normal	6	4.8	24
	Control	5	7.0	42
	Total	11		
Torque to Failure	Normal	6	4.83	29
	Control	5	7.40	37
	Total	11		

Table 6.1 Results of Mann-Whitney test on axial and torsion test results

Mann-Whitney test arranges the numbers in the dataset in an ascending order and assigns a rank (from 1 through n) in that order. Again, it divides the data into its original groups and performs the sum of all the ranks and carries out the analysis. From the table, we can see that there is a difference between the mean values of ranks between normal and control group, for all four parameters. More specifically in all cases, mean value of normal group is lower than mean value of rank of control group. This suggests that the average values for all parameters is higher in case of control group than a normal group; indicating a possible difference between two groups. But by looking at p-value for each parameter we can conclude whether this difference is statistically significant or not.

	Axial Stiffness	Load to Failure	Torsion Stiffness at -3 Nm	Torsion Stiffness at +3 Nm	Torque to Failure
p-value	0.180	0.310	0.537	0.273	0.247

Table 6.2 p-values for axial and torsion test results

Here, as we can see in **Table 6.2**, p-value is more than 0.05 for each parameter. Thus, we can say that the difference in normal and control group is not statistically significant. Looking at each p-values, p-value for axial stiffness is 0.180, for load to failure in axial is 0.310, for torsion stiffness is 0.537 and for load to failure in torsion is, it is 0.247. For axial stiffness p-value being 0.180, it is more close to 0.05, while rest all are quite off from 0.05. This also agrees with the fact that the difference between the mean ranks of the normal and control group is highest for axial stiffness compared to all other parameters. As the p-value for axial stiffness being close to 0.05, there is a possibility of some inconsistency in the process or material used in experiment.

	Group	N	Mean	Standard Deviation
Axial Stiffness	Normal	6	626.29	617.55
	Control	6	1381.88	786.27
Load to Failure	Normal	6	2604.43	389.94
	Control	6	2980.05	658.72
Torsion Stiffness at -3 Nm	Normal	6	0.476	0.122
	Control	5	0.706	0.414
Torsion Stiffness at +3 Nm	Normal	6	0.554	0.073
	Control	5	0.698	0.651
Torque to Failure	Normal	6	6.396	0.622
	Control	5	7.344	1.516

Table 6.3 Mean and standard deviation values for all four parameters

There can be two reasons which led to the higher p-value for axial stiffness and these can be lower sample size and higher standard deviation. **Table 6.3** shows the values of standard deviation and sample size for all four parameters. Sample size being really small, performing more experiments might eventually shift the p-value towards 0.05. Due to the high cost involved in locking compression plate and bone, it was difficult to use larger sample size. Also, the high standard deviation can lead to deviation of p-value from the actual one. Higher value of standard deviation can be due to inconsistencies in the process or material used during the experiments. There were few inconsistencies in regards to the method used in this study to prepare the constructs and performing the experiments.

One of the inconsistencies was in the length of osteotomy gap. The fracture gap length was different for few constructs. It ranged from 2 cm to 2.5 cm. Plate length is dependent on fracture length and the loads applied to the plate [32]. Thus, varying fracture length can result in different biomechanical forces and stresses experienced by the screws and can result in variability in the data and thus high standard deviation. Same as, fracture length, entire construct length was also not consistent. It varied from 12 to 13 cm. This can also eventually lead to higher standard deviation.

In this study, a combination of locking and non-locking screws was used. Stability of locking screws do not depend on initial torque values but non-locking screw stability depends on initial torque value. Initial torque values for all the screws in general were not controlled and thus the failure of them was not consistent.

6.1 Prediction Models

Prediction models are useful to utilize a limited number of experimental data by establishing a relationship between them and predicting the outcome of future test results. Mathematical models were generated using the experimental data to determine loosening torque in different conditions and compare normal and control groups. Following is the list of abbreviations used in the equations.

Parameter	Abbreviation
Loosening Torque (Normal)	LT_N
Loosening Torque (Control)	LT_C
Loosening Torque (NL Screw – Normal)	LT_{NLN}
Loosening Torque (NL Screw – Control)	LT_{NLC}

Loosening Torque (L Screw – Normal)	LT_{LN}
Loosening Torque (L Screw – Control)	LT_{LC}
Torsion Stiffness (Normal)	TS_N
Torque Applied	T_A
Torsion Stiffness (Control)	TS_C
Torque to Failure (Normal)	TF_N
Torque to Failure (Control)	TF_C
Axial Stiffness (Normal)	AS_N
Axial Stiffness (Control)	AS_C
Load to Failure (Normal)	LF_N
Load to Failure (Control)	LF_C

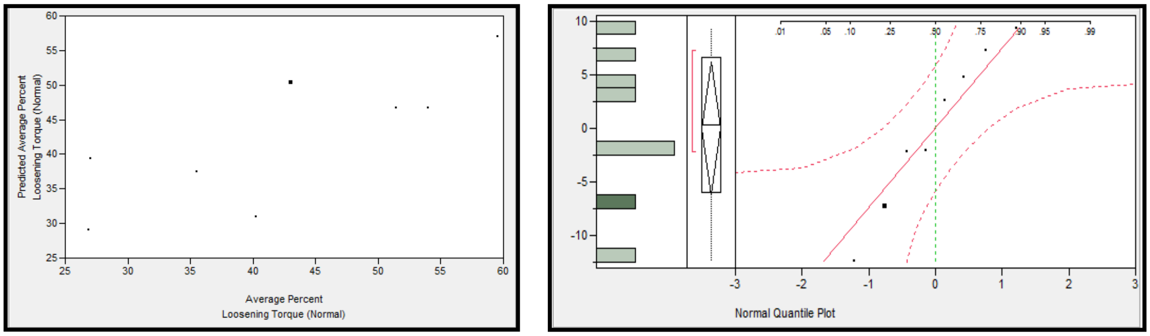
Table 6.4 List of abbreviations for different parameters

Model - 1:

This mathematical model describes the relationship of overall percent loosening torque of all the screws in a construct without the plugs (Normal), with torsion stiffness and torque applied.

$$\% \mathbf{LT_N} = 75.6798 - 21.495\ (TS_N) - 7.443\ (T_A) - 40.803\ ((TS_N - 0.31644) * (T_A - 4.25))$$

Where, $R^2 = 0.62883$



(a) (b)

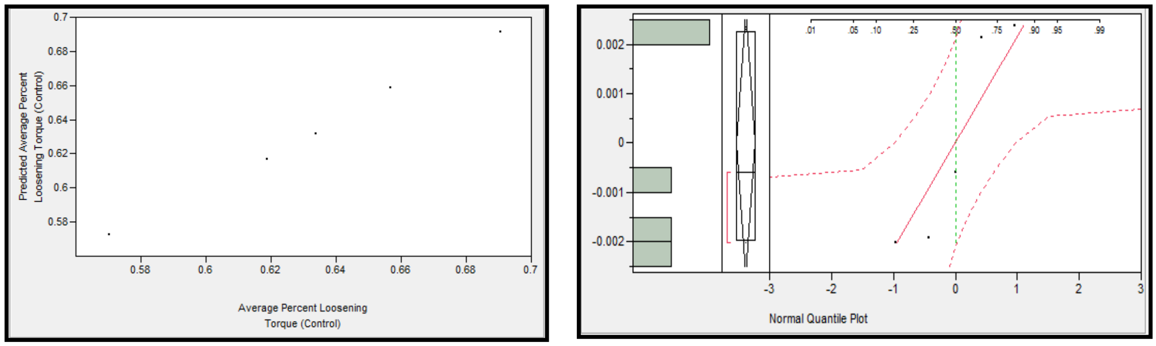
Figure 6.1 Model-1, (a) Distribution of residuals (b) Plot of Predicted values vs. Experimental values

Model – 2:

This model describes the relationship of overall percent loosening torque of all screws in a construct with the plugs (Control), with torsion stiffness and torque to failure.

$$\% \mathbf{LT_C} = 0.414 + 0.103\ (TS_C) + 0.019\ (TF_C) - 0.045\ (TS_C - 0.706) * (TF_C - 7.344)$$

Where, $R^2 = 0.997701$



(a) (b)

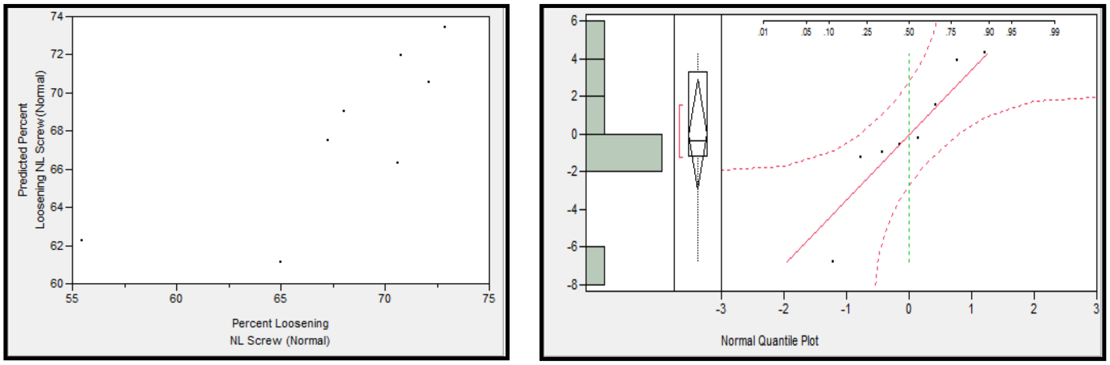
Figure 6.2 Model-2, (a) Distribution of residuals (b) Plot of Predicted values vs. Experimental values

Model – 3:

This model calculates percent loosening torque of only non-locking screws in case of normal group using the data of torsion stiffness and torque applied.

$$\mathbf{\%\ LT_{NLN}} = 83.184 - 15.302\ (TS_N) - 3.127\ (T_A) - 22.412\ (TS_N - 0.316) * (T_A - 4.25)$$

Where, $R^2 = 0.617958$



(a) (b)

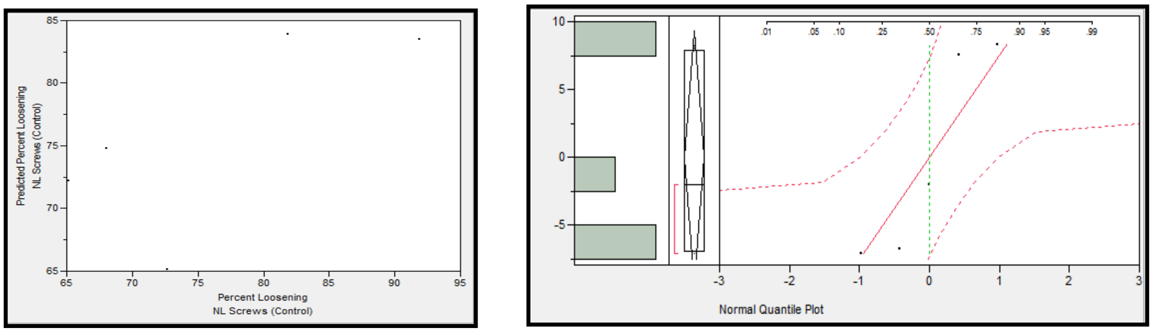
Figure 6.3 Model-3, (a) Distribution of residuals (b) Plot of Predicted values vs. Experimental values

Model – 4:

This model again calculates average percent loosening torque for non-locking screws in case of plugs using torsion stiffness and torque to failure data.

$$\textbf{\% LT}_{\textbf{NLC}} = 92.7587 + 30.413\ (TS_C) - 6.166\ (TF_C) - 42.663\ (TS_C - 0.706) * (TF_C - 7.344)$$

Where, $R^2 = 0.529535$



(a) (b)

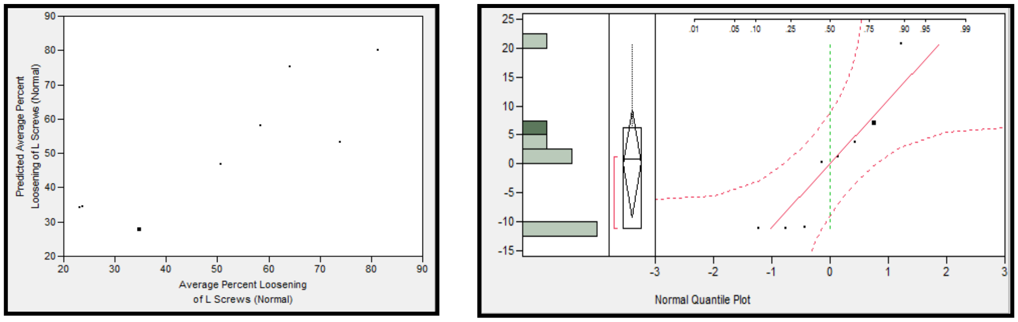
Figure 6.4 Model-4, (a) Distribution of residuals (b) Plot of Predicted values vs. Experimental values

Model – 5:

Following model predicts percent loosening torque of locking screws in case of normal group using torsion stiffness and torque applied data.

$$\mathbf{\%\ LT_{LN}} = -74.361 + 104.95\,(TS_N) + 22.887\,(T_A) + 40.255\,(TS_N - 0.316) * (T_A - 4.25)$$

Where, $R^2 = 0.749942$



(a) (b)

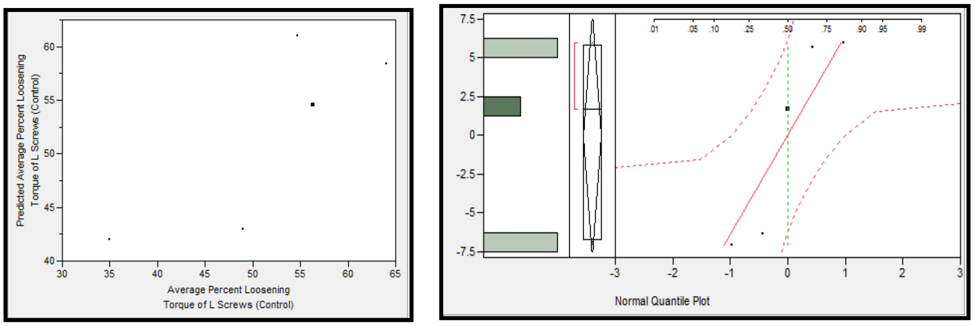
Figure 6.5 Model-5, (a) Distribution of residuals (b) Plot of Predicted values vs. Experimental values

Model – 6:

This equation describes the relationship of average percent loosening torque of locking screw for constructs with plugs, with torsion stiffness and torque to failure.

$$\textbf{\% LT}_{\textbf{LC}} = \text{-}16.468 - 14.59\,(TS_C) + 11.634\,(TF_C) + 42.179\,(TS_C - 0.706) * (TF_C - 7.344)$$

Where, $R^2 = 0.658238$



(a) (b)

Figure 6.6 Model-6, (a) Distribution of residuals (b) Plot of Predicted values vs. Experimental values

Also, in order to establish the relationship between axial stiffness of normal and control group and thereby approximate the axial stiffness of control group if data is available for normal group, following mathematical relationship was determined using the test data.

$$\mathbf{AS_C} = 2164.1402 - 0.3714483 * AS_N - 0.0017294 * (AS_N - 626.286)^2$$

Where, $R^2 = 0.661348$

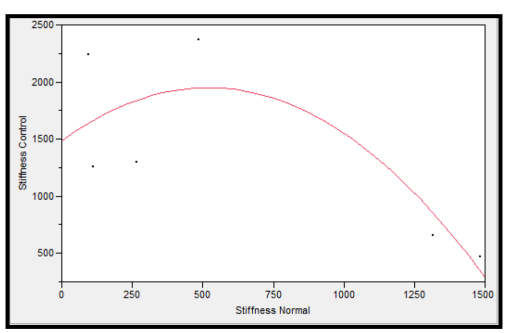


Figure 6.7 Polynomial Fit for Axial Stiffness

Similarly, the relationship was established between torsion stiffness of normal and control groups.

$$\mathbf{TS_C} = 2.0438404 - 3.2221812 * TS_N + 10.963984 * (TS_N - 0.4604)^2$$

Where, $R^2 = 0.604448$

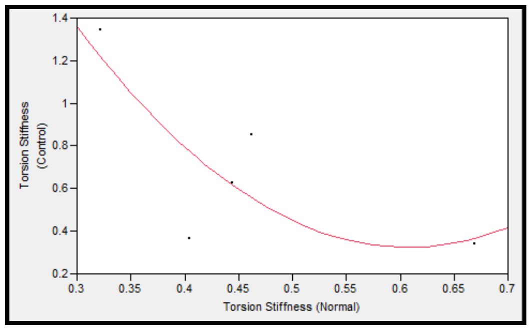


Figure 6.8 Polynomial Fit for Torsion Stiffness

Following expression predicts load to failure for control group when the information is available for normal group.

$$\mathbf{LF_C} = 2226.3161 - 0.3429276 * LF_N - 0.0019697 * (LF_N - 613.558)^2$$

Where, $R^2 = 0.524318$

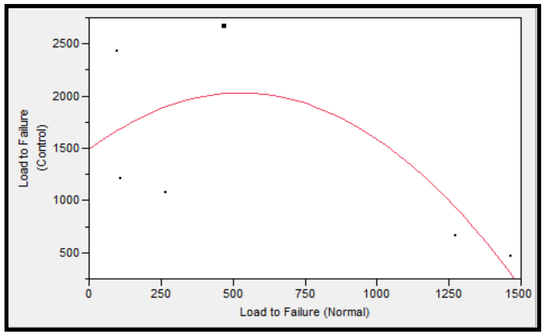


Figure 6.9 Polynomial Fit for Load to Failure

Similarly, torque to failure for control group can be approximated by torque to failure for normal group using following equation.

$$\mathbf{TF_C} = 136.25665 - 20.088274 * TF_N + 27.048453 * (TF_N - 6.3954)^2 + 37.914914 * (TF_N - 6.3954)^3$$

Where, $R^2 = 0.74429$

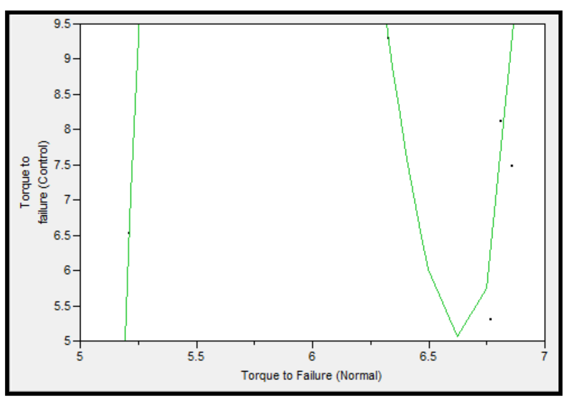


Figure 6.10 Polynomial Fit of degree = 3 for Torque to Failure

7

Conclusion

Experimental study was conducted to determine the effectiveness of plugs, along with screws, in case of locking compression plates using synthetic bone models and following conclusions can be drawn from the results.

1. There is not a statistically significant difference in case of axial loading condition, between the group which used the plugs (control) and the group which did not use the plugs (normal).

2. There is not a statistically significant difference in case of torsion loading condition, between the group which used the plugs (control) and the group which did not use the plugs.

3. Even though both the groups are not different statistically in case of axial loading condition, axial stiffness for control group seems to be significantly different than normal group.

4. Mean value of axial stiffness for control group was more than twice of that of normal group, suggesting the possibility of higher axial stiffness in case of control group even though it is not statistically significant.

5. There is high standard deviation in the results, suggesting large variability in the data points. It is speculated that higher variability was due to initial torque on each screws being different and can also be due to the varying length of the specimen and the fracture gap.

Prediction models developed in this study were found to be effective in determining the loosening torque, stiffness and load to failure in case of both the groups. These models can be used only when similar plate-screws and plugs combinations are used.

7.1 Future Work

The present study describes the comparison of synthetic bone constructs with and without plugs, along with screws in case of locking compression plate. It is recommended to perform finite element analysis of this experimental work and compare the results obtained from both experimental and analytical work. Also, increased number of samples can be used to achieve more statistically viable results. Controlling initial torque, specimen length and osteotomy length is assumed to be effective in obtaining reduced standard deviation. This study focused on using 2 plugs near osteotomy site. Further studies can be conducted to compare the use of 1, 2 or 3 plugs in case of different fracture scenarios. This will be helpful in reducing cost by not using more number of plugs when less is enough to obtain the same results.

8

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