

**THE EFFECT OF INTRAMEDULLARY PIN SIZE AND MONOCORTICAL
SCREW CONFIGURATION ON LOCKING COMPRESSION PLATE-ROD
CONSTRUCTS IN AN *IN VITRO* FRACTURE GAP MODEL**

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This thesis is presented for the degree of Research Masters with Training (RMT) of
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DECLARATION

I declare that this thesis is my own account of my research and contains as its main content work which has not previously been submitted for a degree at any tertiary education institution.

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Dr Timothy James Pearson

ABSTRACT

Objective: To investigate the effect of intramedullary (IM) pin size in combination with various monocortical screw configurations on construct stiffness and strength as well as plate strain in locking compression plate-rod (LCPR) constructs.

Methods: A synthetic bone model with a 40mm fracture gap was used. LCPs with monocortical locking screws were tested with no pin (LCPMono) and IM pins of 20% (LCPR20), 30% (LCPR30) and 40% (LCPR40) of IM diameter. LCPs with bicortical screws (LCPBi) were also tested in the first paper. The first paper used screw configurations with 2 or 3 screws per fragment modelling long (8 hole), intermediate (6 hole) and short (4 hole) plate working lengths. Responses to axial compression, biplanar four point bending and axial load to failure were recorded. The second paper used 2 screws per fragment to model a long (8 hole) and short (4 hole) plate working length and strain responses to axial compression were recorded at 6 regions of the plate via 3D digital image correlation.

Results: In the first paper, LCPBi were not significantly different from LCPMono control for any of the outcome variables measured. In bending, LCPR20 were not significantly different from LCPBi and LCPMono. LCPR30 were stiffer than LCPR20 and the controls. LCPR40 constructs were stiffer than all other constructs. The addition of an IM pin of any size provided a significant increase in axial stiffness and load to failure. This effect was incremental with increasing IM pin diameter. As plate working length decreased there was a significant increase in stiffness across all constructs.

The addition of an IM pin of any size provided a significant decrease in plate strain. For the long working length, LCPR30 and LCPR40 had significantly lower strain than the LCPR20 and plate strain was significantly higher adjacent to the screw closest to the fracture site. For the short working length, there was no significant difference in strain across any LCPR constructs or at any region of the plate. Plate strain was significantly lower for the short working length compared to the long working length for LCPMono and LCPR20 but not LCPR30 and LCPR40.

Conclusions: A pin of any size increases resistance to axial loads whereas a pin of at least 30% IM diameter is required to increase bending stiffness. Short plate working lengths provide maximum stiffness. However, the overwhelming effect of IM pin size obviates the effect of changing plate working length on construct stiffness.

The increase in plate strain encountered with a long working length can be overcome by the use of a pin of 30-40% IM diameter. Where placement of a large diameter IM pin is not possible, screws should be placed as close to the fracture gap as possible to minimize plate strain and distribute it more evenly over the plate.

Both studies showed a consistent effect of increasing IM pin diameter and using a short plate working length. However, a significant interaction effect between these variables was only detected on plate strain with the IM pin largely negating the effect of plate working length on construct stiffness.

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CHAPTER ONE: INTRODUCTION, OBJECTIVES AND HYPOTHESIS

1.1 INTRODUCTION

Plate-rod constructs are used to repair comminuted, femoral diaphyseal fractures in dogs.¹ The addition of an intramedullary (IM) pin to a bone plate increases the stiffness and fatigue life of the construct.² Results of previous plate-rod investigations recommend the use of a pin of 35-40% of IM diameter and a minimum of 3 monocortical and 1 bicortical screw in each fracture fragment. However, these recommendations are based on studies on non-locking compression plates modelling only that specific screw configuration.³ There are currently no published studies documenting the biomechanical effect of IM pin diameter on locking compression plate-rod (LCPR) constructs.

A major technical disadvantage when using conventional non-locking compression plate-rod constructs is the difficulty in consistently placing bicortical screws necessitating placement of monocortical screws to avoid IM pin interference.¹ This creates a biomechanical weakness as non-locking compression screws depend on maximum bone purchase to maintain frictional forces between the plate and the bone.⁴⁻⁶ Consequently, angled bicortical compression screws directed around the pin are preferred to maximise cortical bone purchase.

Pin interference is even more likely when placing locked bicortical screws in LCPRs as there is no flexibility in the angle of screw placement. However, locked screws form a fixed angle, single beam construct which is not as dependent on bone purchase for stability. Therefore, the use of locked monocortical screws has less impact on the stiffness and strength of an LCPR construct.⁷⁻¹⁰ Furthermore, it has been shown that locked monocortical screws outperform bicortical compression screws in fracture gap models.¹¹⁻¹³

Studies on locking compression plates (LCP) with monocortical screws recommend that screws be placed as close to the fracture gap as possible, thereby minimising the plate working length.¹⁴ The working length of the plate is the distance between the screws either side of the fracture gap.⁶ An *in vitro* LCP study concluded that placing more than 3 screws per fragment has no significant effect on the axial stiffness of the construct.¹⁴ These guidelines are based on using a LCP bridging a central fracture gap. The effect of the addition of an IM pin on these guidelines is unknown.

Several studies have attempted to define the effect of screw configuration on plate strain and the results are conflicting.¹⁵⁻¹⁷ Much of this variation can be attributed to different experimental methodology such as the use of different bone models, fracture gaps, plate and screw types, plate lengths and methods of measuring plate strain. There are no studies reporting plate strain in LCPR constructs.

Plate strain is measured to identify areas of mechanical weakness where a construct may fail by acute overload or cyclic fatigue.⁶ The addition of an intramedullary (IM) pin to a bone plate reduces plate strain and increases the fatigue-life of the construct.² All previous veterinary biomechanical studies have used strain gauges placed on the surface of the plate to measure plate strain.^{2,3,15} This study uses 3D digital image correlation which enables measurement of the principal strain across the whole field of view limited only by the resolution of the cameras used and the quality of the speckle pattern created on the construct.

Using a longer plate working length and placing screws away from the fracture site is more suitable for minimally invasive fracture repair. It would be useful to know if this results in an increase in plate strain and, if so, can this increase be overcome with the use of an IM pin as part of an LCPR construct.

1.2 OBJECTIVES

The primary aim of this study was to investigate the biomechanical effect of intramedullary pin size in combination with various monocortical screw configurations, on stiffness, ultimate strength and plate strain in locking compression plate-rod constructs in an *in vitro* fracture gap model.

1.3 HYPOTHESIS

We hypothesised that the addition of pins of incremental size to an LCP with monocortical screws will result in significant incremental increases in axial and bending stiffness and axial strength and will significantly lower plate strain.

We also hypothesised that screw configurations that decrease the working length of the plate will result in significant increases in axial and bending stiffness and axial strength and significantly lower plate strain.

In addition, it was hypothesised that an LCP with locked bicortical screws will have significantly greater axial and bending stiffness and axial strength than an identical plate-screw configuration with locking monocortical screws.

CHAPTER TWO: BACKGROUND AND LITERATURE REVIEW

2.1 ORTHOPAEDIC BIOMECHANICS

The following section describes the fundamental and applied biomechanical terms relevant to this thesis.

2.1 (A) DEFINITIONS & TERMINOLOGY

Force (F): A mechanical disturbance or load equal to an object's mass times acceleration. Measured in Newtons (N).¹⁸

Axial Force: A load applied along the axis of a beam.¹⁹

Moment Arm: The perpendicular distance between the line of action of an applied force and the neutral axis of the construct.²⁰ Measured in metres (m)

Bending Moment: The product of an axial force and the moment arm.¹⁹ Measured in Newtons/metre (N/m)

Deformation: The change in shape of an object as a result of an applied load.⁶

Stiffness: The ability of a structure to resist deformation as a result of an applied load.⁶ It is measured from the slope of the linear elastic portion of the force/deformation or stress/strain curve. The unit of measure in bending and compression is N/mm.

Modulus of Elasticity (E): The known stiffness of a material measured from the slope of the stress/strain curve.²¹

Elasticity: The ability of a material to return to its normal shape after load has been applied and withdrawn.⁶ For most metals the load displacement curve is linear to a point which reflects the elastic properties of that material. Elastic materials can undergo a large amount of displacement before failure whereas brittle materials fail quickly at their yield point and do not undergo plastic deformation prior to failure.

Yield point: The point at which the material fails and undergoes plastic deformation which results in irreversible change to its shape and permanent deformity.¹⁸ The yield point or load of a material is the point at which the material will no longer resume its normal size and shape on unloading – considerable yielding (displacement) can occur without increasing the load.

Plasticity: The residual deformation which exists after a load has been applied beyond its elastic limit.⁶ Ductile materials undergo considerable plastic deformation prior to failure.

Ultimate strength is the largest stress (load/area) that a material can endure.¹⁸ It is the highest point on the stress/strain or load/displacement curve. Increased rate of deformation occurs and continued yielding occurs even by reducing the applied load.

Area Moment of Inertia (AMI): The capacity for the cross sectional profile of an object to resist a bending load.^{6,21} This is dependent on an object's cross sectional area and the direction and magnitude of the applied bending load. It is usually considered with respect to a reference axis located

in the centre of the objects cross section in the x, y or z direction. The further the objects mass is distributed away from the neutral axis the greater the AMI.⁶ Stiffness is proportional to the modulus of elasticity and the AMI of an object.

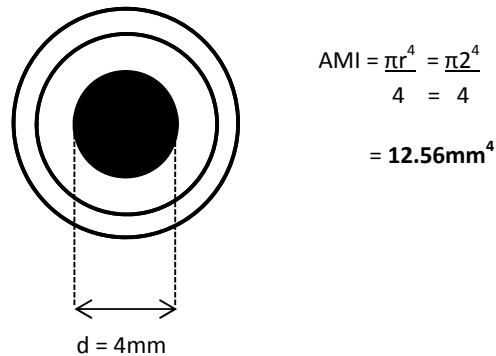


Figure 1 - Area moment of inertia (I) calculations for a 4mm diameter intramedullary (IM) pin in a cylindrical bone model. Rod cross sectional profile = $\pi r^4/4$. Therefore, the larger the radius of the pin, the greater the AMI.

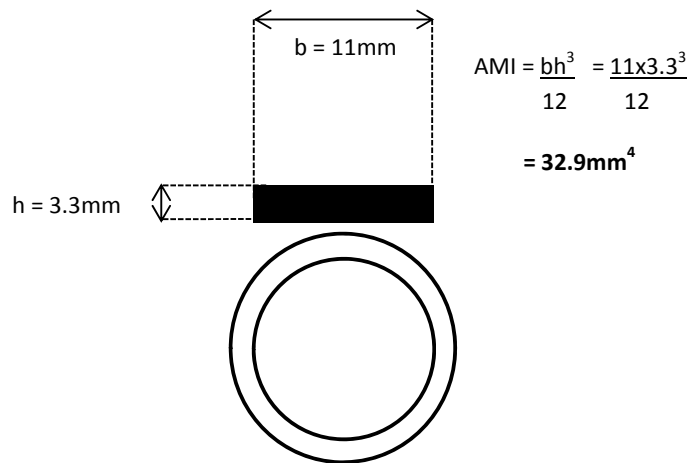


Figure 2 - Area moment of inertia (I) calculations for a 3.5mm locking compression plate (LCP) in a cylindrical bone model. Rectangular cross sectional profile = base x height³/12 - where the base is oriented parallel to the axis moment of inertia and the height is parallel to the direction of the applied load.

Stress (σ): The total force acting over a cross sectional area.²² Measured in N/mm²

Strain (ϵ): The change in length or deformation of a material divided by its original length. Expressed as a percentage of its original length.¹⁸

2.1 (B) APPLICATION OF BIOMECHANICS

The primary concept of fracture repair is that a race exists between fracture healing and implant failure.¹⁹ For a successful outcome, a fracture must heal prior to implant failure. However, the vast majority of orthopaedic biomechanical testing focuses on implant characteristics and gives little consideration to biological factors which influence the rate of fracture healing. Even with the recent popularity of biologic osteosynthesis, which addresses the importance of preserving fracture biology, there is no *ex vivo* or *in vitro* mechanism to combine the 2 concepts and properly replicate the clinical situation.

Whatever the intention of the study, the principles which govern methodology attempt to simulate physiologic loading and subsequent construct responses to provide data which enables relative comparison between constructs or and understanding of their behaviour in certain load situations.

The primary relationship in biomechanic investigations is the load-deformation curve which graphs load on the y axis and deformation or displacement of the construct on the x axis. This may also be presented as a stress-strain curve which simply introduces a specific area of interest.

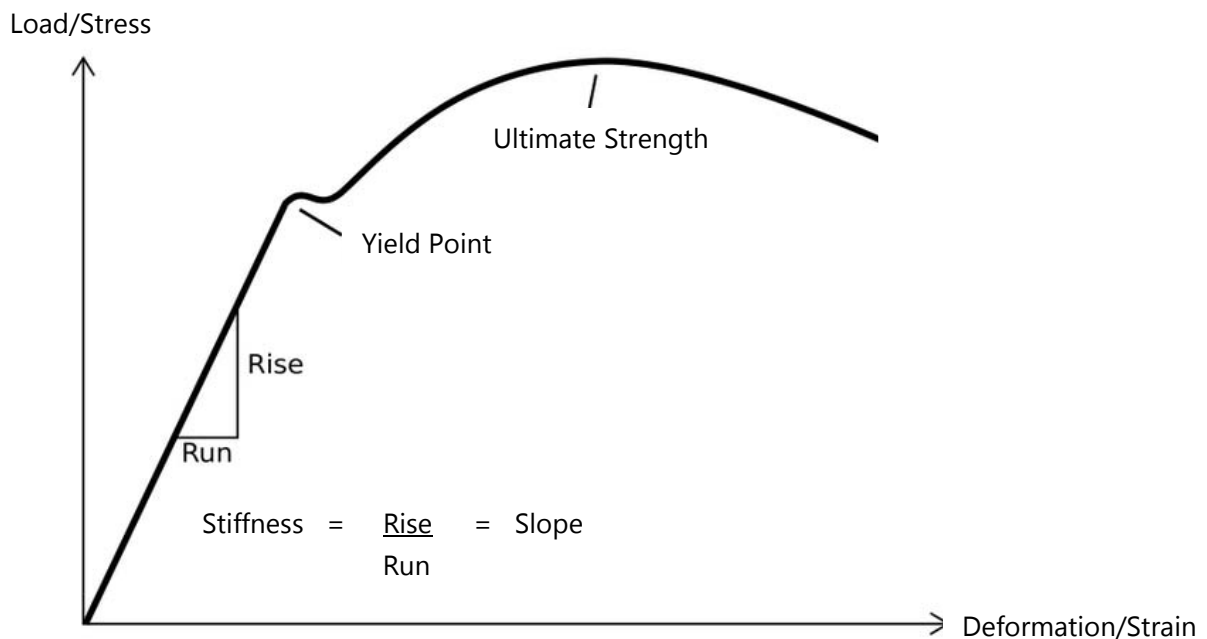


Figure 3 - A typical stress-strain curve. Stiffness is calculated from the slope of the initial linear elastic section of the curve prior to plastic deformation at the yield point. The ultimate strength of a construct is the highest load that a material can endure before breakage.

Loading of a construct within its elastic limit will permit that construct to return to its original shape once the load is removed.¹⁸ This technique is most commonly used when collating stiffness data where the implant is tested in a load range which only brings about temporary deformation.²³ These loads are often taken from previous biomechanical or pilot studies on the implants being tested but are also approximated to physiologic loads exerted on the implant during weight bearing.

Stiffness is a major outcome measure in biomechanical testing for comparison of implants and implant-bone constructs. As previously defined, it is a product of a material's modulus of elasticity and its area moment of inertia.⁶ The AMI is dependent on the implant's cross sectional geometry and the relation of this to the applied axial load and moment arm.⁶ The addition of an IM pin to a bone plate confers a significant increase in the AMI of that construct. The importance of this concept with relevance to plate-rod constructs is discussed later in the plate-rod biomechanics section.

The elastic modulus (Young's modulus) is a property specific to the material being tested and is essentially the stiffness of that material extrapolated from a stress-strain curve. In the context of this study, we are modelling a comminuted diaphyseal fracture with a 40mm fracture gap when no load sharing between the bone and implants can take place even at failure loads. Therefore, the total stiffness of each construct tested will be dictated by the combined AMI of the implants used and the modulus of elasticity of stainless steel 316L.²⁴

The ideal stiffness of an implant is currently not and may never be known but it lies somewhere between too little, resulting in implant failure, and excessive, which results in stress protection and non-union. Without specific data to outline the ideal axial and bending stiffness required for healing of comminuted diaphyseal fractures, stiffness only serves as a relative comparison between constructs rather than a measure for making clinical recommendations.

A construct can also be loaded beyond its elastic limit so that permanent plastic deformation will occur.¹⁸ This type of testing can be done acutely to mimic a single large physiologic load (i.e. an animal jumping onto that limb). Orthopaedic implants have the property of ductility which allows them to tolerate deformation without complete failure. This property is utilised when a plate is anatomically contoured to a bone using plate benders.²⁵ However clinically, plastic deformation will result in a loss of fracture reduction and therefore subject morbidity and fracture malunion or non-union.²⁵ With continued load the implant will go on to complete failure where continued deformation will occur even with reduced load.

Failure can occur by a number of mechanisms depending on the method of implant loading. Plastic failure is most common in static testing where an implant deforms permanently and with a single applied load. This is the mechanism used in this study to achieve load to failure data which will be reported as ultimate strength or load at point of fracture (N). Another mechanism is fatigue failure under cyclic loading, which attempts to simulate weight-bearing in the postoperative period to determine the fatigue life of the construct.

2.1 (C) BIOMECHANICAL TESTING

STATIC vs. CYCLIC TESTING

Static testing which generates results such as stiffness and load to failure enables comparison between constructs. While cyclic loading may mirror postoperative weight bearing and be considered a more clinically relevant testing protocol in animals, where postoperative loading of the fracture is not always well controlled, relative stiffness or acute failure loads are a relevant outcome measure.

Static (or quasi static) testing, where a specific load is applied for a small number of cycles (usually less than 10) is used in order to calculate point data for comparison between constructs within the same testing methodology. The most common data generated is stiffness, which is then described relative to

the direction of the load applied. Strain can also be measured by calculating the deformation at specific points along the construct or at the fracture gap. Stiffness gives an indication of the effect of that load over the entire construct whereas strain data can be used to give information about a particular area of interest.²⁶ For non-destructive static testing, it is essential that the load is kept within the linear elastic zone of the construct.

Acute load to failure is static testing which simulates physiologic overloading of the implants until a failure load is recorded. Static testing is often used as a first step for testing constructs and provides information regarding the levels of force that a construct can withstand prior to failure.

Cyclic loading describes testing when an implant or construct is loaded based on an estimate of the physiologic load and the number of times it may be loaded during a period the post-operative period. The aim of this testing is to assess the endurance of these constructs to determine if they will win the race between fracture healing and implant failure.

The loads used for testing are based on force plate studies where the loads are normalised to body weight to account for dog size (breed) differences.²⁷⁻²⁹ These studies estimate peak vertical forces in the hind limbs of healthy dogs to be 40-50% of body weight at a walk and 76-107% of body weight are achieved in the hind limbs of Labrador retrievers and greyhounds at a trot.³⁰ This equates to 223-315N in the hindlimb of a 30kg dog.

The postoperative period has been estimated to generate 1500-3000 cycles per day for an exercise-restricted, healthy, large breed dog walked 3-4 times per day.³¹ However, some studies have estimated this to be up to 9,000 cycles a day.³ The restricted rate equates to 60,000-120,000 cycles over a 6 week recovery period and in excess of 300,000 cycles if accounting for all movement other than lead walks. The fundamental flaw in cyclic testing is that it does not account for biologic responses such as the change in stiffness and strain afforded by bony callus during the healing period. In addition, it does not account for progressive increase to normal weight-bearing on the operated leg during the recovery period, although some plate-rod studies have made approximations.^{8,32}

Another limitation of cyclic testing is the inability to model bone resorption which occurs around implants when even minute instability exists.³² This resorption can result in loosening of the implants which would then affect the stability of the construct. For this resorption to occur, active blood supply is required and therefore resorption cannot be accurately reproduced in vitro.

Bones and implants can be tested in axial compression, bending and torsion to simulate the 3 main forces which act on a bone during weight bearing.³³

FOUR POINT BENDING

Four point bending describes the parallel application of 2 equal and parallel forces perpendicular to a structure to generate a bending moment which is distributed evenly across its length.³³ This is important for biomechanical testing as the bending moment generated between the 2 load rollers is constant within this zone. If applied beyond the elastic limit, four point bending will cause a structure to fail at its weakest point as force is distributed evenly over the entire length of the construct.²⁰ Therefore the test does not depend on the exact position of the simulated fracture.³⁴ This contrasts with 3 point bending where the force is directed at a single point on the material where failure will

eventually occur if the load is great enough. Four point bending more accurately reflects the clinical scenario where bones are loaded during weight bearing.

In this study a bending moment of 6Nm was chosen as this fits within the elastic range from previous studies.^{35,36} The calculation of the position of the load rollers was done in order to fit with the length of the construct such that both rollers were contacting the jig. The force required to generate this bending moment was calculated according to the equation below:

$$F_b = 2 \times (M_b/a_b)$$

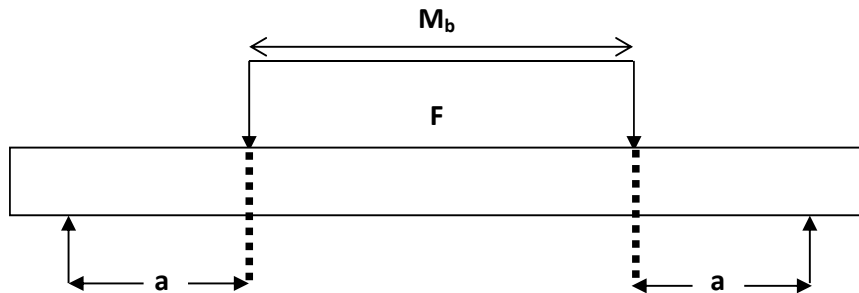


Figure 4 – Diagram to illustrate the 4 point bending loading protocol used in this study. F_b is the calculated bending force (300N), M_b is the bending moment chosen based on previous studies (6Nm) and a_b is the lever arm between the load rollers (0.04m).

AXIAL COMPRESSION

Centric axial load is pure compression which results in homogenous stress distribution within the column.³⁴ This is the exception however, and usually, force is applied with some degree of eccentricity producing axial strains within the column producing tension and compression.³⁴ It is widely recognised that axial compression results in the generation of a bending moment as true centric compression is difficult to achieve. The abaxial location of the implant (bone plate) and the large fracture gap produces a bending moment.^{37,38} Eccentric axial load is equivalent to the centric load application and a bending moment. The bending moment is axial force x distance of the line of application from the neutral axis (moment arm).²⁰

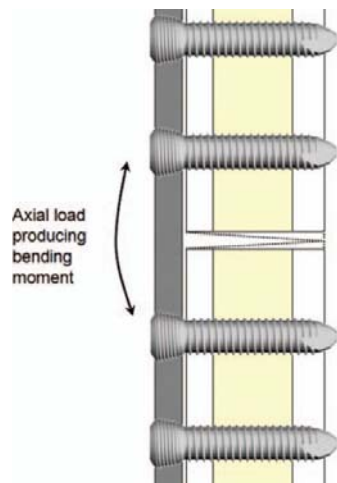


Figure 4 – Diagram of a locking plate illustrating the application and an axial load on the eccentrically positioned plate generating a bending moment.³⁹

The bending stiffness of a plate depends on its cross sectional area and geometric shape, its modulus of elasticity and its position relative to the bending moment applied which is the most important.²⁰ The application of a bone plate on the surface of the bone utilises the shortest distance and creates the shortest moment arm from the neutral axis.

Axial compression is perhaps the most clinically relevant load as it simulates post-operative weight-bearing in the canine femur. In this study, each construct was tested under position control at 10mm/min to a maximum load of 180N. This load was chosen as it represents 60% of body weight which has been said to be a maximum walk load during the recovery period.⁴⁰ It also represents 75% of the load at which the weakest construct failed during pilot testing.

TORSION

Torsional loading requires a torsional moment of force (torque) that acts to twist a structure about its longitudinal axis.¹⁸ It is equal to the product of the force and the moment arm. Measured in Newton meters per degree (Nm/degree).

Although not performed in this study, torsional testing is another important method of static testing which provides comparison between constructs. Indeed it has been shown that *in vivo* loading of the ovine tibia⁴¹ occurs primarily in torsion. A number of studies have shown monocortical screws to be mechanically inferior in torsion when compared to bicortical screws.⁴²⁻⁴⁵ The conclusions of this study comparing the stiffness and strength of constructs with mono and bicortical screws are limited to four point bending and axial compression.

2.2 LOCKING VS NON-LOCKING COMPRESSION PLATES

2.2 (A) COMPRESSION vs. LOCKING MECHANISM

The fundamental difference between locking and non-locking compression plates is the way the screw engages the plate. Compression screws rely on frictional forces between the screw and the plate to compress the plate to the bone. The frictional force generated in non-locking plates is the sum of the insertional torques of all the screws compressing the plate to the bone and the coefficient of friction between the plate and the bone.⁴ Compression screws act independently in series within the plate converting axial and bending loads into shear forces.⁵ To do this they rely on 2 points of bone purchase (bicortical) where possible for stability.⁴⁶ If shear force overcomes these frictional forces then resorption or micro fracture permits the screw to toggle. Unlocked monocortical screws are more likely to toggle about the plate bone interface as they only have 1 point of bone fixation.⁸ This results in screw pullout from the bone and movement of the bone fragment relative to the plate.

Compression plates were originally designed for interfragmentary compression after anatomic reconstruction and therefore load sharing between the implant and fracture fragments. They rely on adequate numbers of screws and their purchase within the bone to compress the plate to the bone.²⁴ However, when used as bridging plates where anatomic reconstruction and load sharing cannot take place, the interfragmentary gap will only be maintained if loads do not exceed the frictional forces exerted by the screws between the bone and the plate. This requires the following 3 circumstances:⁴

- bone quality permits insertional torque >3Nm
- sufficient coefficient of friction between the plate and bone
- physiologic loads <1200N.

If these criteria are not met, then compression plating will fail when used in bridging mode. Where insufficient screw bone interface exists, axial loading can result in loss of reduction and even failure of the implant.⁸

The need for locking plates arose from the inability of conventional compression plates to meet the needs of minimally invasive techniques and to provide an environment ideal for secondary healing subsequent to bridge plating for diaphyseal fractures.⁴ Locking plates create angular stability such that there is no motion between plate and screws.

The locking mechanism ensures that screws do not function individually within the plate but as part of a fixed angle construct which does not rely on the screw to generate frictional forces between the plate and the bone for stability.²⁴ Locking the screw head into the plate ensures angular and axial stability relative to the plate such that individual screws cannot be sequentially loaded. Therefore there is no movement or toggling between the screw and the plate under load. The strength is the sum of all the bone screw interfaces and the locking mechanism of the plate prevents the screws from shearing thus converting shear stress into a compressive force, much the same as a tension band wire.^{4,24}

The fixed angle locking mechanism converts axial and bending forces into compression with all screws acting together in parallel.⁵ Bone has much higher resistance to compressive forces than it does shear forces so this method is much less prone to failure. This feature explains why locking plates perform better in poorer bone stock where significant screw torque cannot either be generated or tolerated.⁴⁷

2.2 (B) CLINICAL CONSIDERATIONS

Compression plates rely on anatomic contouring of the plate to the bone to maximise contact and friction between the plate and the bone. Perren showed that conventional screws compress the plate to the bone at 2000-3000N but locking screws maintain a fixed distance from the plate.⁹

With the recent shift towards biological osteosynthesis and the subsequent use of locking plates as internal fixators bridging comminuted diaphyseal fractures, precise anatomic contouring is no longer necessary. This has 2 advantages. Firstly, it prevents the potential for dislocation of the bone fragments after reduction during screw insertion and compression subsequent to inexact contouring of the plate.⁴⁸ The LCPs do not cause any loss of reduction of the fracture since the bone is not drawn to contact with the plate during screw tightening.^{5,8} Secondly, because LCPs do not rely on plate to bone friction, the plate does not have to be in direct contact with the bone. This permits periosteal blood flow, reduces bone necrosis and infection rates.⁴⁶ This contrasts with compression plates where stability is reliant on compression to the bone which disrupts vascular supply, slows healing and does not permit a MIPO approach.^{8,47} Eijer et al. reported reduced infection rates in human patients with the use of an early internal fixator known as the PC-Fix.⁴⁹ Increased periosteal bloody supply has also been demonstrated in cadaveric and clinical models of the canine radius.^{50,51}

The LCP was initially recommended to be applied over temporary space holders to create an offset between the plate and the bone. The offset minimised damage to periosteal vascularity.⁵² However, this creates a potential biomechanical weakness similar to external fixators where the distance between the connecting bar and the bone should be minimised to maintain stiffness.

Ahmad et al compared LCPs placed flush to the bone, and at a 2mm and 5mm offset. The study found that the construct 5mm from the bone failed at significantly lower axial loads, had greater rotational displacement in static torsion and showed greater displacement in axial and torsional cyclic testing.⁵³ From this study it was concluded that the plate should be placed at a distance less than or equal to 2mm from the bone. Stoffel et al also found that increasing the plate to bone distance from 2mm to 6mm resulted in a significant decrease in axial stiffness by 10-15%.¹⁴

2.2 (C) BIOMECHANICAL COMPARISON

The profile and structure of a locking compression plate is modelled on, and is therefore biomechanically identical, to a limited contact dynamic compression plate (LC-DCP).⁴⁸ Therefore, it is not surprising that many *in vitro* biomechanical studies have found little difference between the stiffness of these 2 plates. It is not the intention of this literature review to provide a comprehensive comparison of these 2 plate types as non-locking compression plates were not used in this study. However, the review of these studies aims to highlight the broad variation in experimental methodology and results which makes comparison challenging between these 2 implants.

STUDIES SHOWING LOCKING PLATES TO BE MECHANICALLY SUPERIOR TO NON-LOCKING PLATES

Uhl et al. compared the mechanical properties of 3.5mm broad DCP, LC-DCP and a 3.5mm narrow LCP in a synthetic fracture gap model designed to replicate healthy and osteoporotic bone.⁵⁴ The plate constructs were axial loaded at 300N/s for 10 cycles from 5-355N to determine gap displacement, then single cycle loaded to failure. They found the LCP to be less stiff than the larger broad DCP which was to be expected, but interestingly, gap strains were highest in DCP and LC-DCP constructs. They concluded that LCP system is more likely to maintain a neutral interfragmentary gap. The translation which took place in the DCPs was at the screw holes suggesting micromotion at the plate-screw interface.⁵⁴

STUDIES SHOWING LOCKING PLATES TO BE EQUIVALENT TO NON-LOCKING PLATES

Aguila et al. compared a LCP to a LC-DCP in 4 point bending and torsion in a cadaveric model using the canine femur and concluded there were no significant differences for stiffness in mediolateral bending or load to failure in torsion.⁵⁵

Goh et al. compared an LCP-rod construct with monocortical screws to an LC-DCP-rod construct. The constructs used 1 bicortical and 3 monocortical screws either side of the fracture gap with a rod of 40% IM diameter and found no significant differences in axial cyclic loading up to 60000 cycles.⁸

De Tora and Kraus compared the bending strength of 4 locking and non-locking bone plates. They found the 3.5mm LCP to have bending stiffness and strength not different from the LC-DCP. This result was expected given the almost identical dimensions and area moment of inertia of these 2 constructs.³⁵

STUDIES SHOWING LOCKING PLATES TO BE MECHANICALLY INFERIOR TO NON-LOCKING PLATES

Fitzpatrick et al. compared non-locking plates to a locking plates with monocortical and bicortical locking and compression screws on composite bone cylinders 2mm thick with a trabecular core of 0.16g/cm³ (osteoporotic bone model) in a bridge plating model with a 10mm fracture gap.⁵⁶ They found locking constructs to be significantly lower in torsional stiffness and bending than conventional plates but no significant difference in axial stiffness. They concluded this was result of the stand-off distance and minimal plate bone contact in locking constructs.

These findings were supported by Stoffel et al.⁵⁷ but Gardner et al. actually demonstrated subtle mechanical superiority of bicortical locked plates in torsional loading in both human cadaveric⁵⁸ and synthetic⁵⁹ bone models of osteoporosis, however these plates were applied directly to the bone with no plate standoff.

Gardner et al, 2005 tested LC-DCP against LCP in cyclic loading of biplanar 4 point bending and torsion using 18 osteoporotic, cadaveric, human radii with a 5mm fracture gap.⁵⁸ The study used 8 hole plates with 3 bicortical screws either side of the fracture gap and loaded at 75% of failure load. Data was collected for stiffness, cycles to failure and motion at the fracture site using high speed infrared motion analysis. The LCP constructs failed earlier (60% less cycles) than the LC-DCP in torsion and absorbed less energy, suggesting less deformation in cranio-caudal bending. Thus, the LC-DCP demonstrated a subtle mechanical superiority.

Irubetagoiena et al³⁷ compared the mechanical behaviour of 10hole 2.4mm LCP and LC-DCP on cadaveric canine femurs with a 20mm fracture gap. Three bicortical screws were applied in each fragment leaving 4 empty holes over the central fracture gap. Constructs were tested in cyclic axial loading for 610,000 cycles at 26-260N and measured stiffness from quasi static cycles every 50,000 cycles. Two out of 9 LCPs broke at the level of the proximal osteotomy between 400000 and 500000 cycles. None of the LC-DCPs broke during cyclic testing. The investigators found the LC-DCP to be significantly stiffer initially and attributed this to the difference in working length between the 2 constructs as the LCP was not in intimate contact with the bone initially. After cyclic loading the stability of the LCP was much less than the LC-DCP suggesting some sort of permanent deformation had occurred. The investigators also identified a biphasic profile to the stiffness curves. The second stiffness appeared at 60-70% of body weight. The authors concluded this was a result of contact between the plate and bone during mechanical loading which shortened the working length of the plate and created a stiffer segment.

2.3 PLATE-ROD BIOMECHANICS

Plate-rod constructs are used to repair comminuted diaphyseal fractures where load sharing between implant and bone does not take place.¹ Technically, the addition of an intramedullary (IM) pin serves to help with fracture reduction and spatial alignment of the major fracture fragments. Biomechanically the central IM pin serves to protect the working length of the plate from bending forces, thereby reducing strain at the fracture gap and increasing the fatigue life of the construct.²

2.3 (A) LINEAR & COMPOSITE BEAM THEORY

Linear beam theory is the basic mechanical method used for stress and strain analysis of a beam subjected to bending or eccentric axial load.²⁰ To use it for calculations involving plate osteosynthesis several assumptions are assumed to hold true:

1. The cross-sectional geometry does not vary along the length of the beam and remains unchanged throughout testing. Therefore there is no increase in compression or decrease in tension.
2. The material is homogenous and strain increases with distance from the neutral zone.
3. Hooke's law is valid, that is stress \sim strain

Most importantly, linear beam theory states that inside a beam there is a neutral axis where no compression or tension is experienced under axial or bending loads.²⁰ In a comminuted fracture where the bone has trans cortical defects and no load sharing capacity, the neutral axis moves from the medullary cavity of the bone to the centre of the plate. The eccentric position of the plate relative to the applied axial force creates a moment arm which is subjected to a bending moment when load is applied. Assuming the cross section of the beam is constant and the material is loaded within its elastic limit, the tensile stresses on the plate increase linearly with distance from the neutral axis during bending.

Bone plates applied in bridging fashion over a central area of comminution are subjected to high mechanical loads and may be subject to plastic deformation in the early post-operative period or cyclic fatigue failure over time if bony callus does not provide additional support.² A plate's resistance to bending loads is proportional to its elastic modulus and its area moment of inertia which for a plate which is the base width x height of the plate to the third power.⁶

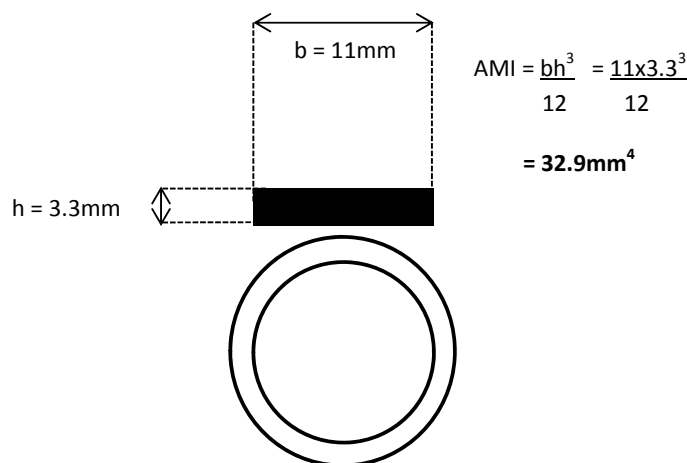


Figure 5 - Area moment of inertia (I) calculations for a 3.5mm LCP loaded on its flat surface on a cylindrical bone model.

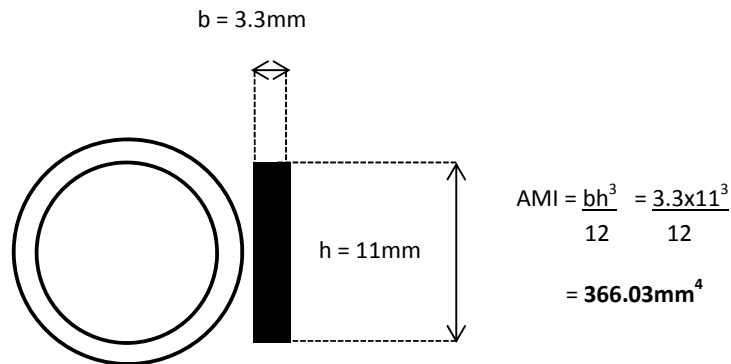


Figure 6 – Area moment of inertia (I) calculations for a 3.5mm LCP loaded on its side on a cylindrical bone model.

Composite beam theory describes the mechanical behaviour of 2 fixed parallel beams. The attachment of the 2 beams is important. If they are loosely attached each will undergo deformation according to its own mechanical properties and the AMI, modulus of elasticity and composite beam theory will not apply. If they are firmly connected the mechanics of composite beam theory are observed and the 2 beams share a common neutral axis.²⁰ This results in different mechanical behaviour where the rigidity of the system is much greater than the sum of the 2 individual beams. The structure bends in a new neutral axis between the neutral axes of the separate beams. This neutral axis is formed where axial stiffness x distance to the neutral axis is equal for each of the beams.

The addition of an IM pin to a bone plate has been reported to fit this model^{2,3} assuming rigid fixation of the rod within the proximal and distal fragments and adequate screw purchase of the screws securing the plate to the bone. The IM pin brings the neutral axis of the construct closer to the medullary canal of the bone thereby reducing the moment arm. The presence of a cylindrical rod in the medullary cavity increases the area moment of inertia of the construct as the radius of the pin⁴ is added to the pre-existing plate area moment of inertia.

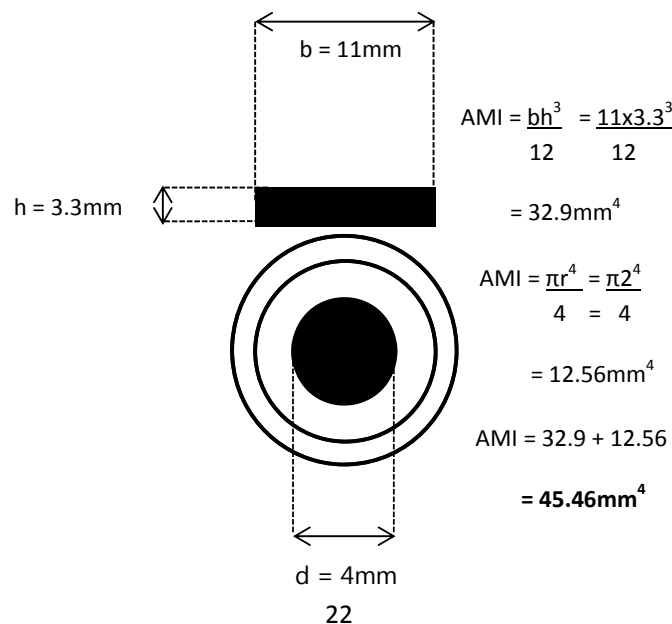


Figure 7 - Area moment of inertia (I) calculations for a plate-rod construct with a 3.5mm LCP and 4mm IM pin on a cylindrical bone model.

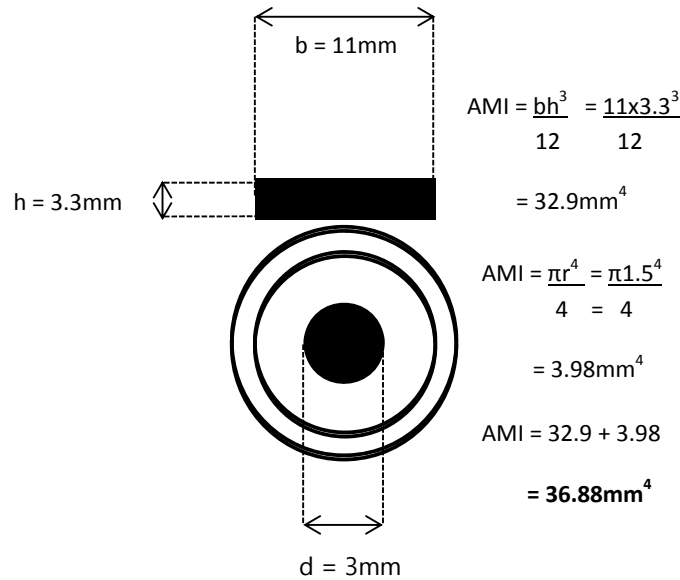


Figure 8 - Area moment of inertia (I) calculations for a plate-rod construct with a 3.5mm LCP and 3mm IM pin on a cylindrical bone model.

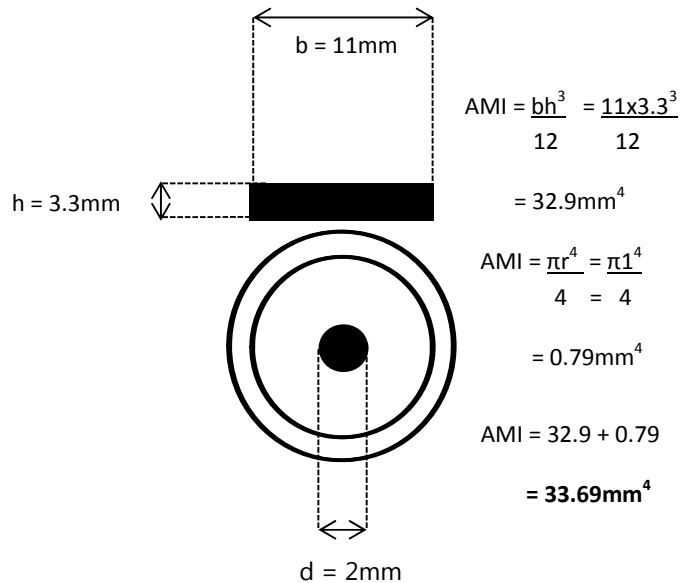


Figure 9 - Area moment of inertia (I) calculations for a plate-rod construct with a 3.5mm LCP and a 2mm IM pin on a cylindrical bone model.

In a comminuted fracture, the neutral axis shifts from the middle of the cross section of the plate towards the centre of the medullary canal shifting stress and strain towards the intramedullary pin and away from the plate.

2.3 (B) NON-LOCKING PLATE-ROD STUDIES

Hulse et al. demonstrated in a dynamic compression plate (DCP) cadaveric model that the addition of an IM pin increased stiffness and reduced plate strain.² Using a 12 hole broad 3.5mm DCP, that study compared plate only constructs with 4 bicortical compression screws with plate-rod constructs containing 1 bicortical and 3 monocortical screws either side of a 60mm fracture gap in five pairs of cadaveric canine femurs. Strain gauges were placed at the solid centre of the plate and another adjacent to the screw hole nearest the fracture gap. Constructs were loaded at 7mm/sec to a maximum of 600N. Strains at 400.5N were used for statistical analysis and showed that the addition of an IM pin occupying 50% of the medullary cavity brought about a 2-fold reduction in strain at the fracture gap. As loads were increased, the protective effect of the pin was amplified.

Mathematical extrapolation of this data to calculate stress within the plate estimated a 10-fold increase in the fatigue life of the plate supported by a 50% IM pin. Stress values were calculated assuming no relative movement occurred between the plate and the rod. Experimental results suggested that dual beam theory most accurately reflects plate-rod biomechanics. Once stress had been calculated, these values were compared against the stress-strain curve for 316L stainless steel to arrive at the values for fatigue life of the implant. The lowest stress strain ratio was 1.7 and depending on the magnitude of stress applied to the implant this brings about anywhere from 10-fold to infinite increase in the number of cycles to failure. This is the most widely referenced conclusion of this seminal plate-rod paper.²

The investigators hypothesised that as bending loads are applied, the pin was assumed to move within the bone, so any variability in strain measurements between constructs was attributed to this micromotion. Pin stability over time will decrease due to micromotion at the pin bone interface which may lead to resorption as a result of high strain at this site. Also, the working length of the pin inside the bone could not be predicted as variability in endosteal contact will result in shorter or longer working length and subsequent decreases or increases in strain.

Failure of the construct by monocortical screw pullout was a concern but the protective effect of the IM pin was believed to adequately reduce stress on the screws. Recommendations were made to place 1 bicortical and 3 monocortical screws in each fragment and if the bicortical could not be placed then 5 monocortical screws was advised.

The same group used a cadaveric canine femoral model with a 20mm fracture gap to investigate the effect of IM pin size on plate strain.³ In their discussion, the investigators had noted slow and non-union in some constructs using a 50% pin leading them to suspect this construct was too rigid causing stress protection and eliminating the microstrain necessary for osteoblast stimulation. This was the reason for assessing the effect of smaller diameter pins. Constructs were created using a 10 hole 3.5mm DCP with 4 monocortical screws either side of a 2 hole gap. Again, 2 strain gauges were fitted to a solid portion of the plate and an empty screw hole within the fracture gap. Each construct was axially loaded to 300N and stiffness and strain at 200N was used as the data set. Each construct was tested first with 30%, then 40% then 50% then no pin. As previously done, stress was then calculated from strain results assuming double beam theory and used to calculate the fatigue life of the implant via stress-strain curves for stainless steel.

There was a significant decrease in plate strain measured at the plate hole over the fracture gap with a 10% increase in diameter resulting in approximately 20% decrease in plate strain. Strain was significantly different between plate alone and 40% and 50% but not 30%. Strain was significantly different between 30% and 50%. Stiffness of each construct increased only by 6% with a 30% pin, but then significantly by 40% with a 40% pin and nearly 80% with a 50% pin. Strain values were extrapolated at loads of 1200N, 1500N, 2000N and 2500N and converted to stress and used to create estimates of fatigue life from S-N curves. All plate-rod constructs were estimated to withstand infinite number of cycles and the plate alone construct 90000 cycles at 1200N – well above physiologic loads. The 50% IM construct was estimated to withstand an infinite number of cycles at all loads.

From this discussion they concluded that a pin of 35-40% IM diameter should be used depending on the size of the fracture gap as it allows microstrain at the fracture gap. This was calculated on the basis of estimated fatigue life and recorded stiffness values but there is no clear reference as to the data used to come to this conclusion. It was also concluded that a 50% pin was unnecessary unless using a structurally weaker plate but again there is no data to support this other than their anecdotal opinion from a case series.

Von Pfeil et al. compared a 3.5mm 11 hole LC-DCP with a 40% IM pin with 5 bicortical screws in each fragment to a 6mm interlocking nail (ILN) in a cadaveric 30kg dog tibial model with a 10mm osteotomy gap in a cadaveric tibial model.⁴⁰ These were tested in 4 point mediolateral bending at 3.5Nm, axial compression at 176N equivalent to 60% of 30kg dog bodyweight and torsion under load control. This study found that there was no difference in bending or axial stiffness but angular deformation in torsion was greater in the ILN. They concluded that at low loads the plate-rod construct was significantly more rigid than the ILN and that ILN instability in torsion resulted from slack and damage to the bolts.

2.3 (C) LOCKING PLATE-ROD STUDIES

Goh et al.⁸ used the same LC-DCP model as Hulse et al.² They compared this to a locking compression plate-rod (LCPR) construct with 4 monocortical screws either side of a 39mm osteotomy gap in a femur model. Eleven hole 3.5mm plates with an IM pin of 40% of mid-diaphyseal diameter were tested in axial loading at 20% of body weight then cyclic axial loading at 20%, 40% and 60% of body weight for 6000 cycles each. Three matched constructs then underwent additional 45000 cycles at 60% of body weight. Constructs were then failed at 5mm/min in axial compression. Results of this study indicated no significant difference between constructs in stiffness and osteotomy gap subsidence (an indirect measure of strain) or in failure mode for each of the constructs despite the differences in angular stability of the screws used in either construct. This study used a 3mm plate to bone distance to approximate the clinical practice of semi contouring LCPs however the LC-DCP was directly contoured to the bone. It was postulated that although no difference between the constructs could be noted, perhaps the negative effect on stiffness of the standoff was countered by increased mediolateral bending stiffness of the LCP relative to non-locking plates.⁵⁵

Delisser et al. used the same canine cadaveric femur model with a 12 hole 3.5mm locking compression plate and a 40% IM pin.³² This study used all non-locking compression screws with bicortical screws in the most proximal and distal screw holes and monocortical screws added incrementally. The constructs were axially loaded to 72N and stiffness calculated from the curve.

They were then loaded sequentially at 20, 40 and 60% of body weight (72, 144, 216N) for 6000 cycles to simulate weight bearing in the early post-operative period. Then, a further 45000 cycles at 216N were added to simulate 3-6 weeks of convalescence. They were then axially loaded to failure. They found a significant increase in stiffness between the shortest and longest plate working lengths and no difference in load to failure for any of the constructs. The reason for this may be attributed to large variance within the cadaveric model but more likely the decision to use non-locking screws and anatomically contour the plate to the bone. This reduces the working length to that of the fracture gap regardless of the position of the screws. Concerns over catastrophic implant failure with small numbers of screws proximally and distally were not supported in this study and it was noted that clinically fewer screws close to the fracture site has the advantage of allowing less dissection around the soft tissue envelope.

The authors justified the use of bicortical screws proximally and distally for added pullout strength given the low numbers of screw used but this could have been avoided with the use of locked screws. There appears to be no clear reason for using compression screws other than cost reduction and the author stating that their use would eliminate plate strength as a variable, allowing comparison between previous and future studies using locking screw constructs.

A more recent study by Rutherford et al. evaluated the effect of IM pin size on 3.5mm String of Pearls (SOP) locking plates.⁶⁰ That *in vitro* study compared 12 hole 3.5mm SOPs with monocortical screws and IM pins of 24, 32 and 40% of IM diameter on a synthetic tibial bone model with a 50mm fracture gap in mediolateral bending. The controls were SOPs with monocortical and bicortical locked screws respectively and a non-locking 3.5mm LC-DCP with a 40% IM pin and a bicortical screw proximally and distally similar to Hulse's original model. They found angular deformation and construct compliance (inverse of stiffness) decreased significantly with increasing IM pin size.

Interestingly, this study found no difference between the SOP32 construct and the LC-DCP40 control with the SOP40 being significantly stiffer than all other constructs. This lead the authors to conclude that augmentation of a locking plate with a 40% IM pin is likely to be unnecessary and may actually be excessively stiff for bridging osteosynthesis. Without any data for clinical comparison, this study concluded that small diameter IM pin may prove beneficial in clinical cases where a locking SOP-rod construct is used.⁶⁰

That study also supported the use of monocortical screws in locking plate-rod constructs. Despite finding significant differences in deformation and compliance between mono and bicortical SOP fixation without a pin, these differences were eliminated by adding a 24% IM pin to the monocortical SOP constructs.

2.4 MONOCORTICAL SCREWS

In the era of compression plating, the use of monocortical screws in veterinary orthopaedics was one not usually made by choice but rather by the inability to place bicortical screws for reasons of fracture comminution, periarticular location or the presence of intramedullary implants. The biomechanical effect of using monocortical screws in locking plate constructs and under what situations they are to be used or avoided will be explored in this section.

There are currently only 2 veterinary biomechanical studies which directly compare the use of locked monocortical screws to locked bicortical screws.^{44,45} Further to this, there are very few human studies which directly compare monocortical and bicortical screws in locking plates in a diaphyseal fracture gap model. Most of studies prefer to compare hybrid screw configurations and the effect of adding locked and unlocked screws of various lengths to locked or hybrid plates. In addition, many of these biomechanical studies use comparison between conventional and locked plates where the screw has a completely different biomechanical function. What further complicates veterinary interpretation of the human literature is the frequency of osteoporotic models for screw placement and in many cases the conclusions of these studies cannot be extrapolated to normal healthy bone which is almost exclusively the case in veterinary orthopaedics.

Gautier and Sommer in their 2003 review of recommendations for use of the LCP state that traditional AO guidelines no longer apply for screw placement in LCPs.⁷ They recommend that self-drilling monocortical screws are used in the diaphysis in cases with excellent bone quality where anchorage of the screw thread is good enough to withstand rotational displacement. From purely mechanical point of view, 2 monocortical screws is the minimum requirement in each major fragment to maintain stability.⁷ They conclude that 2 screws are acceptable when bone quality is good and screws were inserted correctly using the locking mechanism, however 3 screws should be used in all other situations for safety reasons.

Gautier's study advised against the use of monocortical screws in metaphyseal or osteoporotic bone due to the minimal screw working length.⁷ They also highlighted some potential technical issues when using a monocortical screw and that contact with the contralateral endosteum before locking into the plate will result in complete destruction of the cis cortex and subsequently a bicortical screw should be inserted to engage the trans cortex. The same rationale should be used when the presence of an intramedullary pin such as in plate-rod constructs.

Miller explained that torque resistance is directly proportional to working length and therefore monocortical screws will have a lower resistance to torque as they have a shorter working length compared with bicortical screws.²⁴ This may be less relevant in locked plating as screws do not experience significant torque once they are locked into the plate. However, a number of studies have demonstrated the torsional superiority of locked bicortical screws in fracture gap models.^{44,45,61}

A retrospective case series of 47 fractures repaired with LCPs used bicortical screws where possible on a clinical basis.⁶² The authors commented that the holding power of locked monocortical screws was beneficial when implants such as THR stems and plate-rod combinations precluded the use of bicortical screws. In a locking plate review, Wagner stated that in bone of good quality the use of monocortical locking screws are sufficient but at least 3 screws should be inserted in either major

fracture fragment without any specific reference for this. However, in osteoporotic bone at least 1 of these 3 screws should be inserted bicortically.⁶³

2.4 (A) STUDIES SUPPORTING MONOCORTICAL SCREW USAGE

The major advantage of using monocortical screws is the ease of placement, especially when using minimally invasive approaches.⁹ The need to accurately measure the screw is negated as stick out length from the trans cortex is not a concern and therefore interference with adjacent neurovascular, soft tissue structures and bones (such as the ulna after a radial fracture repair) adjacent to the trans cortex is obviated. However, it is still important to measure the screw to ensure no contact with the endosteum of the trans cortex or an intramedullary implant which will prevent proper engagement of the screw head within the threads of the plate.⁷ Other advantages apart from ease of insertion and use with MIPO include decreased damage to the endosteal blood supply.

Egol, in his review of LCP biomechanics, highlights that angular stability of the screw is provided by the locking mechanism within the plate so bicortical purchase is unnecessary to prevent toggling.⁴ That review also references a study which show locked monocortical screws outperform conventional bicortical screws biomechanically.¹²

Marti et al. compared an original locking plate, the Less Invasive Stabilisation System (LISS) with 2 non-locking compression plates in a cadaveric human femoral fracture model with a 10mm gap. Each construct had 2 screws in either fragment with the LISS having only monocortical screws. Constructs were loaded in axial compression and optical displacement transducers were used to measure changes in gap height while loading. A total of 83% of tests showed less subsidence in the LISS implants. It was assumed because insertion torque was the same for all groups that irreversible subsidence was a result of conventional screw toggling rather than primary destruction of the screw bone interface. They concluded that LISS constructs with monocortical screws were biomechanically superior to non-locking DCP plates with bicortical screws in a human distal femoral fracture model.¹²

Hulse et al. conducted the original plate-rod biomechanical studies which have previously been discussed in detail. They concluded, amongst other things, that the use of 3 monocortical screws and 1 bicortical screw should be used in plate-rod constructs. This study did not model any other screw configuration for comparison so the recommendations are not evidence-based.^{2,3}

Goh et al. identified that the use of plate-rod constructs with intramedullary implants often requires the use of monocortical screws because of pin interference. Bicortical screws have been shown to impart greater angular stability in conventional plates however this has not been investigated in LCP.⁸ That study used and the same LC-DCP model as Hulse et al. with a single bicortical screw proximally and distally. The testing methodology of that study has been previously described in this thesis. Goh hypothesised that using monocortical screws in thin canine cortical bone would result in failure of the lateral cortex earlier than the DCP model however they did not fail in that fashion but rather by plate deformation at the fracture gap. However, there were no significant differences in failure mode for each of the constructs despite the differences in angular stability of the screws used in either construct. This result supports the notion that locking technology enables the use of monocortical screws as construct failure via screw toggling and failure of the screw bone interface is rarely an issue in locking constructs.

Delisser et al. used the same canine cadaveric femur model with a 12 hole 3.5mm LCP and a 40% IM pin using all non-locking compression screws with bicortical screws in the most proximal and distal screw holes and monocortical screws added incrementally. They concluded that using fewer monocortical screws has the advantage of allowing less dissection around the soft tissue envelope.³² Concerns over catastrophic implant failure with small numbers of screws were not supported in this study.

In their locking plate review, Kubiak et al. supported the use of monocortical screws, citing studies that showed monocortical screws withstanding loads in excess of physiologic axial and bending loads.^{13,64} In the discussion they mention the concept that bicortical screws strip the near cortex when being inserted effectively achieving only monocortical purchase however this is not referenced.⁵

Korvick et al. examined the effect of screw removal on bone strain in a synthetic fracture gap model under the context of looking for methods which would increase strain at the fracture site to prevent stress shielding and encourage callus formation. Interestingly, they found that replacement of bicortical with monocortical screws significantly reduced strain in their 8 hole 4.5mm DCP model tested in 4 point bending.¹¹ They commented no further than to say it was an inappropriate method of encouraging callus formation.

A more recent locking plate-rod study by Rutherford et al. evaluated the effect of IM pin size on 3.5mm String of Pearls (SOP) locking plates.⁶⁰ That *in vitro* study compared 12 hole 3.5mm SOPs with monocortical screws and IM pins of 24, 32 and 40% of IM diameter to SOP controls with monocortical and bicortical locked screws respectively on a synthetic tibial bone model with a 50mm fracture gap in mediolateral bending. Despite finding significant differences in deformation and compliance between mono and bicortical SOP controls, these difference were eliminated by adding a 24% IM pin to the monocortical SOP constructs supporting the use of monocortical screws in locking plate-rod constructs.

2.4 (B) STUDIES DISCOURAGING MONOCORTICAL SCREW USAGE

Fulkerson et al. compared the stability of various locked and non-locked plate constructs in an osteoporotic, comminuted human ulnar diaphyseal fracture model in cyclic axial loading and 3 point bending.¹³ The study used monocortical and bicortical hybrid configurations in the LCPs and compared them with DCPs with bicortical screws and found that LCPs with bicortical screws withstood significantly more cycles to failure when compared with all other constructs. They concluded that the use of monocortical screws and increased distance from plate to bone could not be recommended for this osteoporotic fracture model. The relevance of this study to dogs is uncertain. However, the study was referenced by Kubiak et al. in a review on locking plates, who concluded in situations where high torsional loads are expected, bicortical locked screws should be used due to their greater screw working length.⁵

Fitzpatrick et al. compared DCP to LCPs using monocortical and bicortical locking and compression screws on composite bone cylinders. The bone cylinders were 2mm thick with a trabecular density of 0.16g/cm³ (osteoporotic bone model in a bridge plating model with a 10mm fracture gap).⁵⁶ They found locking constructs to be significantly lower in torsional stiffness and bending than non-locking plates but no significant difference in axial stiffness. They concluded this was a result of the stand-off distance and minimal plate bone contact in locking constructs. This study found adding a single

bicortical locked screw increased torsional rigidity by 73%.⁵⁶ Monocortical screws performed worse than bicortical screws in this osteoporotic bone model which is consistent with the recommendation of Gautier & Sommer to avoid monocortical screws in poor quality bone due to insufficient screw working length.⁷

Roberts et al. referenced studies which found that non-locking DCPs failed in torsion at the point of fixation furthest from the fracture and bicortical screws greatly improve stability.^{42,43} They hypothesised this would be true for locking constructs as well.⁶¹ They used a synthetic model of the radius with a midshaft osteotomy and fixed 8 hole 3.5mm LCP plates with 3 screws either side. The control was 3 monocortical locked which was compared to 3 bicortical unlocked screws as well as replacing the most distal hole with unlocked and locked bicortical screws. The constructs were tested in biplanar 4 point bending and torsion. They found monocortical constructs to be the weakest under torsional loads compared with all bicortical constructs and that the additional of a single locked or unlocked bicortical screw significantly improved the torsional stiffness. They concluded that the dominant factor in torsional stability was screw working length and that locked or unlocked fixation has little effect.⁶¹

Roberts et al. also found the locked hybrid construct to be significantly stiffer in anterior-posterior bending than the other constructs and postulated that despite identical working length of the plate, bicortical purchase from the screw with the largest working distance strengthens the bending stability of the construct. There was only a 1mm osteotomy gap but the authors maintain that no contact occurred in non-destructive bending or torsion.

These studies were supported by 2 recent veterinary studies which found no difference between mono and bicortical screws in axial compression but significant differences in torsion.^{44,45} Demner et al. tested 10 hole 3.5mm LCPs applied a synthetic tibial fracture gap model in 4 point bending and torsion.⁴⁵ Each construct was randomly assigned either mono or bicortical locking screws in the 2 most proximal and distal holes with the plate contoured to the bone to minimise variation in plate standoff. This study found no difference in bending stiffness or load to failure but significantly greater torsional stiffness for bicortical constructs. They concluded that greater torsional stiffness was probably related to the greater screw working length of the bicortical constructs. This study also found the monocortical constructs were more likely to fail as a result of screw pullout than bone fracture and reference a human study showing the pullout strength of monocortical locked screws is only 70% of bicortical screws.⁶⁵

Demianiuk et al. tested 3.5mm String of Pearls locking plates in torsion on a synthetic tibial bone model with a 50mm fracture gap and also found a significant effect of screw type and the position of bicortical screws on construct stiffness.⁴⁴ They concluded that a minimum of 1 bicortical screw should be used per fragment to increase torsional stability and that this screw should be positioned as close to the fracture gap as possible. After stating that *in vitro* results should be extrapolated to the clinical setting with caution, this study then concluded that fractures could not be safely stabilised using an all monocortical screw configuration.

In summary, monocortical screws should be avoided in situations where cortical bone is thin such as metaphyseal region or disease states such as osteoporosis. More importantly they should be avoided at anatomical locations expected to experience high torsional loads⁶⁵ such as the tibia and humerus.^{7,41}

2.5 EFFECT OF SCREW CONFIGURATION

Gautier and Sommer published a series of recommendations for using LCPs in fracture repair.⁷ The main principles outlined in this paper were to ensure adequate **plate span ratio** for comminuted fractures such that the plate length was 2-3 times the length of the area of comminution. In addition, they recommended keeping the **screw ratio** to 0.4 or 0.5 such that no greater than 50% of plate holes should be filled by screws. These recommendations along with the findings from Stoffel et al. on screw placement comprise the primary reference material for screw placement in LCP constructs.¹⁴

2.5 (A) WORKING LENGTH

Studies investigating the effect of plate working length have yielded variable results and this remains an area of controversy.^{14-17,66} Most of this variability arises from methodological variations where non-locking plates or LCPs are anatomically contoured and compressed to the bone with cortical compression screws thereby reducing the working length to that of the fracture gap regardless of the position of the screws. Experimental models which use LCPs with a small plate to bone clearance and locking screws only, generate consistent data that shows the effect of plate working length on construct stiffness and strength.¹⁴

Stoffel et al. investigated which factors affected stability of a LCP in a non-load sharing fracture. This study investigated working length, number and position of screws, plate length and the distance between the plate and the bone.¹⁴ They tested 12 hole 4.5mm titanium LCPs in axial compression and torsion on a synthetic bone model. The plates were applied with monocortical locked screws in various screw configurations with a plate to bone distance of 2mm or 6mm. Stoffel et al. found that working length of the plate (the distance between screws either side of the fracture) was the most important factor affecting axial stiffness and torsional rigidity. This study recommended placing screws as close to the fracture gap as possible with a 300% decrease in axial stiffness recorded when the screw closest to the fracture gap was moved 1 hole further away.

Using finite element analysis, Stoffel's study determined that Von Mises stresses in the plate increase as the screws are placed further from the fracture site. (increasing working length) so to reduce plate stress place screws should be placed closer to the fracture gap.

Hoffmeier et al¹⁷ tested stainless steel and titanium distal femoral plates on cadaveric human femora with a 10mm fracture gap. Both torsion and 4 point bending were reported. They hypothesised that despite applying the plate flush to the bone which limits the working length of the plate to that of the fracture gap, that the distance between the screws adjacent the fracture site would affect the plate's endurance. They found no difference in stiffness or fatigue life for stainless steel plates. For titanium plates, there was no difference between short and middle working length and only 16% loss of stiffness with a longer working length. The authors justified their decision to place the plate flush with the bone on clinical grounds. However, this ignores a major advantage of locking technology. The lack of difference in stiffness when screws were omitted adjacent to the fracture site can be put down to the plate contact with the bone making the working length equal to the fracture gap in all screw configurations.

Chao et al conducted an almost identical study comparing the stiffness and fatigue life of 12hole 2.4mm LCPs on cadaveric canine femurs with long (8 hole) and short (2 hole) working lengths and

found no significant difference between constructs.⁶⁶ However, they only used a single locking screw in hole 2 of each fragment and bicortical compression screws in all other holes so the plate was compressed to the bone. Therefore this study was met with the same limitation since the working length of the plate was limited to that of the 10mm fracture gap.

Delisser et al modelled a 12 hole 3.5mm LCP with all non-locking compression screws, applying bicortical screws in the most proximal and distal screw holes and monocortical screws added incrementally.³² That study only found a significant increase in stiffness between the shortest and longest plate working lengths and no difference in load to failure for any of the constructs. The reason for this may be attributed to large variance within the cadaveric model but more likely the decision to use non-locking screws and anatomically contour the plate to the bone. This reduces the working length to that of the fracture gap regardless of the position of the screws. In their discussion, they noted that no studies have assessed the optimum number or configuration of screws, either biomechanically or clinically, for a plate-rod construct and that surgeons may place more screws than previously recommended.³

More recently, Tomlinson et al. evaluated the effect of plate working length a new locking plate in a Delrin synthetic fracture gap model.⁶⁷ Again, the plate was applied flush to the bone for all screw configurations but 1, and as a result, a significant increase in stiffness was only found between the extremes of plate working length. The authors identified that contact between the plate and the bone model meant the functional working length was reduced to that of the fracture gap once a bending moment was applied which may have resulted in the failure to find differences between some of the other configurations tested in the study.

2.5 (B) SCREWS PER FRAGMENT

Stoffel et al. found that the addition of a 3rd screw on either side of the fracture significantly increased axial stiffness especially if this screw was placed close to the fracture site.¹⁴ Leaving 1 screw hole either side closest to the fracture gap resulted in 60% decrease in axial stiffness and 34% decrease in torsional stiffness. Any more than 3 screws per fragment did little to increase axial rigidity of the construct. However, up to 4 screws either side increased torsional stiffness. This study recommended 3 screws in each fragment with 2 of those screws placed as close to the fracture gap as is practical and to limit plate to bone distance to 2mm or less.

2.5 (C) PLATE LENGTH

Prior to the application of biologic osteosynthesis, shorter plates were used to minimise the length of incision. However, with internal fixators such as the LCP placed percutaneously via epiperiosteal tunnels, this tissue damage is no longer a concern.²⁴ The plate span ratio is the total length of the plate divided by the length of the fracture site or area of comminution.⁷ One of the main principles of LCP placement in people is to ensure adequate plate span ratio for comminuted fractures such that the plate length is 2-3 times the length of the area of comminution. The reason for this was that longer plates allow better distribution of bending forces along the plate and subsequently lower the pull out forces acting on individual screws.⁹

Stoffel also recommended to use the longest plate possible in comminuted fractures.¹⁴ That study showed a larger plate resulted in significant stress reductions under axial load. Increasing plate length

increases axial stiffness but not torsional stiffness. A shorter plate with an equal number of screws caused a reduction in axial rigidity but not torsional.

A biomechanical study by Tornkvist et al. tested a number of different length broad 4.5mm DCPs on synthetic polyurethane foam blocks with a 5mm fracture gap.⁶⁸ The investigators tested a variety of screw configurations and plate lengths in 4 point bending to failure. Results indicated that the bending strength can be more effectively increased by wider spacing of screws in longer plates than by increasing the number of screws in shorter plates thereby supporting the use of longer plates and more widely spaced screw configurations.

Sanders et al. compared 6, 8 and 10 hole DCPs in 4 point bending on human cadaveric ulnae and also found that longer plates with fewer screws were stronger than shorter plates with all holes filled. The authors concluded that the number of screw was less important than the length of the plate in providing multi-planar bending strength.⁶⁹ Similarly, Weiss et al. showed greater bending strength when comparing 10 hole plates to 8 hole plates for the same near-far screw configuration either side of a human cadaveric ulna fracture gap model.⁷⁰

Goh et al⁸ who used 11 hole 3.5mm plates as the most appropriate length for their comminuted femoral fracture model. They justified their selection by commenting that the plate spans the length of the diaphysis but screws were not placed in metaphyseal bone proximally or distally. Zahn et al also used 12 hole plates in order to cover the entire length of the average size canine diaphysis.³⁶

2.6 STRAIN

Strain can be defined as the percentage change in length or relative deformation of an object under load.⁷¹ Fracture stabilisation requires selecting a fixation that resists implant failure but allows sufficient interfragmentary motion to stimulate callus formation.⁹ Some authors have suggested that LCP constructs are too stiff to allow for sufficient interfragmentary strain.²⁶ Others authors have suggested the elastic properties of stainless steel are ideal for elastic osteosynthesis and the use of implants in bridging fashion provides the perfect environment for elastic osteosynthesis.⁹ The optimal amount of micromotion at the fracture site is unknown. With insufficient construct stiffness, fracture site motion exceeds the strain tolerance of reparative tissues and eventually leads to delayed union or non-union. Strain at the fracture site determines the tissue type which will form as tissue cannot exist under conditions which exceed its elongation and rupture. Bone will develop between 2 and 10% strain and bone resorption and non-union will occur between 10-20%. Absolute stability has been shown to delay healing.⁹

Whilst fracture healing may be delayed because of extremes of bone strain at the fracture site, implants fail because of excessive strain on the implant itself. This is especially important in comminuted fractures where load sharing between the implants and the bone does not take place. Implants may fail acutely because of mechanical overload as is often the case in veterinary orthopaedics. Alternatively, in people (and in well controlled animals), where weight bearing is controlled after surgery, hardware failures occur from cyclic implant fatigue rather than acute failure. Plate strain is measured to identify areas of mechanical weakness where a construct may fail by acute overload or cyclic fatigue.⁶

2.6 (A) MEASURING STRAIN

The most frequently used method to measure strain in biomechanical testing is the resistance strain gauge.^{2,3,15,16} These are thin non-conducting substrates with a pattern of fine conductive wires printed on the surface. Stretching the gauge elongates and thins the conductors, increasing the electrical resistance, which can be measured to determine the strain. Such gauges are sensitive and reliable, if properly installed, and can measure high frequency variation in strain.

A single strain gauge can only measure strain at a point and along its axis, which can make them sensitive to positioning errors. In very small sizes, such as are required to measure the strain between screw holes, angulation errors are hard to avoid. A strain rosette made up of 3 stacked gauges at different angles allows the calculation of the local principal strain, regardless of direction. This requires 3 measuring channels (2 wires for each channel) for each gauge position, which limits the number of positions that can be measured simultaneously. Excess glue thickness or bonding problems can also cause strain gauges to give incorrect measurements.²²

Digital image correlation uses HD cameras and a random speckle pattern on the surface of the construct to calculate surface strain by correlation-based displacement measurements.⁷² The system uses specialised software to interpret construct deformation in 3 dimensions from the raw video files. Video recording of the construct enables principal strain measurement across the whole field of view and multiple areas of interest can be positioned to give simultaneous strain measurements in many locations, limited only by computation time.⁷³ Regions of interest can even be chosen after the full-field video analysis has identified interesting areas on the surface of the construct.

The resolution of the system is limited by the resolution of the cameras used and the quality of the speckle pattern. The physical resolution can be made very high by selecting the right lens and camera combination, at the expense of a reduced field of view. The maximum sampling rate is limited by the frame rate of the camera system and is typically between 5 and 50 frames per second range.

The quality of strain measurements also depends on the speckle pattern. A good pattern has sharp differentiation between the black and white regions, with a random distribution of sizes, shapes and positions of the speckles. Speckle size and variation limits the minimum region size and thus the resolution of the strain measurements. If a single speckle completely filled a region, there would be no information about displacements within that region. The same is true for regions with no speckles. With accurate camera calibration and a good speckle pattern displacements of 0.01 pixels can be resolved.^{72,73}

2.6 (B) STRAIN STUDIES

Hulse et al. demonstrated in a canine cadaveric model that the addition of an IM pin to a DCP increased stiffness and reduced plate strain.² Using a 12 hole broad 3.5mm DCP, that study compared plate only constructs with 4 bicortical compression screws with plate-rod constructs containing 1 bicortical and 3 monocortical screws either side of a 60mm fracture gap in five pairs of cadaveric canine femurs. Strain gauges were placed at the solid centre of the plate and another adjacent to the screw hole nearest the fracture gap. Constructs were loaded at 7mm/sec to a maximum of 600N. Strains at 400.5N were used for statistical analysis and showed that the addition of an IM pin occupying 50% of the medullary cavity brought about a 2-fold reduction in strain at the fracture gap. Further mathematical extrapolation of this data, depending on the magnitude of stress applied to the implant, brings about anywhere from 10-fold to infinite increase in the number of cycles to failure.

The same group used a similar cadaveric canine femoral model with a 10 hole 3.5mm DCP and a 20mm fracture gap to investigate the effect of IM pin size on plate strain.³ Again, 2 strain gauges were fitted to a solid portion of the plate and an empty screw hole within the fracture gap. Each construct was axially loaded to 300N and stiffness and strain at 200N was used as the data set. Each construct was tested first with 30%, then 40% then 50% then no pin. The study concluded that a pin of 35-40% IM diameter should be used depending on the size of the fracture gap. This was calculated on the basis of estimated fatigue life and recorded stiffness values but there is no clear reference as to how the authors came to this specific conclusion. The effect of different IM pin sizes on plate strain in locking plate-rod constructs has not been previously reported.

Numerous studies have attempted to define the effect of screw configuration on plate strain and the results are conflicting.¹⁵⁻¹⁷ Much of this variation can be attributed to discrepancies in experimental methodology including use of different bone models, plate and screw types and combinations, plate lengths and methods of measuring plate strain.

Maxwell et al. reported the effect of screw omission on plate strain under axial load in a Delrin model with a 10mm fracture gap.¹⁵ That study used 11 hole DCP and LC-DCP on Delrin with 6 and 5 bicortical screws either side of a 10mm gap. Strain gauges were positioned on the solid portion of the plate between screw holes over the gap and then 1 hole proximally. The constructs were axially loaded in compression to 300N, then cyclically loaded to failure by fatigue from 50-500N. Strain was greatest over the fracture gap but did not significantly increase with any screw configuration. The omission of

screws closer to the fracture gap resulted in increased strain at those empty screw holes but no change in strain at the fracture gap. The authors concluded that this corresponded to redistribution of strain across the plate but that could not be proven statistically.¹⁵ To validate the results from the experimental model, the effect of screw removal on strain was modelled by finite element analysis within the same study. This showed a 6-fold increase in strain at the gap when all screw holes were filled but when screws were omitted, it predicts a reduction in strain at the gap and a near uniform distribution of strain across the plate with a 2-fold increase in strain at these gauges to when all screws were placed. The authors concluded that the experimental model was similar in its findings but not nearly as uniform as predicted by the idealised finite element model¹⁵

Overall, Maxwell's study concluded that the addition of more screws to the construct does not protect against strain but rather focuses strain at the fracture gap. The removal of screws results in increased strain at those empty screw holes. Placement of additional screws did not improve fatigue resistance contrary to what was expected, possibly as a result of motion at the screw-plate and screw-delrin interface. This finding suggests surgeons can rely on screws placed in the proximal and distal cortices with less motivation to place screws adjacent to the fracture environment. The addition of an IM pin may further serve to reduce strain at the gap and investigations are warranted.¹⁵

Korvick et al. investigated the effect of screw removal on 8 hole 4.5mm DCP in a synthetic bone model in 4 point bending.¹¹ They found that as screws were removed, strain increased along the plate. This study advised staged removal of screws to overcome stress protection osteopenia in people and animals. Removal of the middle screws closest to the fracture gap resulted in the greatest increase in stress and made the plate more flexible. Removal of the end screws had very little effect on stiffness or strain.

Ellis et al. examined the in vitro effect of screw position on plate strain over a 10mm gap and a 40mm gap over the 2 central screw holes.¹⁶ Using 4.5mm 20 hole DCP tested and 11 different configurations of 4 screws either side of the fracture gap, they tested 1 construct per configuration in single cycle axial compression to 600N. Maximal plate strain was lowest when screws were placed close to the fracture gap and they concluded that screws should be placed as close to the fracture gap as possible to reduce strain. This conflicts with Maxwell's findings of no reduction in plate strain at the gap regardless of screw configuration. Ellis et al. also found that widely spaced screw configurations experienced less strain than those close together. This study used 20 hole 4.5mm DCP loaded to 600N with small numbers of screws so these methodological variations may account for this discrepancy.¹⁶

Field et al.⁷⁴ evaluated the effect of symmetrical screw omission on stiffness and bone surface strain in an equine cadaveric bone model in four point bending and torsion using a 10 hole 4.5mm DCP. The study modelled a variety of configurations with 3 screws per fragment for the 5 available plate holes either side of a 10mm fracture gap. The context of this paper was to investigate methods to increase bone strain so as to avoid stress protection and promote bone deposition. They found no significant difference in stiffness when using 3 screws per fragment in a variety of positions. However, they did find that bone surface strain was noted to increase with various screw positions but found no pattern with regard to working length. The authors concluded that bone mass could be increased in accordance with Wolff's law with various screw configurations but there was no deleterious effect on construct stiffness.

2.7 BONE MODELS

2.4 (A) CADAVERIC MODELS

Bone models eliminate the biological variation associated with *ex vivo* and *in vivo* investigation. Studies using bone have used bone densitometry, even on paired bones, to validate the repeatability of the model.³² Other studies have sighted the inconsistent published mechanical properties of human femora in torsion (42-318Nm), and bending strength (52-605N) as the reason for using a model of the femoral diaphysis to eliminate variability.⁵⁶

The use of cadaveric bone models may result in data sets with large standard deviations and thus increases the potential to make a statistical type 2 error. This was seen in the studies by Hulse et al. which comprise the major literature base for plate-rod constructs.^{2,3} In fact, all previous plate-rod studies prior to this study have used cadaveric bone models in an attempt to closely approximate the original study by Hulse.^{8,32} Goh et al. suggested the use of a bone model would have eliminated biological variation in their study but stated that it may have prevented meaningful interpretation of the study data. They then sited the fact that the contralateral femur of each dog served as an internal control for testing but did not perform bone densitometry to prove this. Delisser et al. performed bone densitometry on their paired femurs prior to their plate-rod study to avoid this critique of their study.³²

The primary reason for using cadaveric models is to simulate the viscoelastic properties of bone and the screw-bone interface which may be useful when assessing modes of failure.⁷⁵ The methodology for specimen preparation can be variable between studies and caution should be exercised before generalizing to a clinical scenario. Studies using cadaveric bone often demonstrate failure due to mechanisms other than plastic deformation of the implants which makes comparison across implants of questionable value.³⁶

2.4 (B) SYNTHETIC MODELS

Many different synthetic cortical bone models have been described for both human and veterinary biomechanical studies. In a fracture gap model the structural characteristics of the model need to closely replicate bone if possible but more importantly for implant testing, the model needs to outlast the plastic limit of the implants being tested. Synthetic bone models are specifically indicated when the objective is to compare and test implants.

Zahn et al³⁶ used Canevasit rods (not tubes) to eliminate biologic variation and highlighted the small standard deviations of their test results to confirm that each test was highly reproducible. This study tested a number of AO plates in bending and torsion using 16mm diameter rods to model the femur of dogs 15-30kg. They had 4 screw holes positioned over the gap. The authors chose to tap each of the drill holes 5 times to reduce friction between the synthetic bone and screw thread during fixation. However, this is only relevant when using compression plates that rely on screw insertional torque to compress the plate to the bone. That study referenced a clinical case series highlighting that the majority of fractures are comminuted without any bony support.^{1,62} The osteotomy gap in a fracture model helps to eliminate other variables which arise from bone to bone contact.

Uhl et al⁵⁴ used hollow polyurethane foam (PUF) cylinders of 20mm outer diameter to simulate compact (high density 0.8g/cm³) or osteopaenic (low density 0.32g/cm³) diaphyseal cortical bone in a

study which compared broad compression plates to narrow locking compression plates. They did this to eliminate biologic variability. They sighted that the PUF used in their model had been previously validated as a cortical and cancellous bone model.⁷⁶ This study also highlighted that PUF cylinders manufactured by Pacific Research Laboratories have been approved for testing orthopaedic devices and instruments by the ASTM.

Fitzpatrick et al⁵⁶ used 3rd generation composite bone cylinders and a trabecular core of PUF (0.16g/cm³) which was bonded to the inside of their cortical model to model an osteoporotic human femoral diaphysis. This model had been previously validated as an osteoporotic femoral model in the human literature but the bonding of the PUF to the composite bone cylinders closely replicated the model used in our study.

Stoffel et al used homogenous composite cylinders composed of epoxy reinforced glass fibres filled with rigid PUF to exclude high variation in geometry and quality of real bone, thus increasing the reproducibility of results.¹⁴

Fulkerson et al¹³ used a Sawbones[®] PUF model of a comminuted mid-diaphyseal ulna fracture in osteoporotic bone. They chose not to use epoxy as it would represent clinically healthy not osteoporotic bone. Interestingly, they intended to use cadaveric bone but encountered problems with fractures through the screw holes at a wide range of loads at inconsistent locations in the construct. They justified their choice by saying the purpose of their experiment was to compare stability of fixation methods so minimising the variability of the bone substrate was essential which reflects the intentions and desire of our project. They did discuss the relevance of using anatomic bone models so that implants and screws were more accurately reproduced than with foam blocks.

Similarly, Roberts et al⁶¹ used a composite human radius Sawbones[®] model to compare locking constructs with monocortical and bicortical fixation. They cited the advantage of inter-specimen consistency and low variability which permits the use of much smaller sample sizes to detect significance between constructs.

Ahmad et al⁵³ used 3rd generation composite humeral Sawbones[®] for their study investigating the effect of plate to bone distance. These models have an epoxy glass cortex with a homogenous cancellous core of PUF (0.32g/cm³).

Ellis et al¹⁶ used polyvinylchloride pipe in their study which looked at the effect of screw position on plate strain in a 20 hole 4.5mm DCP. They stated their intent was to investigate plate strain, not the pullout strength of the construct so a uniform cheap structure which maintained screws in rigid fixation was selected over cadaveric bone or composite bones.

Korvick et al¹¹ used an intact aluminium tube 25mm diameter as a bone model in their study which investigated the effects of screw removal from an 8 hole 4.5mm DCP on bone strain. Hoffmeier et al¹⁷ used an abstracted synthetic bone model based on the angles and dimension of a 3rd generation femoral composite Sawbone.[®] This model used replaceable aluminium frames with PVC plates of 3mm thickness as a femoral surrogate. Tornqvist et al. used a homogenous PUF block as a synthetic bone model for testing the strength of DCP fixation depending on the number and spacing of screws.⁶⁸

Maxwell et al¹⁵ used solid Delrin rods of 19mm diameter affixed with 12 hole 3.5mm DCP and LC-DCPs which investigated the effect of screw placement on plate strain. They note the limitations of delrin

rods as not accounting for *in vivo* factors such as blood supply, bone healing and screw purchase which can vary between cases.

Silbernagal et al⁷⁶ validated the use of polyurethane foam as a canine cortical and cancellous bone model. Using bone densitometry and calculating volume of bone in mature canine cadaveric bone they arrived at densities of 0.34g/cm³ for cancellous bone and 0.84g/cm³. They then tested these models with screw pullout and no significant differences between cadaveric bone and the bone model could be detected. This was supported by the work of Marti et al. who performed bone densitometry on the distal femoral metaphysis in human cadavers and found the density to be 0.15-0.38g/cm³.¹²

Cordey³⁴ explains that many engineers prefer to use PUF instead of cancellous bone because it is homogenous and less offensive to use. However, he is quite critical of this stating that foam is a set of bubbles with a hexagonal structure which is not trabecular as the holes are not interconnected as they are in orthogonal cancellous bone.

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CHAPTER THREE: PAPER ONE

3.1 TITLE PAGE

The effect of intramedullary pin size and monocortical screw configuration on locking compression plate-rod constructs in an *in vitro* fracture gap model.

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3.2 ABSTRACT

Objective: To investigate the effect of intramedullary (IM) pin size in combination with various monocortical screw configurations on locking compression plate-rod (LCPR) constructs.

Methods: A synthetic bone model with a 40mm fracture gap was used. LCPs with monocortical locking screws were tested with no pin (LCPMono) and IM pins of 20% (LCPR20), 30% (LCPR30) and 40% (LCPR40) of IM diameter. LCPs with bicortical screws (LCPBi) were also tested. Screw configurations with 2 or 3 screws per fragment modelled long (8 hole), intermediate (6 hole) and short (4 hole) plate working lengths. Responses to axial compression, biplanar four point bending and axial load to failure were recorded.

Results: LCPBi were not significantly different from LCPMono control for any of the outcome variables. In bending, LCPR20 were not significantly different from LCPBi and LCPMono. LCPR30 were stiffer than LCPR20 and the controls. LCPR40 constructs were stiffer than all other constructs. The addition of an IM pin of any size provided a significant increase in axial stiffness and load to failure. This effect was incremental with increasing IM pin diameter. As plate working length decreased there was a significant increase in stiffness across all constructs.

Clinical Significance: A pin of any size increases resistance to axial loads whereas a pin of at least 30% IM diameter is required to increase bending stiffness. Short plate working lengths provide maximum stiffness. However, the overwhelming effect of IM pin size obviates the effect of changing plate working length on construct stiffness.

3.3 INTRODUCTION

Plate-rod (PR) constructs are used to repair comminuted, femoral diaphyseal fractures in dogs.¹ The addition of an intramedullary (IM) pin to a bone plate increases the stiffness and fatigue life of the construct.² Results of PR investigations recommend the use of a pin of 35-40% of IM diameter and a minimum of 3 monocortical and 1 bicortical screw in each fracture fragment. However, these recommendations are based on studies on non-locking compression plates modelling only that specific screw configuration.³ There are currently no published studies documenting the biomechanical effect of IM pin diameter on locking compression plate-rod (LCPR) constructs.

A major technical disadvantage when using conventional non-locking PR constructs is the inability to place bicortical screws and therefore the need to place monocortical screws to avoid IM pin interference.¹ This creates a biomechanical weakness as non-locking compression screws depend on maximum bone purchase to maintain frictional forces between the plate and the bone.⁴⁻⁶ Consequently, angled bicortical compression screws directed around the pin are preferred to maximise cortical bone purchase.

Pin interference is even more likely when placing locked bicortical screws in LCPRs as there is no flexibility in the angle of screw placement. However, locked screws form a fixed angle, single beam construct which is not as dependent on bone purchase for stability. Therefore, the use of locked monocortical screws has less impact on the stiffness and strength of an LCPR construct.⁷⁻¹⁰ Furthermore, it has been shown that locked monocortical screws outperform bicortical compression screws in fracture gap models.^{4,11-13}

Studies on locking compression plates (LCP) with monocortical screws recommend that screws be placed as close to the fracture gap as possible, thereby minimising the plate working length.¹⁴ The working length of the plate is the distance between the screws either side of the fracture gap.⁶ That in vitro LCP study concluded that placing more than three screws per fragment has no significant effect on the axial stiffness of the construct.¹⁴ These guidelines are based on using a LCP bridging a central fracture gap. The effect of the addition of an IM pin on these guidelines is unknown.

The primary aim of this study was to investigate the effect of intramedullary pin size, in combination with various monocortical screw configurations, on the stiffness and strength of LCPR constructs. We hypothesized that the addition of IM pins of incremental size to an LCP with monocortical screws will result in significant, incremental increases in axial and bending stiffness, and axial strength. We also hypothesized that screw configurations that decrease the working length of the plate will result in a significant increase in axial and bending stiffness. In addition, it was hypothesized that LCPs with bicortical screws will have significantly greater axial and bending stiffness and axial strength compared to an identical plate/screw configuration with monocortical screws.

3.4 MATERIALS & METHODS

Bone Model

A synthetic fracture gap model based on the femur of a 30kg dog was used. Cortical measurements were obtained at the femoral isthmus in addition to proximal and distal cancellous bone dimensions using digital calipers on 10 paired sagittal sectioned cadaveric femurs from greyhounds euthanized for reasons unrelated to this study.

The model comprised two Delrin^a tubes 100mm in length with a 15.875mm (0.625") outer diameter and an inner diameter of 9.525mm (0.375") separated by a 40mm fracture gap. To ensure repeatable placement of the plates, the Delrin tubes were pre-drilled with a numerically controlled mill using a 2.8mm drill bit as per AO recommendations for the placement of 3.5mm locking screws.¹⁵ Four screw holes and a jig positioning hole were drilled on the same axis of each Delrin tube perpendicular to the surface and in the axial midline.

Cellular rigid polyurethane foam (PUF), previously validated as a healthy canine cancellous bone model¹⁶ (density 0.32g/cm³), was machined into cylinders of 9.5mm outer diameter and 20mm in length by the manufacturer^b. Prior to placement, the PUF cylinders were concentrically pre-drilled on a lathe to 0.5mm less than the pin diameter intended for that construct to ensure accurate central location and to facilitate passage of the intramedullary pin during manual placement. The PUF cylinders were then pushed into the ends of the predrilled Delrin tubes to a depth of 30-35mm and secured concentrically to the inner wall of the Delrin with cyanoacrylate glue^c. This ensured a fixed, constant working length for each IM pin and that the most proximal and distal screws of each construct would not penetrate the PUF cylinders.

Two custom designed loading jigs were made with an 8mm central hole to avoid any impingement on intramedullary pins protruding from the constructs during testing (Figure 1). The delrin tubes were fixed within the loading jigs with a 4mm screw in the predrilled jig positioning hole.



Figure 1 – Two custom designed loading jigs were made with an 8mm central hole to avoid any impingement on intramedullary pins protruding from the constructs during testing.

Constructs

Five different constructs were created; each with 5 replicates, making a total of 25 specimens to be tested. Constructs were: **LCPMono** - LCP with monocortical screws, **LCPBi** - LCP with bicortical screws, **LCPR20** - LCP with monocortical screws + 20% IM pin, **LCPR30** - LCP with monocortical screws + 30% IM pin and an **LCPR40** - LCP with monocortical screws + 40% IM pin (Figure 2A,B).

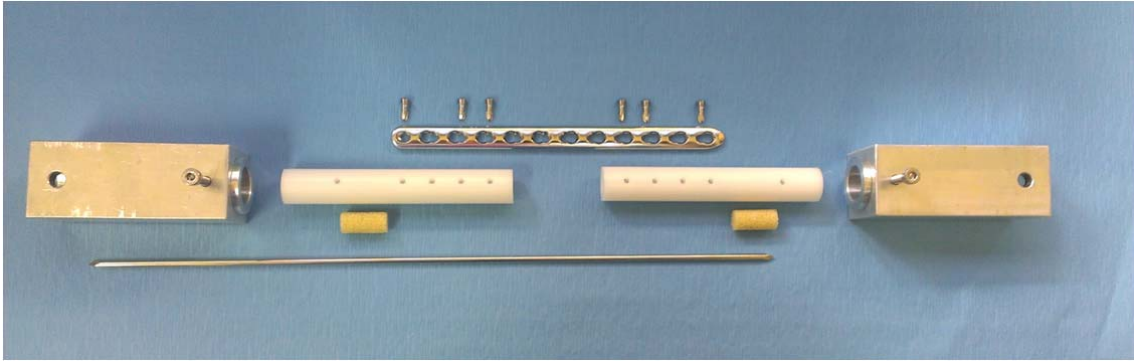


Figure 2A - Exploded diagram of an LCPR construct showing the relative positioning of the components of the construct prior to assembly.

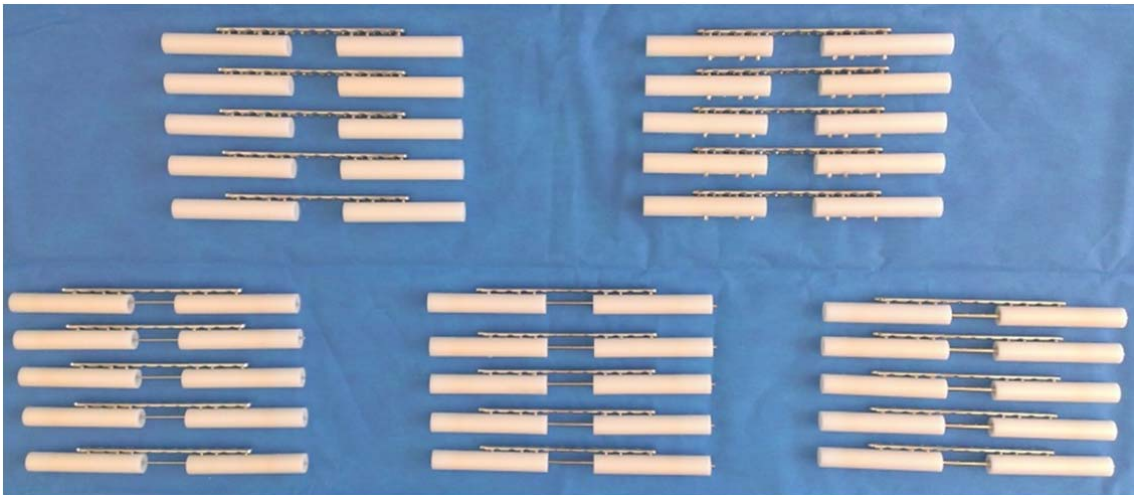


Figure 2B – Five different constructs were created; each with 5 samples, making a total of 25 specimens to be tested.

LCP Placement

A 12 hole, 3.5mm LCP^d was secured to each construct with self-tapping locking screws with the use of a battery powered orthopaedic drill^e. A 1.5Nm torque-limited screw driver was used to comply with current AO recommendations for 3.5mm LCPs¹⁵. Monocortical (10mm) self-tapping locking screws^f were used for the LCPMono and LCPR constructs and 24mm self-tapping locking bicortical screws were used for the LCPBi constructs. Plates were applied over a 2.0mm spacer to ensure uniform plate to bone distance.

IM Pin Placement

Pin sizes were based on the inner diameter of the Delrin tubes such that pins were 20% (2.0mm), 30% (3.0mm) and 40% (4.0mm) of medullary diameter. A battery powered orthopaedic drill was used to insert the IM pins^g normograde from the proximal end of the delrin through the pre-drilled PUF cylinders until the trocar tip could be visualised protruding 5mm distal to the PUF cylinder but still within the distal Delrin tube (Figure 3). The remainder of the pin protruding from the proximal end of the construct was cut off flush with the delrin tube using pin cutters. Construct assembly and testing was randomised via the use of a random number chart^h.

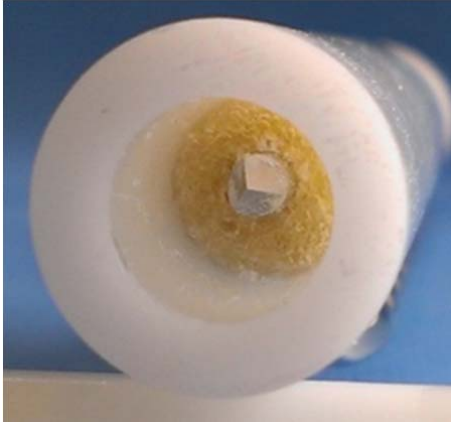


Figure 3 - Intramedullary pins were inserted through the pre-drilled polyurethane foam (PUF) cylinders until the trochar tip could be visualised protruding 5mm distal to the PUF cylinder but still within the distal Delrin tube.

Screw Configuration (Working Length)

Screw holes in either end of the plate were numbered (1 to 4) from the ends of the plate towards the fracture gap leaving four empty screw holes over the central 40mm fracture gap. Initially, screw configurations with 3 screws per fragment modelled the shortest (4 holes) and then intermediate (6 holes) working lengths. Subsequently, screw configurations with 2 screws per fragment modelled the longest (8 holes) and then the shortest (4 holes) working length of the plate (Figure 4). Destructive testing was conducted with 3 screws per fragment and the shortest (4 holes) working length.

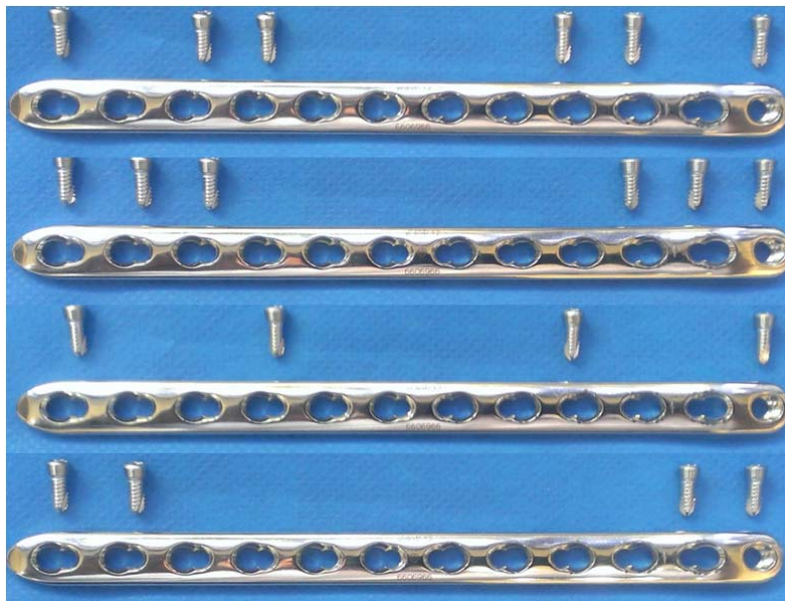


Figure 4 - 12 hole 3.5mm locking compression plates with various screw configurations presented in order of testing. Screw configurations with 3 screws per fragment modelled the shortest (4 hole) and intermediate (6 hole) working lengths. Screw configurations with 2 screws per fragment then modelled the longest (8hole) and shortest (4 hole) and plate working lengths.

Biomechanical Testing

Non-destructive testing was conducted for all 25 specimens in all 4 screw configurations.

1. Non-destructive biplanar four point bending (Mediolateral & Craniocaudal)

Each construct was manually centred using a 300mm gap between the two support rollers and a 220mm gap between the load rollers. This device applied a constant bending moment along the plate. A manual preload of 1N was applied to each construct to remove slack from the system. Testing was conducted in two planes on a materials testing machineⁱ with a 10kN load cell. Each construct was ramp loaded for 3 cycles under displacement control at 10mm/minute with a load range of 0-300N to produce a peak bending moment of 6Nm. The first test simulated mediolateral bending with the implant on the tension side of the construct (Figure 5).



Figure 5 – An LCPMono construct tested in non-destructive mediolateral bending. Each construct was manually centred using a 300mm gap between the two support rollers and a 220mm gap between the load rollers. The materials testing machine applied a constant bending moment along the plate.

Subsequently the construct was rotated 90 degrees to an orthogonal position with the applied load perpendicular to the screw axis simulating craniocaudal bending. Bending stiffness was determined from the slope of the linear elastic portion of the load displacement curve between 150-300N.

2. Non-destructive Axial Compression

Each construct was mounted vertically and axially loaded through 25mm ball bearings at either end. Samples were constrained with respect to axial displacement but were unconstrained with respect to torsion or bending. A manual preload of 5N was applied to each construct to remove slack from the system. Testing was conducted on a materials testing machine^j with a 2kN load cell. Each construct was ramp loaded for 3 cycles under displacement control at 10mm/min to a maximum load of 180N. Axial stiffness (N/mm) was determined from the slope of the linear elastic portion of the load displacement curve between 130-180N.

For all non-destructive testing data was collected with computer software^k sampling at 10 Hz. Load and actuator displacement measurements from the third cycle were used for statistical analysis as a pilot study of five cycles per construct demonstrated no difference after the first cycle.

3. Axial load to failure testing

The loading configuration was the same as non-destructive axial compression. Load was applied under displacement control at 6mm/minute until failure. Load to failure or ultimate strength (N) was defined as maximum load prior to permanent plastic deformation (Figure 6).



Figure 6 – An LCPR construct in axial load to failure. Each construct was mounted vertically and axially loaded through 25mm ball bearings at either end. All constructs failed by plastic deformation of the plate.

Statistical Methods

Sample size was estimated from results of previous studies.^{3,17} With an effect size estimated as 3.5, assuming a power of 0.8 and alpha at 0.05, the sample size required to detect this effect using an unpaired design would be 5.

All responses (stiffness (N/mm), ultimate strength (N)) were found to follow a normal distribution using the Shapiro-Wilk test with failure to reject the null hypothesis of normality at $p < 0.05$. All responses were summarised as mean with a 95% confidence interval.

For bending and axial stiffness, a two-way ANOVA was used to test the effects of pin size and screw configuration, and their interaction on the response. If there was significant interaction, post-hoc, pre-planned, multiple comparisons were made. In the absence of significant interaction, but where there were significant main effects at $p < 0.05$, contrasts were made across pin size and across screw configurations using Scheffe's adjustment to maintain type I error at 0.05. For destructive testing of the single screw configuration, a one-way ANOVA was used to test the effect of pin size. Where F was significant at $p < 0.05$, contrasts were made across pin size using Scheffe's adjustment to maintain type I error at 0.05. Statistical software^l was used for the analyses.

3.5 RESULTS

For all non-destructive responses, there were significant main effects of pin size and screw configuration but no significant interaction effect. Therefore, only main effect contrasts were performed and presented.

Effect of Pin Size

In mediolateral and craniocaudal bending, LCPR20 constructs were not significantly stiffer than the LCPMono and LCPBi constructs. LCPR30 constructs were significantly stiffer than LCPMono, LCPBi and LCPR20 constructs. LCPR40 constructs were significantly stiffer than all other constructs (Table 1 & 2).

In axial compression, the addition of an IM pin of any size provided a significant increase in axial stiffness. This effect was incremental with increasing IM pin diameter (Table 3).

The addition of an IM pin of any size also provided a significant increase in axial load to failure. This effect was incremental with increasing IM pin diameter (Table 4). All constructs failed by plastic deformation of the plate.

Effect of Working Length

In mediolateral bending, as plate working length decreased there was a significant increase in stiffness across all constructs (Table 1). In craniocaudal bending, as plate working length decreased from 8 holes to 6 holes there was a significant increase in stiffness across all constructs (Table 2). In axial compression, the shortest plate working length (4 holes) was significantly stiffer than those with longer (6 or 8 holes) working lengths (Table 3).

There was a significant increase in stiffness when using 3 monocortical screws per fragment for the short (4 holes) working length in axial compression and craniocaudal bending but not in mediolateral bending.

Monocortical vs Bicortical Screws

LCPBi constructs did not differ significantly from the LCPMono control for any of the outcome measures tested.

MEDIOLATERAL BENDING	1,2^x (8 holes)	1,2,3^y (6 holes)	1,4^z (4 holes)	1,3,4^z (4 holes)
LCPMono^a	64 (62-67)	75 (72-77)	80 (77-82)	84 (82-85)
LCPBi^a	67 (65-68)	77 (75-79)	83 (82-83)	85 (83-87)
LCPR20^a	70 (66-74)	75 (73-77)	95 (92-98)	85 (84-86)
LCPR30^b	73 (70-76)	83 (82-85)	90 (87-94)	95 (93-97)
LCPR40^c	95 (92-98)	106 (101-111)	113 (108-117)	112 (106-117)

Table 1 – Mean (95% CI) mediolateral bending stiffness (N/mm) of locking compression plate (LCP) and plate-rod (LCPR) constructs. LCPs with monocortical locking screws were tested with no pin (LCPMono) and IM pins of 20% (LCPR20), 30% (LCPR30) and 40% (LCPR40) of IM diameter. LCPs with bicortical locking screws (LCPBi) were also tested. Screw configurations with 2 or 3 screws per fragment modelled long (8 holes), intermediate (6 holes) and short (4 holes) plate working lengths. When comparing the main effect of pin size or screw type down the table (a,b,c) and working length across the table (x,y,z) constructs with different superscripts are significantly different.

CRANIOCAUDAL BENDING	1,2^x (8 holes)	1,2,3^y (6 holes)	1,4^y (4 holes)	1,3,4^z (4 holes)
LCPMono^a	144 (140-147)	188 (181-195)	191 (187-195)	202 (195-208)
LCPBi^a	150 (146-154)	194 (191-197)	195 (193-198)	200 (195-206)
LCPR20^a	148 (144-151)	192 (187-197)	197 (194-199)	205 (197-213)
LCPR30^b	154 (147-160)	199 (192-206)	203 (195-211)	209 (199-218)
LCPR40^c	166 (158-174)	208 (196-219)	213 (203-223)	216 (205-228)

Table 2 – Mean (95% confidence interval) cranio-caudal bending stiffness (N/mm) of locking compression plate (LCP) and plate-rod (LCPR) constructs. See Table 1 for testing definitions. comparing the main effect of pin size or screw type down the table (a,b,c) and working length across the table (x,y,z) constructs with different superscripts are significantly different.

AXIAL COMPRESSION	1,2^x (8 holes)	1,2,3^x (6 holes)	1,4^y (4 holes)	1,3,4^z (4 holes)
LCPMono^a	16 (14-18)	41 (34-48)	74 (60-88)	93 (87-99)
LCPBi^a	20 (17-24)	43 (40-46)	77 (67-86)	98 (82-114)
LCPR20^b	31 (21-41)	67 (42-92)	116 (68-164)	132 (107-156)
LCPR30^c	68 (43-92)	101 (74-129)	144 (108-181)	164 (136-192)
LCPR40^d	117 (98-135)	135 (121-149)	167 (140-193)	255 (127-382)

Table 3 – Mean (95% confidence interval) axial compressive stiffness (N/mm) of locking compression plate (LCP) and plate-rod (LCPR) constructs. See Table 1 for testing definitions. When comparing the main effect of pin size or screw type down the table (a,b,c,d) and working length across the table (x,y,z) constructs with different superscripts are significantly different.

FAILURE	1,3,4 (4 holes)
LCPMono	257 ^a (250 – 264)
LCPBi	266 ^a (261 – 270)
LCPR20	279 ^b (274 – 284)
LCPR30	324 ^c (312 – 336)
LCPR40	428 ^d (424 – 432)

Table 4 –Mean (95% confidence interval) axial load to failure (N) (N/mm) of locking compression plate (LCP) and plate-rod (LCPR) constructs. See Table 1 for testing definitions. Destructive testing was conducted with 3 screws per fragment and a short (4 hole) working length. Constructs with different superscripts are significantly different (a,b,c,d).

3.6 DISCUSSION

The results of this study confirm our hypothesis that the addition of IM pins of incremental size to an LCP with monocortical locking screws would result in significant incremental increases in bending and axial stiffness and axial strength. In mediolateral and cranio-caudal bending, a pin of at least 30% of IM diameter was required to provide a significant increase in stiffness over the LCP alone. Additional significant stiffness was gained with the use of a 40% IM pin. A pin of any size provided a significant increase in axial stiffness and axial load to failure. Throughout all testing, this effect was incremental as pin diameter increased.

The findings of this study are similar to a previous study on the effect of IM pin size on non-locking PR constructs conducted on 6 cadaveric canine femurs. Using mathematical extrapolations of measured strain results with large variance, that study concluded that a pin of 35-40% IM diameter should be used depending on the size of the fracture gap.³ In that study, axial stiffness increased by approximately 6% with a 30% pin and by 40% with a 40% pin when compared to the plate only control. In our study, the magnitude of this increase was much greater. Approximations by comparing means show a 20% IM pin provided 40-60% increase, a 30% IM pin provided 75-150% increase and a 40% IM pin provided 125-225% increase in axial stiffness depending on screw configuration. The reason for the substantially larger increments in stiffness may reflect variations in experimental methodology such as the use of a synthetic bone model with much less variance or a fundamental difference in the biomechanical behaviour of LCPR constructs compared to non-locking PR constructs.

Pure 4 point bending stiffness for plate-rod constructs has not been previously reported. In our study, the addition of a 20% IM pin provided no additional stiffness, a 30% IM pin provided between 10-15% increase and a 40% IM pin provided approximately 40% increase in mediolateral bending stiffness. Bending stiffness depends on the second moment of inertia which is proportional to the distance of the implant from the neutral axis of the construct. Therefore, an IM pin placed close to the neutral axis of the construct has less effect on bending stiffness than it would in axial compression where stiffness is proportional to the area moment of inertia of the construct. Cranio-caudal bending stiffness results followed the same pattern of significance but the effect of the IM pin was much less in than in mediolateral bending as there is less relative contribution of the pin to the second moment of inertia when the plate is loaded on its highest dimension.¹⁸

A pin of 20% intramedullary diameter was modelled in this study to assess what effect, if any, a pin of this size would have on these constructs. Pins of smaller diameter than previously recommended have been used in PR constructs to engage sufficient distal cancellous bone and avoid pin interference.^{19,20} The finding that a pin of any size significantly increased the load to failure of LCPR constructs over the LCP constructs in this study was interesting. Approximations based on comparing means showed the load to failure of the LCPR20 construct was only 8% greater than that of the LCPMono and only 5% greater than that of the LCPBi. In contrast, the load to failure of the LCPR30 construct was 26% greater and the LCPR40 was 67% greater than the LCPMono, demonstrating a much larger incremental effect when using a pin of 30-40% IM diameter consistent with the greater area moment of inertia of these constructs.

There was no observable interaction effect between pin size and screw configuration indicating that various screw configurations which change the plate working length do not modify the effect of a given IM pin size on these constructs. This was a result of the overwhelming effect of the IM pin on

each construct.

Screw configurations which shortened the plate working length provided a significant increase in axial and bending stiffness. Therefore our second study hypothesis was also accepted. Studies investigating the effect of plate working length have yielded variable results and this is often reported as an area of controversy.^{14,21-25} Most of this disparity in results arises from methodological variations where non-locking compression plates or LCPs were anatomically contoured and compressed to the bone with non-locking compression screws. A recent cadaveric PR study used LCPs with a non-locked bicortical and monocortical screw proximally and distally and added non-locked monocortical screws to decrease the plate working length.²⁵ That study only found a significant increase in stiffness between the shortest and longest plate working lengths and no difference in load to failure for any of the constructs. The reason for this may be attributed to large variance within the cadaveric model but more likely the decision to use non-locking screws and anatomically contour the plate to the bone. This reduces the working length to that of the fracture gap regardless of the position of the screws. Experimental models which use LCPs with a small plate to bone clearance and locking screws only, as in our study, generate consistent data that shows the effect of plate working length on construct stiffness and strength.¹⁴

Stoffel et al. investigated factors affecting the stability of LCPs with locked monocortical screws in a synthetic bone model and found that axial stiffness and torsional rigidity were mainly influenced by the working length of the plate.¹⁴ That study concluded that screws should be placed as close to the fracture gap as possible with a 300% decrease in axial stiffness detected when the screw closest to the fracture gap was moved one hole further away. In our study, the same change in working length resulted in approximately 200% decrease in axial stiffness. The reason for this disparity can be attributed to the difference in fracture gap between the experiments (6mm vs 40mm), making the change in screw configuration in Stoffel's study a much greater relative increase in working length. The effect of working length in our study was more exaggerated when no IM pin was used confirming the protective effect of the IM pin.

The effect of working length was much less in bending with only a 5-15% decrease in stiffness when changing from the short to intermediate working length with 3 screws per fragment. This suggests the protective effect of the IM pin is more evident in bending than in compression as would be expected given the role of the pin to resist bending loads within the construct.

When using a 12 hole LCP in bridging fashion over a 6mm central fracture gap, Stoffel et al. found using any more than 3 screws per fragment did not increase axial stiffness.¹⁴ For this reason we did not model a screw configuration using 4 screws per fragment. In addition, that study found that adding a third screw either side closest to the fracture gap resulted in a 60% increase in axial stiffness. The effect of adding a third screw for the same short working length was not as profound in our study with approximations showing only a 10-25% increase in axial compression and no difference in mediolateral bending. This again may be attributed to the difference in fracture gap between the two experiments.

The data from our study suggests bicortical locked screws offered no significant advantage over monocortical screws for any of the outcome responses investigated. This is a novel finding as screw type in LCPs has not previously been compared as a single variable on a non-osteoporotic, diaphyseal fracture gap model.

Goh et al. compared an LCPR with all monocortical screws and a non-locking PR with 1 bicortical and 3 monocortical screws per fracture fragment in a cadaveric femoral model and found no significant difference in cyclic axial loading.⁷ The results of that study may have been limited by variance within the cadaveric model and/or variation in the working lengths of each construct given the non-locking plate was anatomically contoured and the LCP had a 3mm plate clearance. However, that study modelled a worst case scenario where pin interference precluded the placement of any locked bicortical screws. By placing all locked monocortical screws this study was the first LCPR study to recognise the importance of not sacrificing the clinical and biomechanical advantages of locking technology for the desire to place bicortical screws. Other studies have shown a reduction in strain and subsidence at the fracture gap when using monocortical locked screws over non-locked bicortical compression screws.^{4,11-13}

A 2mm plate clearance was chosen for a number of reasons. Firstly, we wished to model LCPs as internal fixators with minimal plate contouring and ensuring preservation of periosteal blood supply for use in minimally invasive fracture repair. Secondly, no contact between the plate and Delrin ensured the working length of the plate was determined by screw configuration and not contact between the plate and Delrin adjacent to the fracture gap. Thirdly, biomechanical studies have found a reduction in stiffness when using a plate clearance of greater than 2mm.^{14,26}

Previous studies on PR constructs have tested each construct in axial compression only.^{2,3,7,25} Our study tested in biplanar four-point bending as well as axial compression and axial load to failure. Bending is perhaps the most biomechanically relevant force to test as pins are used in fracture repair to resist bending loads. A bending moment of 6Nm was chosen for this study as it fits within the elastic range of a 3.5mm LCP according to previous studies.^{27,28} Axial compression is the most clinically relevant force for a fracture gap model as it most closely approximates weight bearing.²⁹ Each construct was axially tested under position control to a maximum load of 180N. This load was chosen as it represents 60% of body weight of a 30kg dog which approximates to maximum walk load during the recovery period.^{30,31}

A synthetic bone model was chosen to ensure repeatability during testing and to minimise the variance between constructs which is often seen in cadaveric studies. The fracture gap, although an accepted model of non-load sharing comminuted fractures is an idealised model. Neither *in vitro* or *ex vivo* studies reflect the clinical situation. Recent biomechanical PR studies have used cyclic loading to simulate the period of post-operative convalescence. These studies demonstrated that all constructs survived prolonged testing at pre-selected, physiologic loads but provided no means for biomechanical comparison between constructs.^{7,25} Whilst cyclic loading data would be an interesting addition to the data provided in this study, we chose to perform quasi-static testing on a bone model to provide repeatable biomechanical data which permits relative comparisons between these constructs.

The variance in this model was very low, especially in bending and load to failure, which increased the power to detect small effect sizes which may not have been detected in a cadaveric or clinical model. The clinical relevance of some of the smaller effect sizes detected in this study is unknown. Whilst this study focuses on *in vitro* biomechanical comparison, maximum stiffness is not always the goal. In the clinical case there are biologic considerations which affect the type of surgical exposure, choice of pin size and screw configuration which should be considered by the surgeon.

Whilst approximately 85% of mechanical loads on canine bones have been estimated to be bending loads,²² the lack of torsional data in this study is a limitation. Given the inability of IM pins to resist torsional loads, it was less relevant to the objectives of this study. However, it has been shown that a construct's resistance to torque is proportional to screw working length (ie. the length of the screw) so it is possible results comparing the LCPMono and LCPBi constructs may be different under torsional testing.^{8,32-35}

CONCLUSIONS

The addition of IM pins of any size to an LCP with monocortical screws provides a significant increase in axial stiffness and axial load to failure. This effect is incremental with increasing IM pin diameter. A pin of 30% IM diameter is required to increase bending stiffness. Additional significant stiffness is gained by the use of a 40% IM pin. Screw configurations which shorten the plate working length provide maximum axial and bending stiffness. However, the overwhelming effect of the IM pin obviates the effect that changing plate working length has on these constructs. In this model, the use of locked bicortical screws offers no increase in stiffness or strength over locked monocortical screws under axial and bending loads.

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^a Delrin[®] Acetal Polymer: Plastics International, Eden Prairie, MN, USA.

^b Polyurethane foam: Sawbones[™] Pacific Research Laboratories Inc., Vashon Island, WA, USA.

^c Superglue: Henkel, Thomastown, VIC, Australia.

^d Vet: LCP[®], Synthes GmbH, Oberdorf, Switzerland

^e Cordless Driver III: Stryker Instruments[™], Kalamazoo, MI, USA.

^f Vet: Locking Screw Star drive[®], Synthes GmbH, Oberdorf, Switzerland

^g Steinmann Pin: E&H Stoerk Instrumente GmbH, Tingen, Germany

^h Microsoft Excel[®] Random Number Generation: Microsoft Corp., Seattle, WA, USA.

ⁱ Instron 5566: Instron, Canton, MA, USA

^j Instron 5848: Instron, Canton, MA, USA.

^k Bluehill v2.5.391: Instron, Canton, MA, USA.

^{ll} SAS v9.3: SAS Institute, Cary, NC. USA.

CHAPTER 4: PAPER TWO

4.1 TITLE PAGE

The effect of intramedullary pin size and plate working length on plate strain in locking compression plate-rod constructs.

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4.2 ABSTRACT

Objective: To investigate the effect of intramedullary (IM) pin size and plate working length on plate strain in locking compression plate-rod (LCPR) constructs.

Study Design: *In vitro* study.

Sample Population: Synthetic fracture gap model.

Methods: LCPs with monocortical locking screws were tested with no pin (LCPMono) and IM pins of 20% (LCPR20), 30% (LCPR30) and 40% (LCPR40) of IM diameter. Two screws per fragment modelled a long (8 hole) and short (4 hole) plate working length. Strain responses to axial compression were recorded at 6 regions of the plate via 3D digital image correlation.

Results: The addition of an IM pin of any size provided a significant decrease in plate strain. For the long working length, LCPR30 and LCPR40 had significantly lower strain than the LCPR20 and plate strain was significantly higher adjacent to the screw closest to the fracture site. For the short working length, there was no significant difference in strain across any LCPR constructs or at any region of the plate. Plate strain was significantly lower for the short working length compared to the long working length for LCPMono and LCPR20 but not LCPR30 and LCPR40.

Conclusions: The increase in plate strain encountered with a long working length can be overcome by the use of a pin of 30-40% IM diameter. Where placement of a large diameter IM pin is not possible, screws should be placed as close to the fracture gap as possible to minimize plate strain and distribute it more evenly over the plate.

4.3 INTRODUCTION

Plate strain is measured to identify areas of mechanical weakness where a construct may fail by acute overload or cyclic fatigue.¹ The addition of an intramedullary (IM) pin to a bone plate reduces plate strain and increases the fatigue-life of the construct.² Recommendations from plate-rod (PR) investigations suggest the use of a pin of 35-40% of IM diameter to reduce plate strain, however these studies were conducted on non-locking compression plates.³ The effect of different sized IM pins on plate strain in locking compression plate-rod (LCPR) constructs has not been reported.

Studies on locking compression plates (LCP) with monocortical screws suggest screws be placed as close to the fracture gap as possible, thereby minimizing the plate working length.^{4,5} The working length of a locking plate is the distance between the screws either side of the fracture gap.¹ Several studies have attempted to define the effect of screw configuration on plate strain and the results are conflicting.⁶⁻⁹ Much of this variation can be attributed to different experimental methodology such as the use of different bone models, fracture gaps, plate and screw types, plate lengths and methods of measuring plate strain. There are currently no studies reporting plate strain in LCPR constructs.

All previous veterinary biomechanical studies have used strain gauges placed on the surface of the plate to measure plate strain.^{2,3,6} This study uses a method of measuring full field strain, widely validated in mechanical engineering and human biomechanics but previously unreported in the veterinary literature. 3D digital image correlation enables measurement of strain across the whole field of view limited only by the resolution of the cameras used and the quality of the speckle pattern created on the construct.¹⁰⁻¹²

A recent study found that the overwhelming effect of the IM pin in LCPR constructs obviates much of the reduction in stiffness as the plate working length is increased.⁵ This is an important practical finding as placing screws away from the fracture site is more suitable for minimally invasive fracture repair. It would be useful to know if increasing the working length of the plate by placing screws distant to the fracture site results in an increase in plate strain and, if so, can this increase be overcome with the use of an IM pin as part of an LCPR construct.

This study investigated the effect of IM pin size across two monocortical screw configurations that modelled a short and a long plate working length on plate strain in LCPR constructs. We hypothesized that the addition of IM pins of incremental size to an LCP with monocortical screws will result in significantly lower plate strain. We also hypothesized that the monocortical screw configuration with the short plate working length will have significantly lower plate strain than the long working length.

4.4 MATERIALS & METHODS

Bone Model

This study was part of a larger biomechanical study previously reported and as a result, most of the methodology has been previously described.⁵ A synthetic fracture gap model based on the dimensions of the femur of a 30kg dog was used. Cortical measurements at the femoral isthmus and proximal and distal cancellous bone dimensions were obtained using digital calipers on 10 paired sagittal sectioned cadaveric femurs from greyhounds euthanatized for reasons unrelated to this study.

The model comprised 2 Delrin[®] (Acetal Polymer: Plastics International, Eden Prairie, MN) tubes 100 mm in length with a cortical diameter of 3.25mm (15.875 mm outer diameter and an inner diameter of 9.525 mm) separated by a 40 mm fracture gap. To ensure repeatable placement of the plates, the Delrin tubes were pre-drilled with a numerically controlled mill using a 2.8 mm drill bit as per AO recommendations for the placement of 3.5 mm locking screws.¹³ Four screw holes and a jig positioning hole were drilled on the same axis of each Delrin tube perpendicular to the surface and in the axial midline.

Cellular rigid polyurethane foam (PUF), previously validated as a healthy canine cancellous bone model (density 0.32 g/cm³), was machined into cylinders of 9.5 mm outer diameter and 20 mm in length by the manufacturer (Polyurethane foam: Sawbones™ Pacific Research Laboratories Inc., Vashon Island, WA).¹⁴ Prior to placement, the PUF cylinders were concentrically pre-drilled on a lathe to 0.5mm less than the pin diameter intended for that construct to ensure accurate central location and to facilitate passage of the intramedullary pin during manual placement. The PUF cylinders were then pushed into the ends of the predrilled Delrin tubes to a depth of 30 mm at the slipper toe end and 35 mm at the stacked hole end of the plate, accounting for the asymmetry of the LCP, and were secured concentrically to the inner wall of the Delrin with cyanoacrylate glue (Superglue: Henkel, Thomastown, VIC, Australia). This ensured a fixed, constant working length for each IM pin and that the most proximal and distal screws of each construct would not penetrate the PUF cylinders.

Two custom designed loading jigs were made with an 8 mm central hole to avoid any impingement on intramedullary pins protruding from the constructs during testing. The Delrin tubes were fixed within the loading jigs with a 4 mm screw in the predrilled jig positioning hole.

Constructs

Four different constructs were created; each with 5 replicates, making a total of 20 specimens to be tested for each plate working length. Constructs were: **LCPMono** - LCP with monocortical screws, **LCPR20** - LCP with monocortical screws + 20% IM pin, **LCPR30** - LCP with monocortical screws + 30% IM pin and an **LCPR40** - LCP with monocortical screws + 40% IM pin (Fig 1).

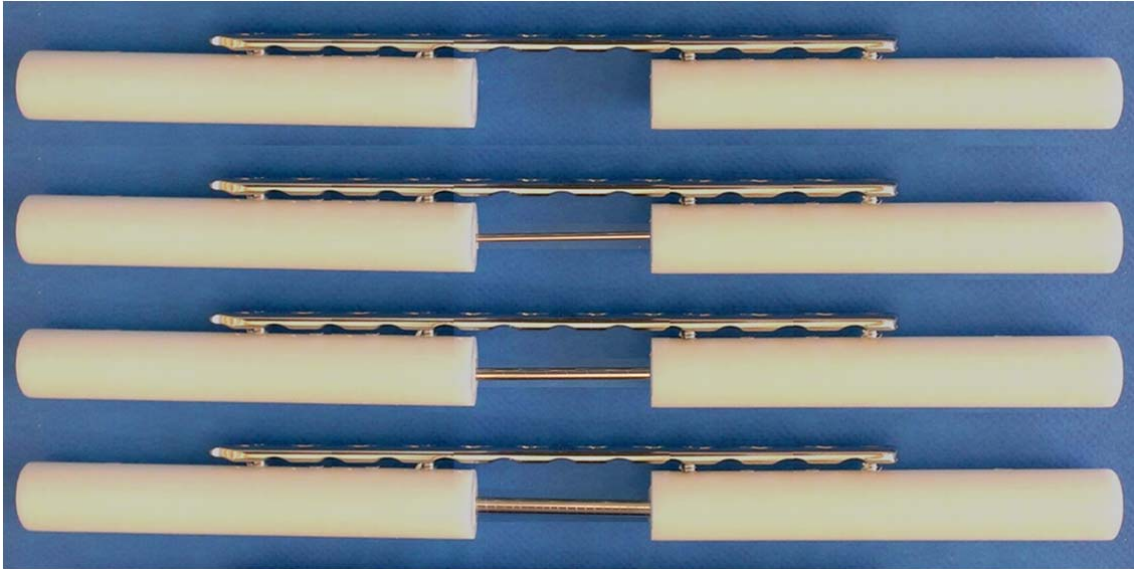


Figure 1 - Four different constructs were created; each with 5 replicates, making a total of 20 specimens to be tested for each plate working length. Constructs were: LCPMono - LCP with monocortical screws, LCPR20 - LCP with monocortical screws + 20% IM pin, LCPR30 - LCP with monocortical screws + 30% IM pin and an LCPR40 - LCP with monocortical screws + 40% IM pin.

LCP Placement

A 12 hole, 3.5 mm LCP (Vet: LCP[®], Synthes GmbH, Oberdorf, Switzerland) was secured to each construct with self-tapping locking screws with the use of a battery powered orthopedic drill (Cordless Driver III: Stryker Instruments[™], Kalamazoo, MI). A 1.5 Nm torque-limited screw driver was used to comply with current AO recommendations for 3.5 mm LCP.¹³ Monocortical (10mm) self-tapping locking screws (Vet: Locking Screw Star drive[®], Synthes GmbH, Oberdorf, Switzerland) were used and plates were applied over a 2.0 mm spacer to ensure uniform plate to bone distance.

IM Pin Placement

Pin sizes were based on the inner diameter of the Delrin tubes such that pins were 20% (2.0mm), 30% (3.0 mm) and 40% (4.0 mm) of medullary diameter. A battery powered orthopaedic drill was used to insert the IM pins (Steinmann Pin: E&H Stoerk Instrumente GmbH, Tingen, Germany) normograde from the proximal end of the Delrin through the pre-drilled PUF cylinders until the trochar tip could be visualised protruding 5mm distal to the PUF cylinder but still within the distal Delrin tube. The remainder of the pin protruding from the proximal end of the construct was cut flush with the Delrin tube using pin cutters. Construct assembly and testing was randomised via the use of a random number chart (Microsoft Excel[®] Random Number Generation: Microsoft Corp., Seattle, WA).

Plate Working Length (Screw Configuration)

Screw holes in either end of the plate were numbered (1 to 4) from the ends of the plate towards the fracture gap leaving 4 empty screw holes over the central 40 mm fracture gap. Two screw configurations were used, the first with screws at 1 and 2, modelling the long (8 holes) working length, and the second, with screws at 1 and 4 modelling the short (4 holes) working length (Fig 2).



Figure 2 - Two screw configurations were used, the first with screws at 1 and 2, modelling the long (8 holes) working length, and the second, with screws at 1 and 4 modelling the short (4 holes) working length.

Six regions on the plate were chosen for measurement of plate strain corresponding to the segment of the plate between each screw hole with region 6 being the centre of the plate (Fig 3).

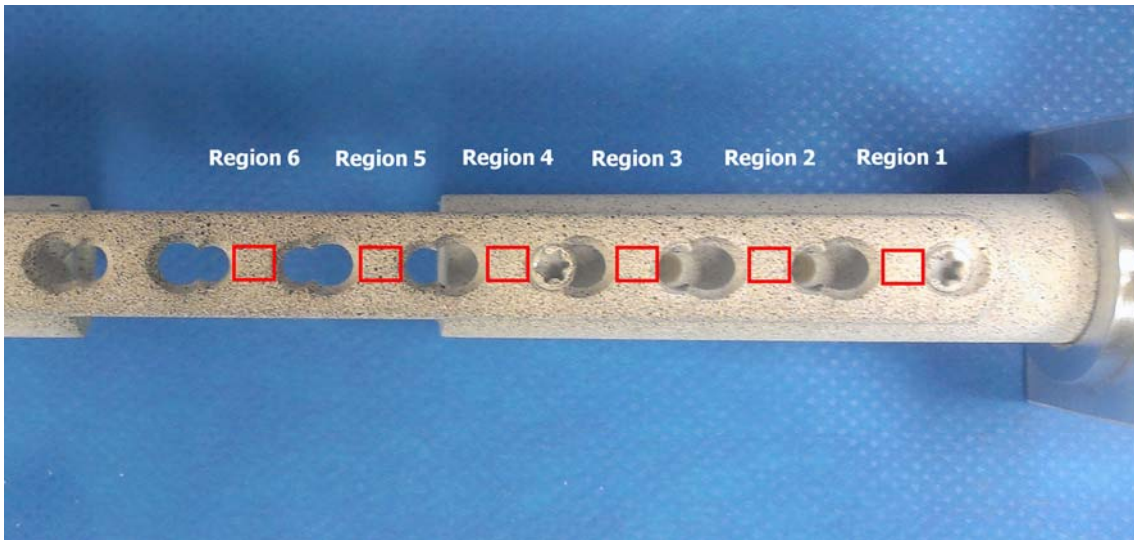


Figure 3 - Six regions on the plate were chosen for measurement of plate strain corresponding to the segment of the plate between each screw hole with position 6 being the centre of the plate. The speckle pattern was created by spray painting each construct completely white to establish a uniform base colour. Following this, a thin spatter of black spray paint was applied to give a speckle pattern covering the entire construct ensuring no areas of the construct were without a speckle pattern.

Digital Image Correlation

Digital image correlation uses correlation-based displacement measurements to calculate local surface strain. A random pattern on the surface of the test object is imaged in the initial (unloaded) and then deformed (loaded) states. The region of interest is divided into small multi-pixel subsets and each

subset in the initial image is matched to the corresponding subset in the deformed image. The software matches stereo image pairs from two cameras approximately 60 degrees apart to determine the surface shape and strain in three dimensions. A random speckle pattern ensures that each pixel in both images can be uniquely matched, as the random pattern will only match in one position.¹¹

The speckle pattern was created by spray painting each construct completely white to establish a uniform base colour (Flat White Quick Dry, White Knight). Following this, a thin spatter of black spray paint was applied to give a speckle pattern covering the entire construct ensuring no areas of the construct were without a speckle pattern (Fig 3).

Two high resolution video cameras (Point Grey 5.0 Megapixel Grasshopper) with a resolution of 2448 x 2048 pixels were set up approximately at 60 degrees to each other facing the surface of the plate such that approximately half of the plate filled the field of view to maximise physical resolution (Fig 4).

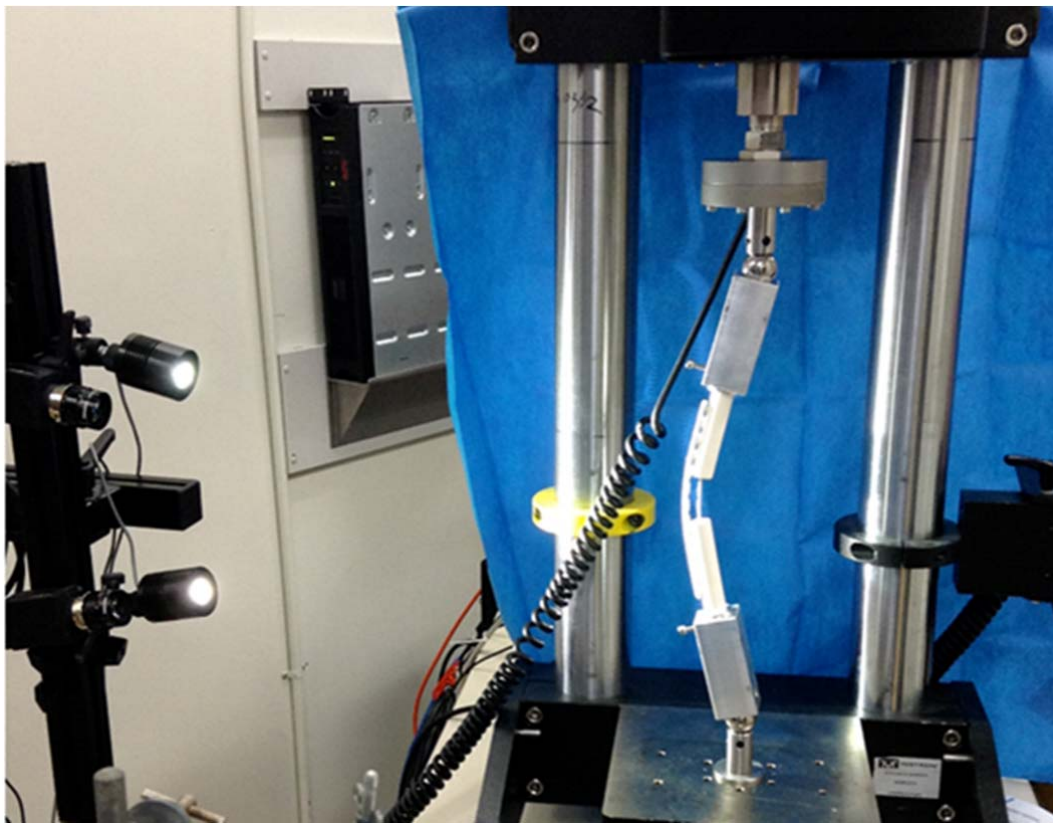


Figure 4 - Each construct was mounted vertically and axially loaded on a materials testing machine. Two high resolution video cameras were set up approximately at 60 degrees to each other facing the surface of the plate.

Physical resolution for the system was 0.11 mm/pixel (9 pixels/mm). The camera pair was calibrated with a standard VIC3D grid chosen to match the field of view to ensure accurate measurement of displacement between the initial and deformed states.¹⁰

During the tests, the cameras were run with an exposure of 11 ms, giving a frame rate of approximately 5.5 frames per second. Synchronised, high definition recordings of the construct while

undergoing non-destructive axial compression were captured with VicSnap software (VicSnap[®], Correlated Solutions, NC).

Post hoc evaluation of the video files identified regions of interest between each screw hole and the average strain within each of these 6 plate regions was calculated from the raw video files using VIC3D software (VIC3D[®], Correlated Solutions, NC) (Supplementary File 1). The peak strain under maximum load at each plate region was determined by picking the peaks of each of the 3 cycles and averaging them using computer software (Microsoft Excel[®]: Microsoft Corp., Seattle, WA).

Biomechanical Testing

Non-destructive testing was conducted for all 20 specimens for both screw configurations.

Each construct was mounted vertically and axially loaded through 25 mm ball bearings at either end. Samples were constrained with respect to axial displacement but were unconstrained with respect to torsion or bending (Fig 4). A manual preload of 5 N was applied to each construct to remove slack from the system. Testing was conducted on a materials testing machine (Instron 5848: Instron, Canton, MA) with a 2kN load cell. Each construct was ramp loaded for 3 cycles under displacement control at 10mm/min to a maximum load of 180 N.

Statistical Methods

The microstrain at each plate region was the response of interest and found to follow a normal distribution using the Shapiro-Wilk test with failure to reject the null hypothesis of normality at $P < .05$. The strain at each plate region for each pin size and working length were summarized as mean with a 95% confidence interval (CI).

A 3-way ANOVA was used to test the effects of pin size, working length and plate region, and their interaction on the strain response. If there was significant three-way interaction, post-hoc, pre-planned, multiple comparisons were made. In the absence of significant three-way interaction, but where there were significant two-way interaction or main effects at $P < .05$, appropriate contrasts were made across pin size, working length and plate region using Scheffe's adjustment to maintain type I error at 0.05. Statistical software (SAS v9.4: SAS Institute, Cary, NC) was used for the analyses.

4.5 RESULTS

Strain data is presented in Table 1 and 2 for the long and short working length respectively.

There was no significant 3-way interaction but significant two-way interaction between pin size and working length ($P<.001$) as well as plate region and working length ($P<.001$) was detected. There was no interaction between pin size and plate region ($P=0.72$). Two-way contrasts are described below:

Effect of Pin Size Across Working Length For All Plate Regions (Fig 5)

The addition of an IM pin of any size provided a significant decrease in plate strain for all LCPR constructs compared to the LCPMono. For the long working length, LCPR30 and LCPR40 constructs had significantly lower strain than the LCPR20. For the short working length, there was no significant difference in strain across any LCPR constructs.

Plate strain was significantly lower for the short working length compared to the long working length for the LCPMono and LCPR20 constructs but was not for LCPR30 and LCPR40.

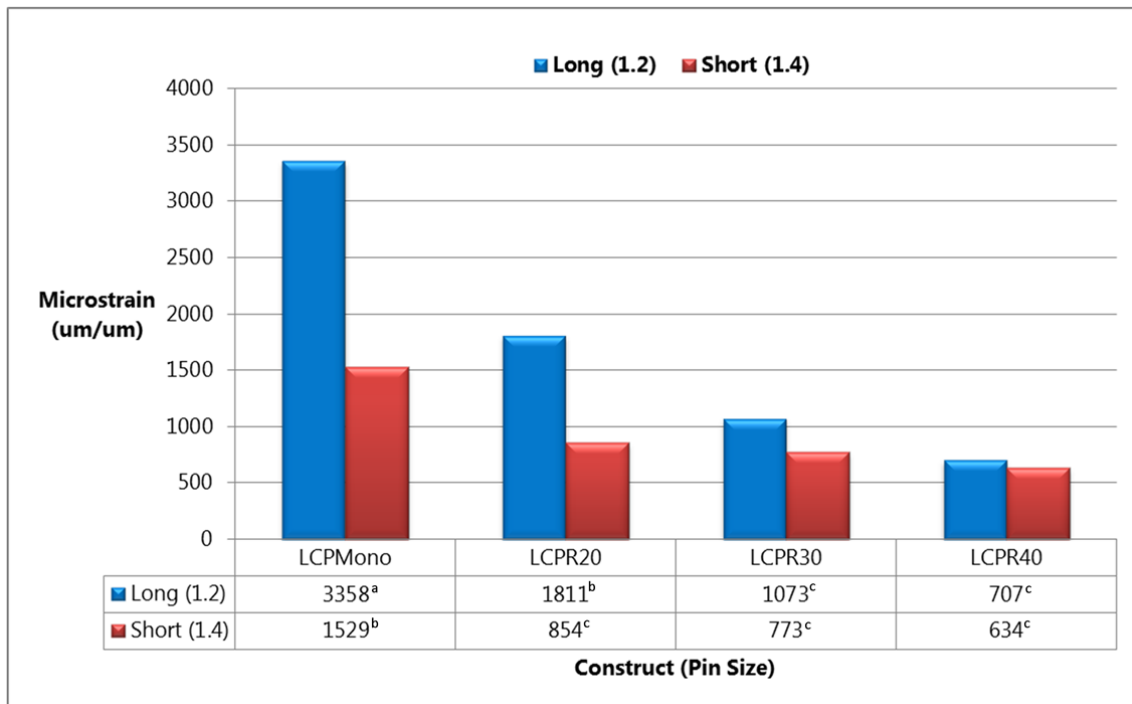


Figure 5 - Effect of Pin Size and Plate Working Length on Plate Strain. (Least Square Means Across All Plate Regions) Constructs with different superscripts are significantly different.

Effect of Plate Working Length Across Plate Region For All Pin Sizes (Fig 6)

For the long working length, plate strain was significantly higher at region 2 than regions 5 and 6. For the short working length, plate strain was not significantly different at any region of the plate.

Plate strain was significantly lower at regions 1, 2 and 3 for the short working length compared to the long working length but not significantly different at regions 4, 5 and 6.

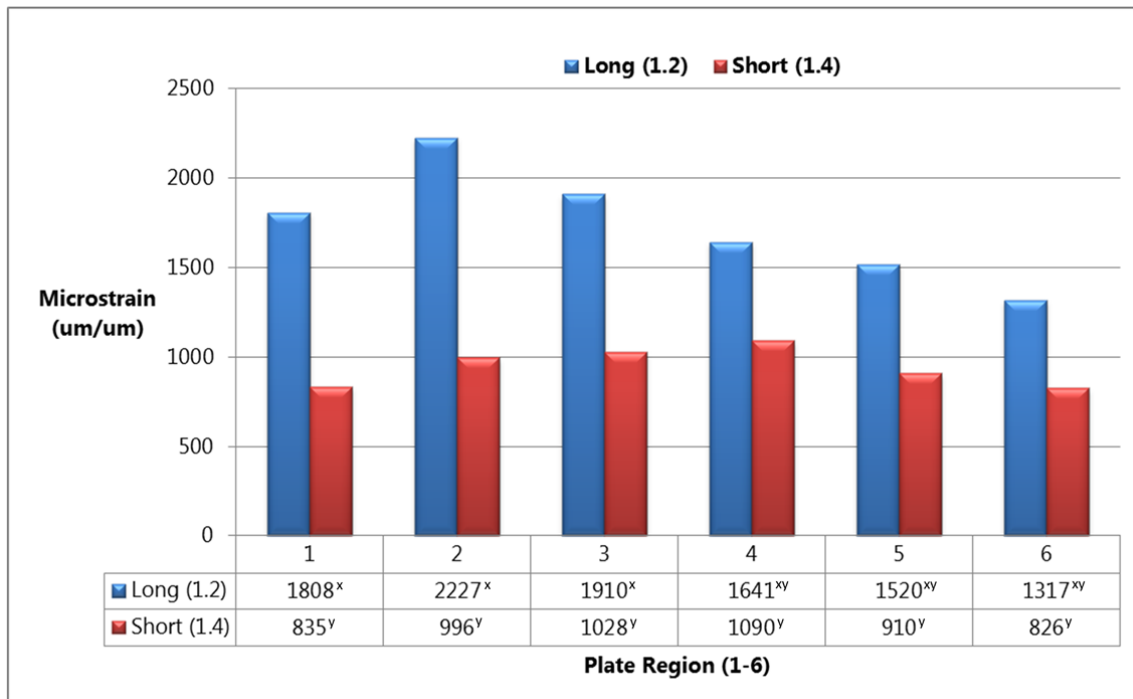


Figure 6 - Effect of Plate Working Length and Plate Region on Plate Strain. (Least Square Means Across All Pin Sizes) Constructs with different superscripts are significantly different.

	Region 1 ^{xy}	Region 2 ^x	Region 3 ^{xy}	Region 4 ^{xy}	Region 5 ^y	Region 6 ^y
LCPMono^a	3548 (1748-5347)	4183 (3571-4795)	3659 (3085-4231)	3290 (2477-4104)	2960 (2240-3680)	2508 (2165-2850)
LCPR20^b	2006 (596-3416)	2135 (1360-2910)	1940 (1222-2659)	1726 (958-2494)	1660 (937-2384)	1398 (935-1861)
LCPR30^c	917 (517-1317)	1612 (1269-1954)	1267 (884-1650)	913 (600-1226)	867 (465-1269)	863 (581-1144)
LCPR40^c	762 (225-1299)	978 (402-1553)	773 (443-1104)	635 (367-903)	593 (244-942)	500 (329-672)

Table 1 – Mean (95% confidence interval) plate strain (um/um) between plate holes under axial compression of locking compression plate (LCP) and plate-rod (LCPR) constructs for the long working length (8 holes). LCPs with monocortical locking screws were tested with no pin (LCPMono) and IM pins of 20% (LCPR20), 30% (LCPR30) and 40% (LCPR40) of IM diameter. When comparing the main effect of pin size down the table (a,b,c) and plate region across the table (x,y) constructs or regions with different superscripts are significantly different.

	Region 1^x	Region 2^x	Region 3^x	Region 4^x	Region 5^x	Region 6^x
LCPMono^a	1242 (554-1931)	1689 (1345-2033)	1646 (1393-1899)	1771 (1373-2169)	1512 (898-2126)	1318 (1196-1439)
LCPR20^b	841 (128-1553)	776 (570-983)	917 (510-1324)	911 (505-1317)	875 (563-1187)	801 (556-1045)
LCPR30^b	694 (403-985)	813 (424-1202)	835 (489-1183)	904 (416-1392)	710 (484-936)	679 (437-921)
LCPR40^b	563 (373-753)	705 (466-944)	713 (441-986)	772 (455-1089)	543 (357-730)	505 (357-653)

Table 2 – Mean (95% confidence interval) plate strain (um/um) between plate holes under axial compression of locking compression plate (LCP) and plate-rod (LCPR) constructs for the short working length (4 holes). LCPs with monocortical locking screws were tested with no pin (LCPMono) and IM pins of 20% (LCPR20), 30% (LCPR30) and 40% (LCPR40) of IM diameter. When comparing the main effect of pin size down the table (a,b) and plate region across the table (x), constructs or regions with different superscripts are significantly different.

4.6 DISCUSSION

The results of this study confirm our hypothesis that the addition of IM pins of incremental size to an LCP with monocortical locking screws results in significantly lower plate strain. Constructs with a short plate working length had significantly lower plate strain than those with a long working length, therefore confirming our second hypothesis.

Interestingly, an interaction effect was also detected between these 2 variables. For constructs with a long plate working length, the higher plate strain could be overcome by using an IM pin of 30 to 40% IM diameter. This might be useful in a clinical setting where veterinary surgeons practicing minimally invasive LCPR repair of comminuted diaphyseal fractures may utilise a pin of this size and place monocortical screws away from the fracture site. However, for constructs with a short working length, there was no additional reduction in plate strain with the use of pins of larger (30-40%) diameter. This gives surgeons the option to use a shorter plate working length when the placement of a 30-40% IM pin is impractical or contraindicated.

The findings of this study are similar to those of an investigation on the effect of IM pin size on non-locking PR constructs conducted on 6 cadaveric canine femurs. Using mathematical extrapolations of measured strain and despite a large variance, the investigators concluded for each 10% increase in pin size, there was a 20% reduction in plate strain and a pin of 35-40% IM diameter should be used depending on the size of the fracture gap.³ Our study found greater incremental decreases in plate strain as pin size increased however comparison between studies is made difficult by variations in experimental methodology. The difference in results may reflect the use of a synthetic bone model, the method and region of the plate used for strain measurement, or a fundamental difference in the biomechanical behaviour of LCPR constructs compared to non-locking PR constructs.

Stoffel et al. investigated factors affecting the stability of LCP with locked monocortical screws in a synthetic bone model and concluded that screws should be placed as close to the fracture gap as possible, thereby shortening the working length of the plate.⁴ Numerous studies have attempted to define the effect of working length on plate strain and the results are conflicting.⁶⁻⁹ Much of this variation can be attributed to experimental methodology, including the use of different bone models, fracture gaps, plate and screw types, screw configurations, plate lengths and methods of measuring plate strain.

In this study, strain was highest adjacent to the screw closest to the fracture gap for the constructs with the long working length. This contrasted with the short working length where there was no significant difference in plate strain at any region of the plate. This result indicates that placing screws further apart and closer to the fracture gap not only reduced strain but also distributed it more evenly across the plate.

It has been theorized that the longer the plate working length, the larger the radius of curvature will be and the more evenly strain will be distributed on the gap bridging section.^{6,9} This is based on studies which found a reduction in internal plate stresses with longer working length¹⁵ and concentration of stresses in plates with a short working length.¹⁶ This is in direct contrast to the findings of this study and others which found plate strain was lowest when screws were placed close to the gap and that widely spaced screw configurations created less strain than those placed close together.^{4,7,8} The reason

for this may be attributed to differences in the types of plates tested (locking vs. non-locking), plate lengths, sizes and screw configurations.

There are currently no published studies documenting the effect of plate working length on plate strain in LCPRs therefore our comparison are limited to studies using non-locking plates which are fundamentally different in the way they distribute load and therefore plate strain. The locking mechanism ensures that screws do not function individually within the plate but as part of a fixed angle construct which does not rely on individual screw purchase in the bone for stability.¹⁷ Locking the screw head into the plate ensures angular and axial stability relative to the plate such that individual screws cannot be sequentially loaded. Therefore, there is no movement or toggling between the screw and the plate under load.

Maxwell et al. investigated the effect of screw position on plate strain in non-locking compression plates under axial load in a Delrin fracture gap model.⁶ In vitro testing found the highest strain at the fracture gap and when screws were omitted, there was a significant increase in strain at those empty screw holes but no decrease in strain at the gap. They concluded that placing screws close to the fracture gap did not reduce strain as expected but actually focussed strain at this site. As a result, the authors suggested surgeons could rely on screw placement distant from the fracture gap and further reduce strain with the addition of an IM pin. The reason for this strain concentration was most likely a result of micromotion at the screw-plate interface as individual non-locking screws were loaded independently. Interestingly, in our study, plate strain was significantly lower at the fracture gap than other regions for the long working length. This may reflect the ability of locking plates used in bridging fashion to better distribute strain away from the fracture gap.

A common method of strain measurement in biomechanical testing is the resistance strain gauge.^{2,3,6,7} These are thin non-conducting substrates with a pattern of fine conductive wires printed on the surface. Stretching the gauge elongates and thins the conductors, increasing the electrical resistance, which can be measured to determine strain. Such gauges can be very sensitive and reliable, if properly installed, and can measure high frequency variation in strain. Strain gauges and digital image correlation both measure strain on the surface of a specimen. Each method has advantages and disadvantages.

A single strain gauge can only measure strain at a point and along its axis, which can make them sensitive to positioning errors. In very small sizes, such as are required to measure the strain between screw holes, angulation errors are hard to avoid. A strain rosette made up of 3 stacked gauges at different angles allows the calculation of the local principal strain, regardless of direction. This requires 3 measuring channels for each gauge position, which limits the number of regions of interest that can be measured simultaneously. Excess glue thickness or bonding problems can also cause strain gauges to give incorrect measurements.¹⁸

Digital image correlation can give principal strain measurements across the whole field of view. Multiple areas of interest can be positioned to give simultaneous strain measurements in many locations, limited only by computation time. The measurement locations can even be chosen after the full-field analysis has identified interesting regions, as was the case in this study. The resolution of the system is limited by the resolution of the cameras used and the quality of the speckle pattern. The physical resolution can be made very high by selecting the right lens and camera combination, at the

expense of a reduced field of view. The maximum sampling rate is limited by the frame rate of the camera system and is typically between 5 and 50 frames per second.

The quality of strain measurements also depends on the speckle pattern. A good pattern has sharp differentiation between the black and white regions, with a random distribution of sizes, shapes and positions of the speckles. With accurate camera calibration and a good speckle pattern displacements of 0.01 pixels can be resolved.^{11,12} The randomness of the speckle pattern limits the size and position of the region of interest and thus the resolution of the strain measurements. In this study, the plate regions were chosen after post hoc video analysis identified the areas between the screw holes as regions of interest where von Mises strain was seen to change significantly under load. These regions also enabled repeatable analysis of a consistent region of the plate with a good quality speckle pattern. Analysis of strain in the small section of the plate beside each screw hole or over the entire surface of the plate was not performed as the contour of the plate and the presence of empty screw holes in the region of interest may have resulted in some variability in the software interpretation of the speckle pattern.

Each construct was axially tested under position control to a maximum load of 180 N. This load was chosen as it represents 60% of body weight of a 30 kg dog which approximates to maximum walk load during the recovery period.^{19,20} This load permits relative comparison of strain data within the elastic zone prior to permanent deformation which is in agreement with methodology used in previous strain studies.^{3,7,21} Von Mises strain is a combination of all strains at a particular area of interest and therefore does not have a direction. It is used as a means of determining a likely point of failure by comparing it to the yield strength of a material so failure load is not required to generate this data.²²

The axial load to failure of these constructs has been reported in a previous study.⁵ Axial compression is the most clinically relevant force for a femoral fracture gap model as it most closely approximates weight bearing.²³ The eccentric position of the plate with respect to axial loads within the bone creates a moment arm which, when load is applied, subjects the implant to a bending moment which is suitable for evaluating the effect of IM pins.²⁴

Recent biomechanical plate-rod studies have used cyclic loading to simulate the period of postoperative convalescence. These studies demonstrated that all constructs survived prolonged testing at preselected, physiologic loads but provided no means for biomechanical comparison between constructs.^{25,26} Whilst reporting the endurance of the constructs in this study would be an interesting addition, we chose to perform quasi-static testing on a bone model to provide repeatable strain data which permits relative comparisons between these constructs.

Only 2 previous plate-rod studies have modelled a worst case scenario where pin interference precluded the placement of any locked bicortical screws.^{5,25} By placing all locked monocortical screws, these studies utilised the clinical and biomechanical advantages of locking technology to obviate the need for bicortical screws. Other studies have reported a reduction in strain and subsidence at the fracture gap with monocortical locked screws over non-locked bicortical compression screws.^{8,27-29} The use of 2 monocortical screws per fragment in this paper was not intended as a clinical recommendation but rather to permit comparison between the longest and shortest working length available in this model.

A synthetic bone model was chosen to ensure repeatability during testing and to minimize variance

between constructs which can often be seen with cadaveric studies. The fracture gap, although an accepted model of non-load sharing comminuted fractures, is an idealized model. Neither in vitro or ex vivo studies reflect the clinical situation. In the live animal, there are biologic considerations which affect the type of surgical exposure, choice of pin size and screw configuration which should be considered by the surgeon.

CONCLUSIONS

The increase in plate strain encountered with a long working length of the LCPR can be overcome by the use of a large (30-40%) diameter IM pin. Where placement of a large diameter IM pin is not feasible, screws should be placed as close to the fracture gap as possible to minimize plate strain and distribute it more evenly over the plate.

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CHAPTER FIVE: CONCLUSION AND DISCUSSION

The research questions from this study arose while conducting a cadaveric study on locking compression plate rod placement in canine humeri. The primary purpose of that study was to describe a repeatable anatomic location for distal normograde IM pin insertion and a technique for combining this approach with an LCP over an area of theoretical distal diaphyseal comminution. We anticipated significant pin interference when placing bicortical screws distally within the humeral condyle but this was not the case in any of the 20 specimens tested. However, within the mid to proximal diaphysis, 28 out of 60 proximal screw placements encountered pin interference when placing fixed angle locked screws which necessitated monocortical screw placement.

A number of biomechanical questions arose out of this simple descriptive cadaveric study. To answer these questions, we developed the studies presented in this thesis using a synthetic bone model of delrin tubes and polyurethane foam cylinders. The bone model in this study was a novel design using Delrin® tubes which have been previously used as a cortical bone model for biomechanical testing in the veterinary literature. The dimensions of the Delrin tubes represented the external and internal cortical dimensions of a 25-30kg canine femur with polyurethane foam cylinders in each end to simulate cancellous bone. The synthetic model reduced inter-specimen variance during testing, thus reducing the likelihood of type I and II error, and allowing a sensitive comparison of implants.

Locked monocortical screws have been shown to provide greater construct stiffness when compared to non-locking bicortical compression screws in fracture gap models.¹⁻³ Wishing to maintain the advantage of locking technology, our research question aimed to assess the effect of locked monocortical screws compared with locked bicortical screws in a LCP. The first paper in this thesis tested the hypothesis that bicortical screws would be biomechanically superior to monocortical screws in 4 point bending, axial compression axial load to failure. This study found the use of locked bicortical screws offered no increase in stiffness or strength over locked monocortical screws under axial and bending loads. The human literature and more recent veterinary studies have reported similar results under axial and bending loads.⁴

In this study, we modelled a worst case scenario where pin interference precluded placement of any bicortical screws within the construct. In order to utilise the biomechanical advantages of locking technology we chose to use all monocortical screws within our LCPR constructs and LCPMono control. With that in mind, our primary research question was to consider whether the current recommendations for IM pin size for non-locking plate-rod constructs is applicable to LCPR with monocortical screws.

This study found that a pin of 30% IM diameter was required to increase bending stiffness and additional significant bending stiffness was gained by the use of a 40% IM pin. This is the first reported four point bending data for plate-rod constructs. This is consistent with recommendations from previous non-locking PR studies although they were tested only in axial compression.^{5,6} In our study, we found the addition of IM pins of any size provided a significant increase in axial stiffness and axial load to failure and a significant decrease in plate strain. This effect was incremental with increasing IM pin diameter consistent with the greater area moment of inertia of those constructs. This result was quite surprising in that even a 20% IM pin made a significant difference under axial load. This may reflect concentric axial loading and the perfectly central position of the rods in this experimental

model. This may also explain the magnitude of the increase in stiffness for the larger diameter pins which were 2-3 times greater than previous reports.⁵ Alternatively, as these previous studies were on non-locked plate-rod models it is possible this may also reflect a fundamental difference in the biomechanical behaviour of locking plate-rod constructs.

The final question arose more from a clinical perspective and our desire to use LCPR constructs via minimally invasive techniques in order to preserve fracture biology in non-reconstructable fractures. The first aspect was to assess the effect of different screw configurations (i.e. plate working length) on construct stiffness. We found, as expected, that screw configurations which shorten the plate working length provide maximum axial and bending stiffness. The more important question was to assess how changing plate working length interacts with the use of various sized IM pins in LCPRs. It would be interesting to know whether there was benefit in simply placing the largest IM pin possible with screws placed distant to the fracture site (long working length) or whether the current recommendation to place screws as close to the fracture site as possible (short working length) holds true even in the presence of an IM pin.

The first paper found no statistical interaction between these 2 variables concluding that the overwhelming effect of the IM pin obviates the effect that changing plate working length has on the stiffness and strength of these constructs. The subsequent paper reported plate strain as an outcome measure and found an interaction effect between pin size and working length. This study concluded the significant decrease in plate strain is only incremental with increasing IM pin diameter when a long plate working length is used. For constructs with a short plate working length, there was no additional reduction in plate strain with the use of larger IM pins.

This is an important finding which can be used clinically as the increase in plate strain encountered when using a long working length of the LCPR, such as in MIPO, can be overcome by the use of a large (30-40%) diameter IM pin. Where placement of a large diameter IM pin is not possible or contraindicated, screws should be placed as close to the fracture gap as possible to minimize plate strain and distribute it more evenly over the plate.

These findings on the effect of plate working length are in agreement with that of a previous human study.⁷ However, they are in conflict with the only previously reported study in the veterinary literature on the effect of screw position on plate strain which advises the placement of screws away from the fracture site to avoid stress concentration.⁸ Comparison with previous plate strain studies is complicated by significant differences in methodology, not noticeably the use of non-locking compression plates and absence of an IM pin but the disparity in these findings represents a significant deviation from the current veterinary understanding of the effect of screw position on plate strain.

These results and conclusions must be interpreted in the context of a synthetic bone model which is a common limitation of most biomechanical studies. The intention of this study was not to provide direct clinical recommendations but to provide data which allows a sensitive comparison between constructs to assist with clinical decision making when planning LCPR construct configuration for repair of comminuted diaphyseal fractures.

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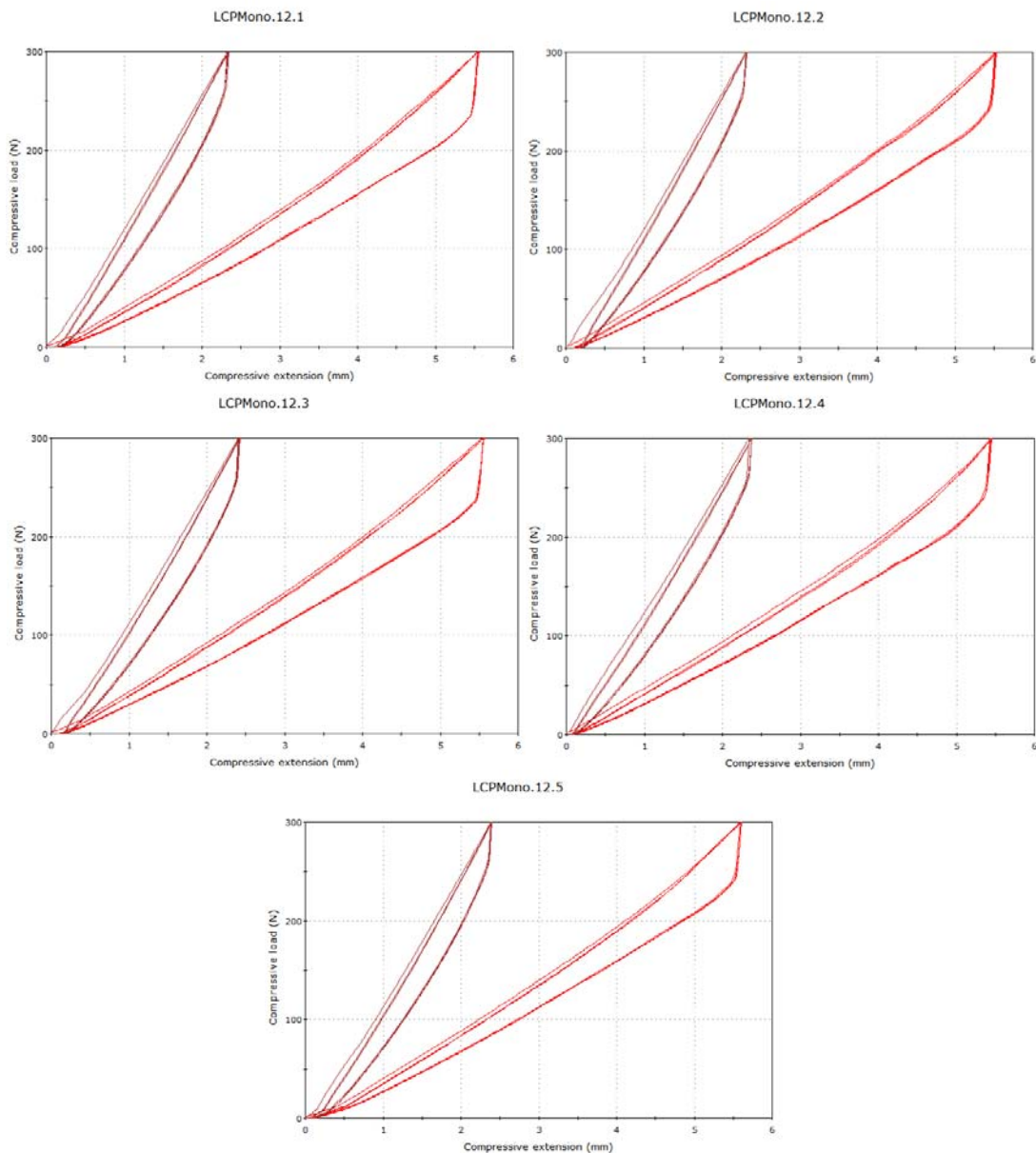
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CHAPTER SIX: APPENDICES

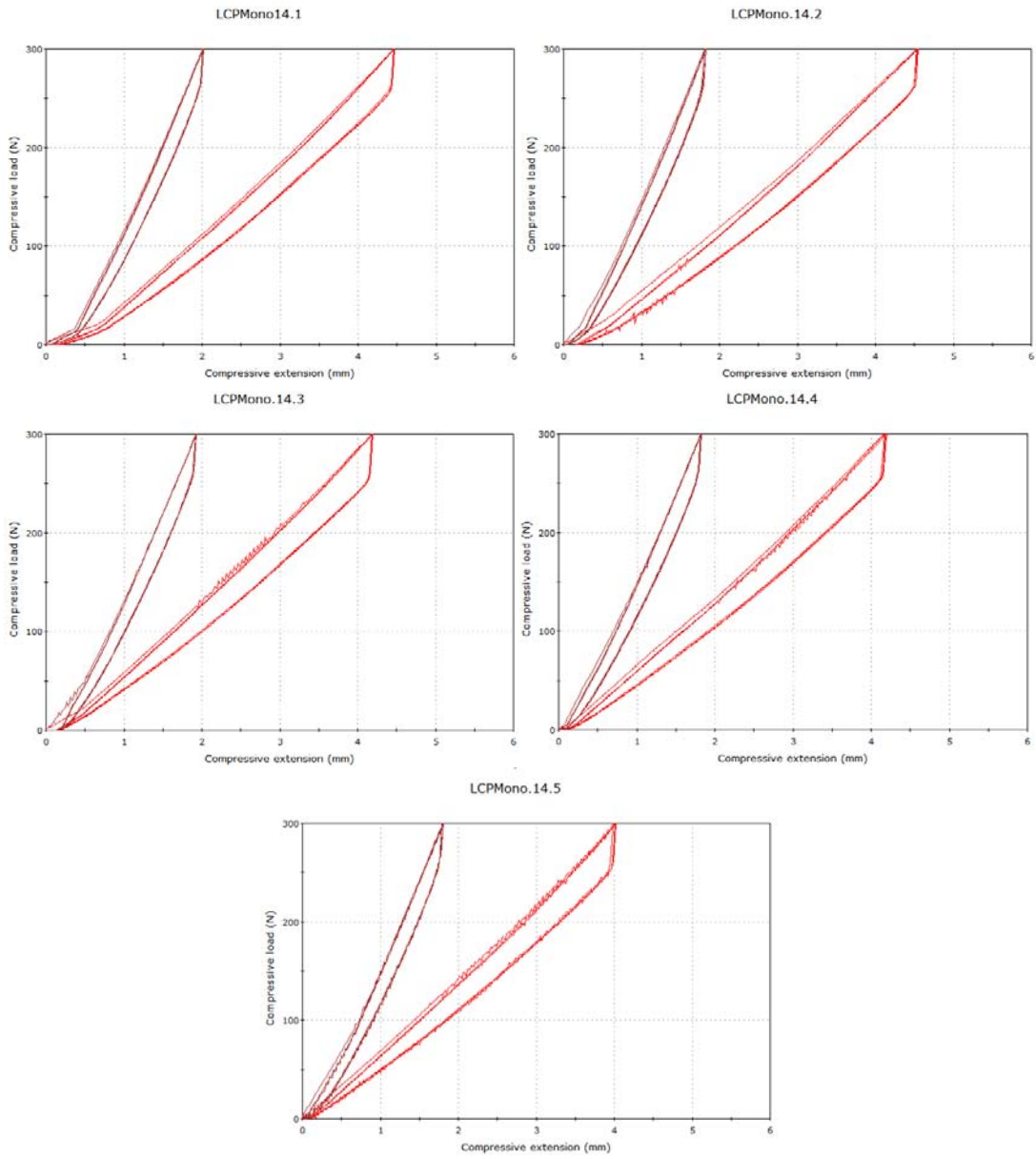
APPENDIX 1: LOAD DEFORMATION CURVES: MEDIOLATERAL & CRANIOCAUDAL BENDING.

Five different constructs were created; each with 5 replicates, making 25 specimens to be tested. **LCPMono** - LCP with monocortical screws, **LCPBi** - LCP with bicortical screws, **LCPR20** - LCP with monocortical screws + 20% IM pin, **LCPR30** - LCP with monocortical screws + 30% IM pin and **LCPR40** - LCP with monocortical screws + 40% IM pin. Screw configurations with 2 screws per fragment then modelled the longest (1.2) and shortest (1.4) plate working lengths. Screw configurations with 3 screws per fragment modelled the intermediate (1.2.3) and shortest (1.3.4) working lengths.

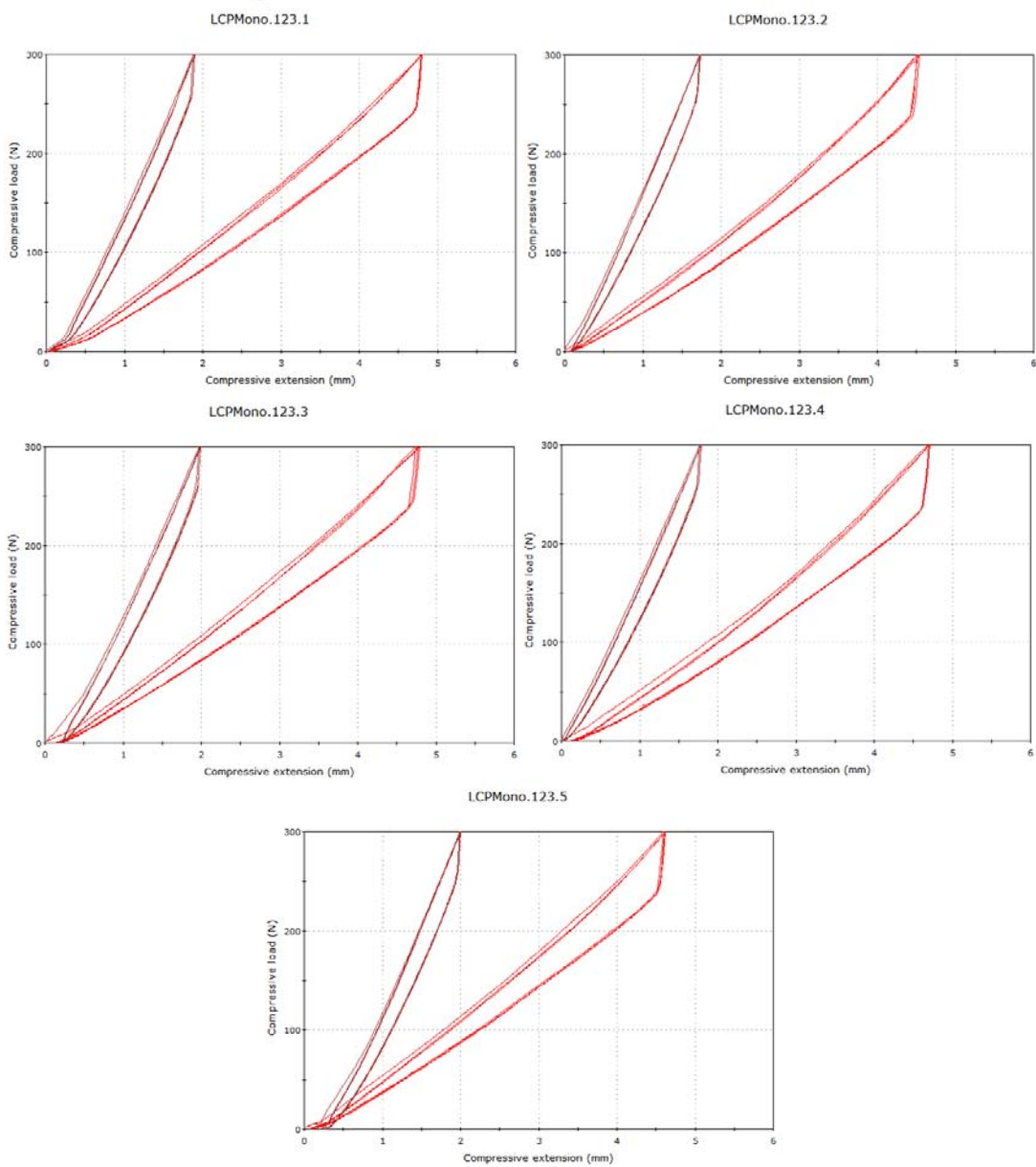
LCPMono.12 (5 replicates)



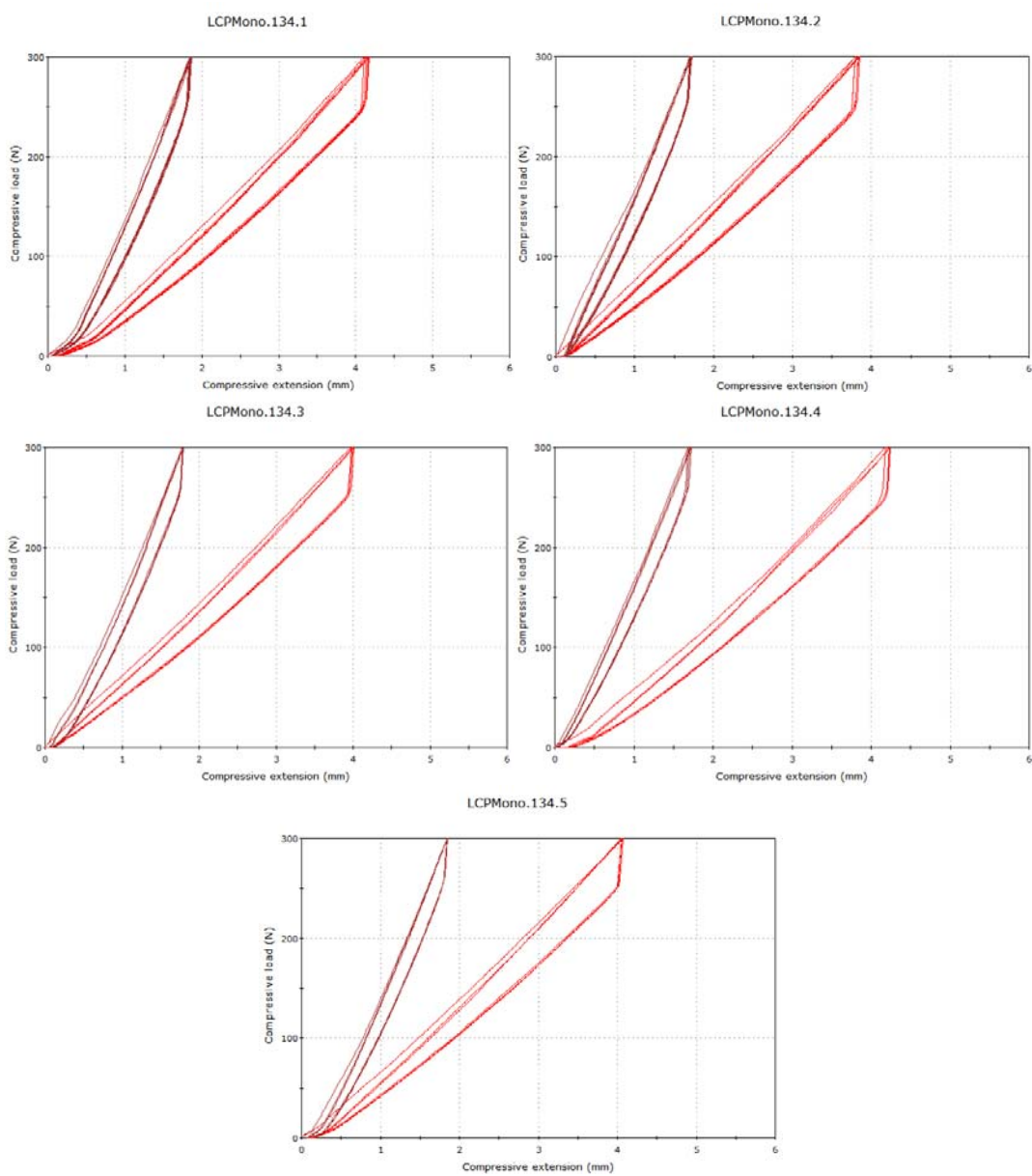
LCPMono.14 (5 replicates)



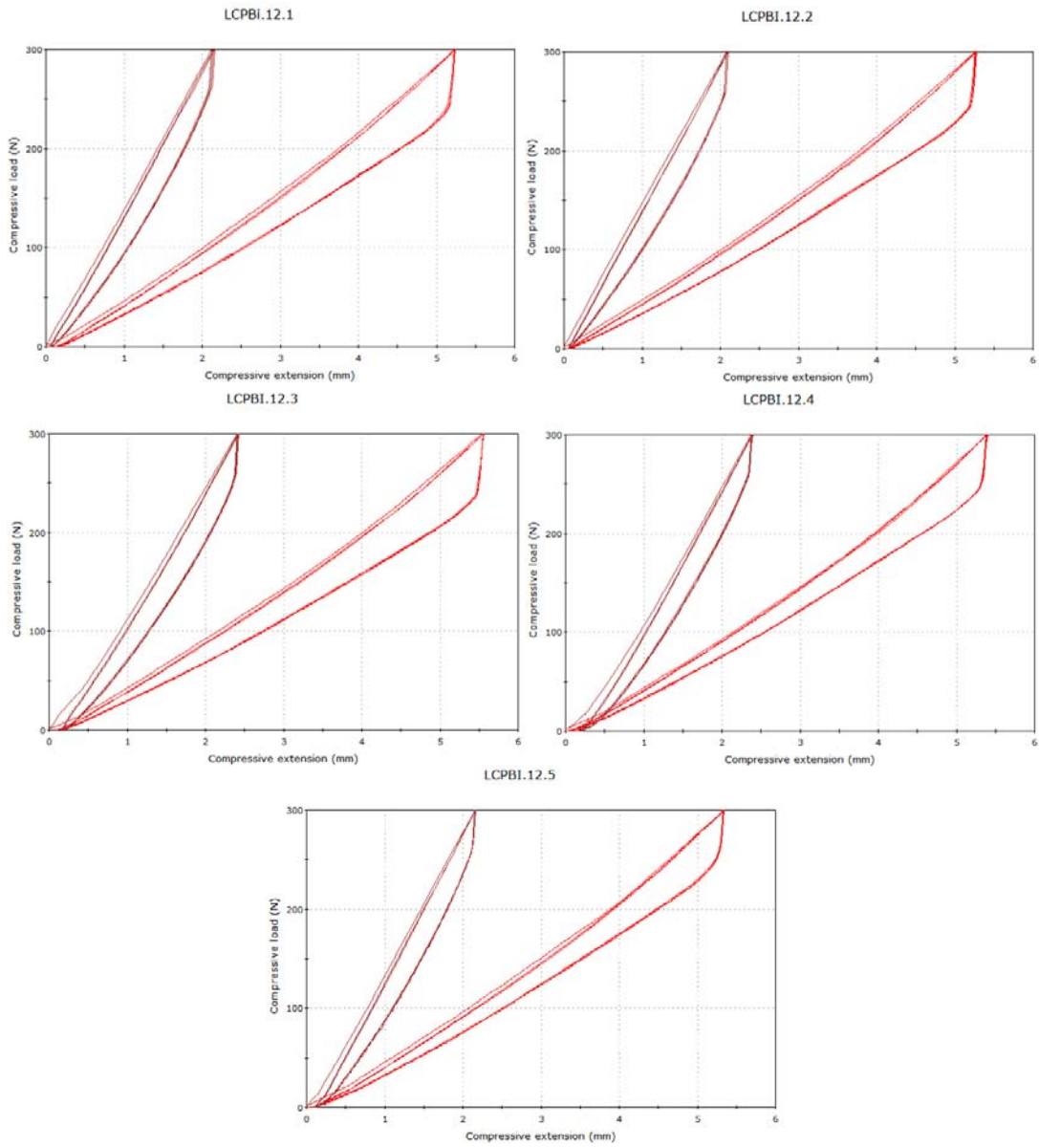
LCPMono.123 (5 replicates)



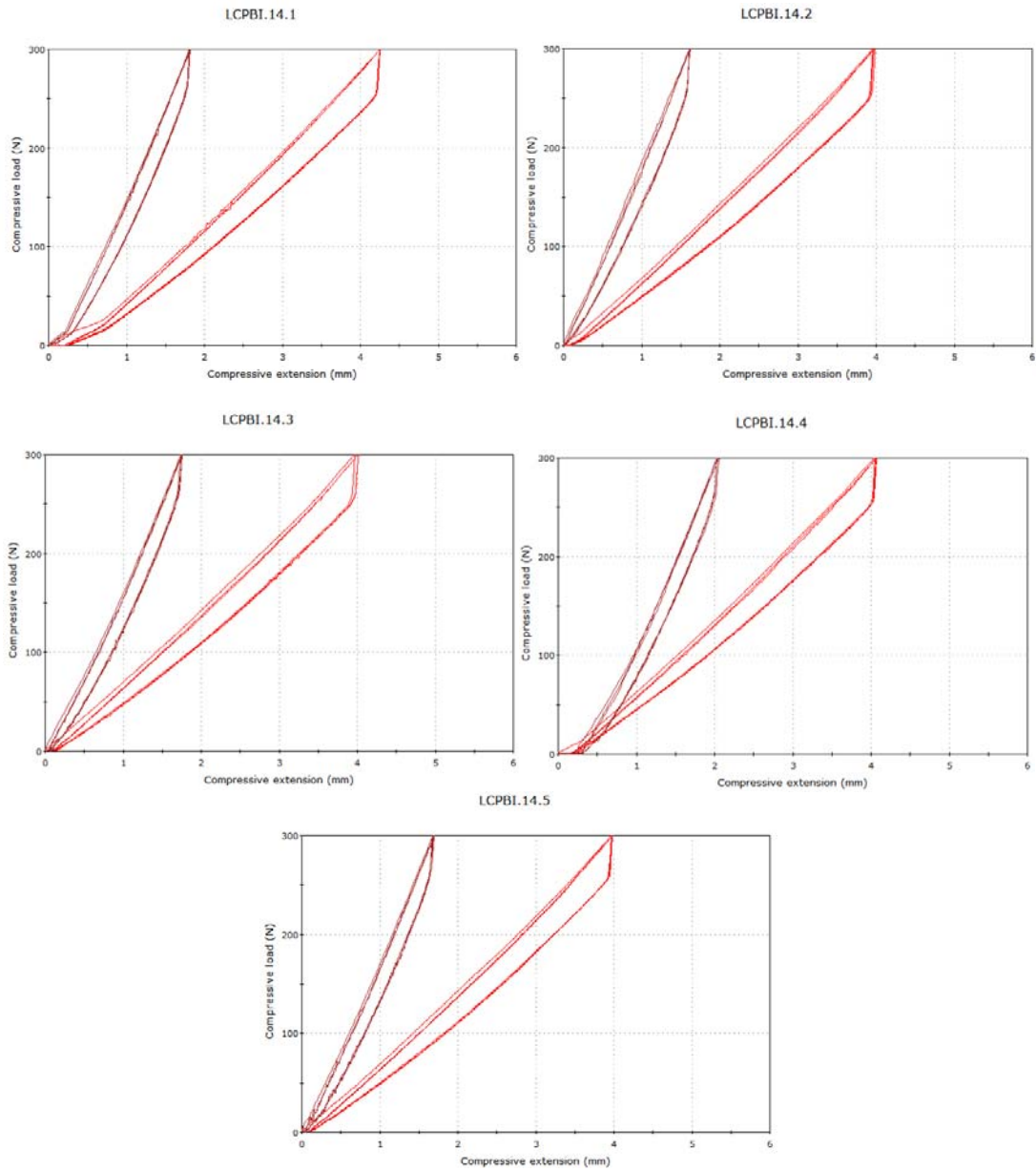
LCPMono.134 (5 replicates)



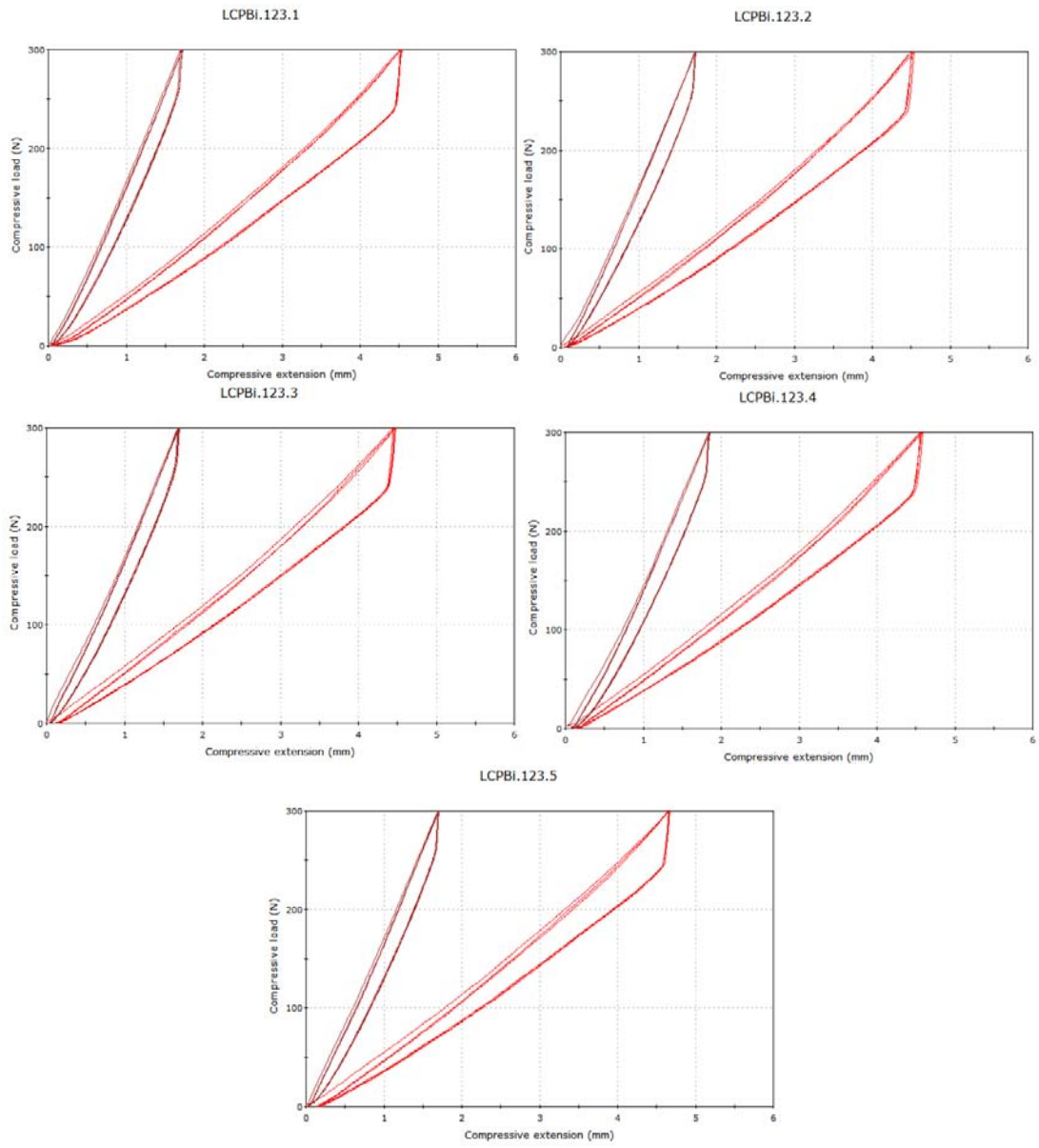
LCPBi.12 (5 replicates)



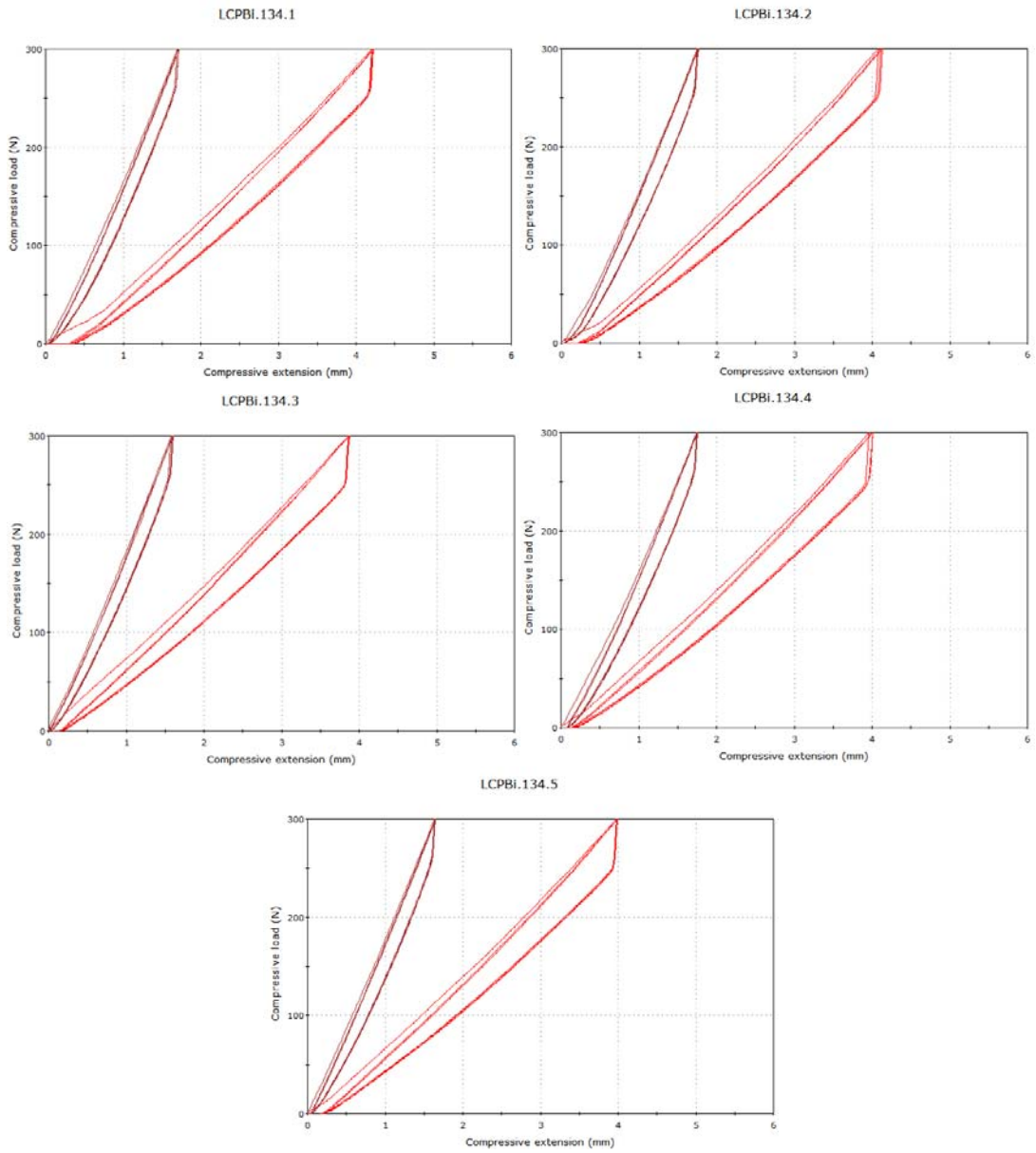
LCPBi.14 (5 replicates)



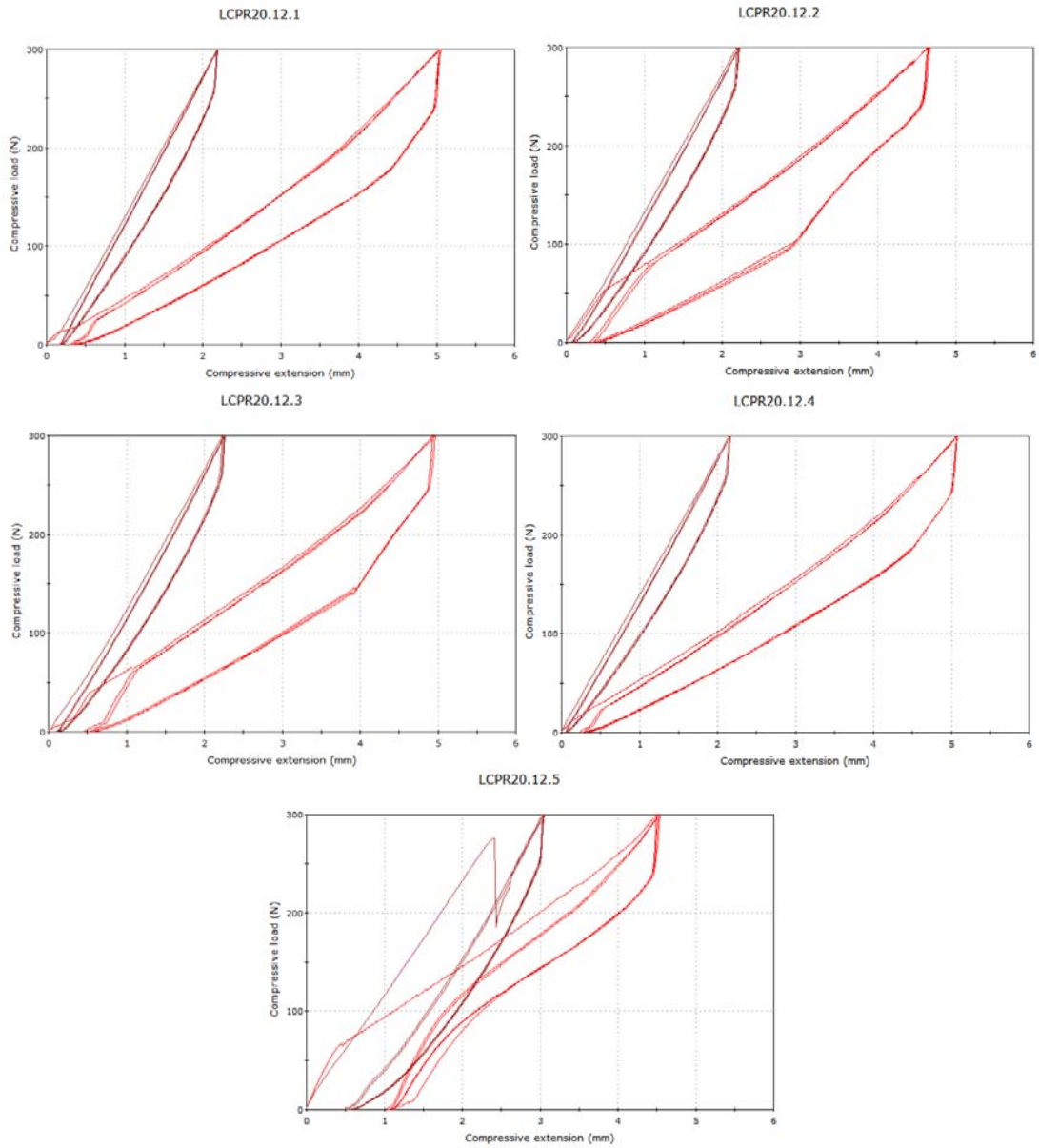
LCPBi.123 (5 replicates)



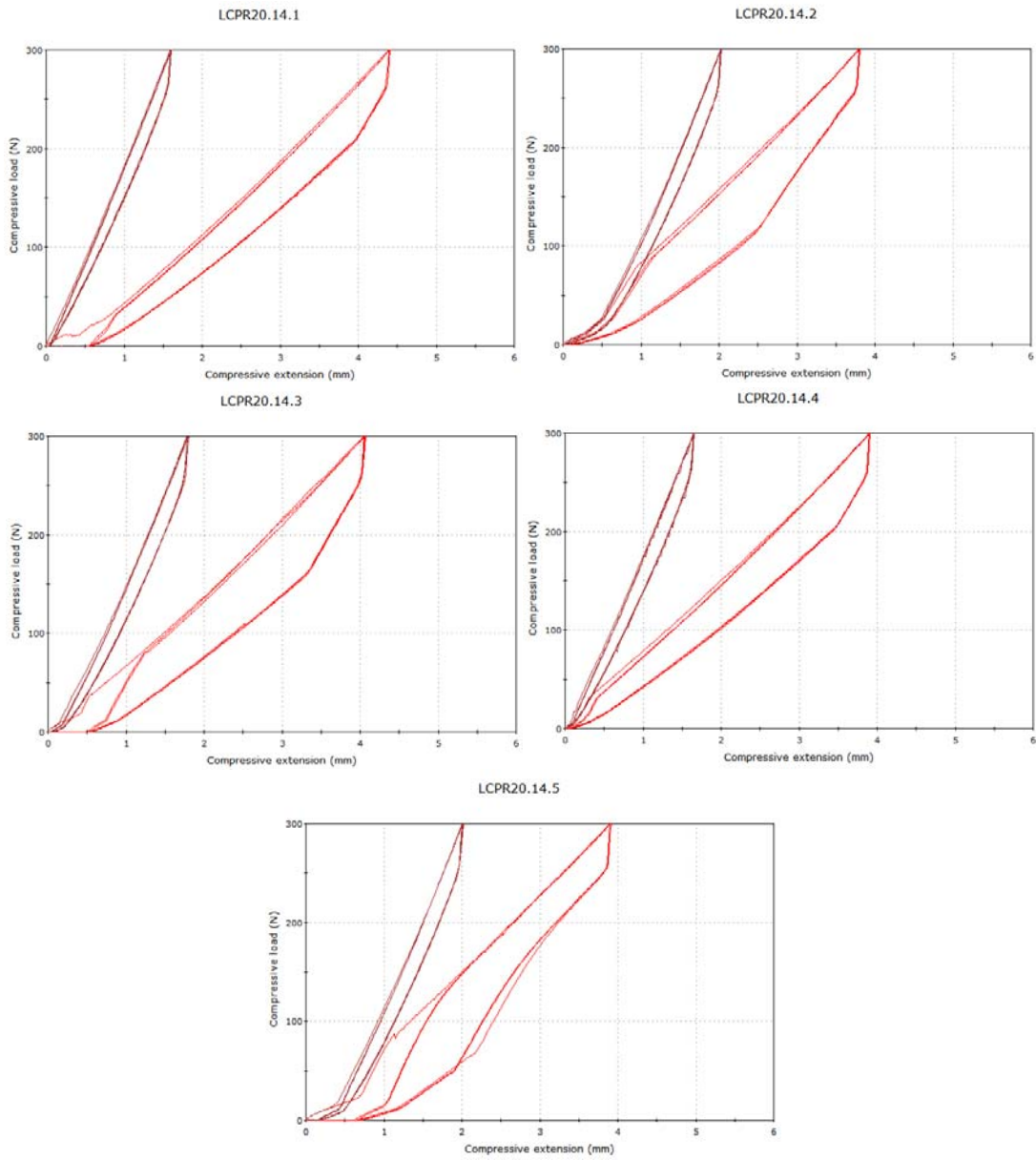
LCPBi.134 (5 replicates)



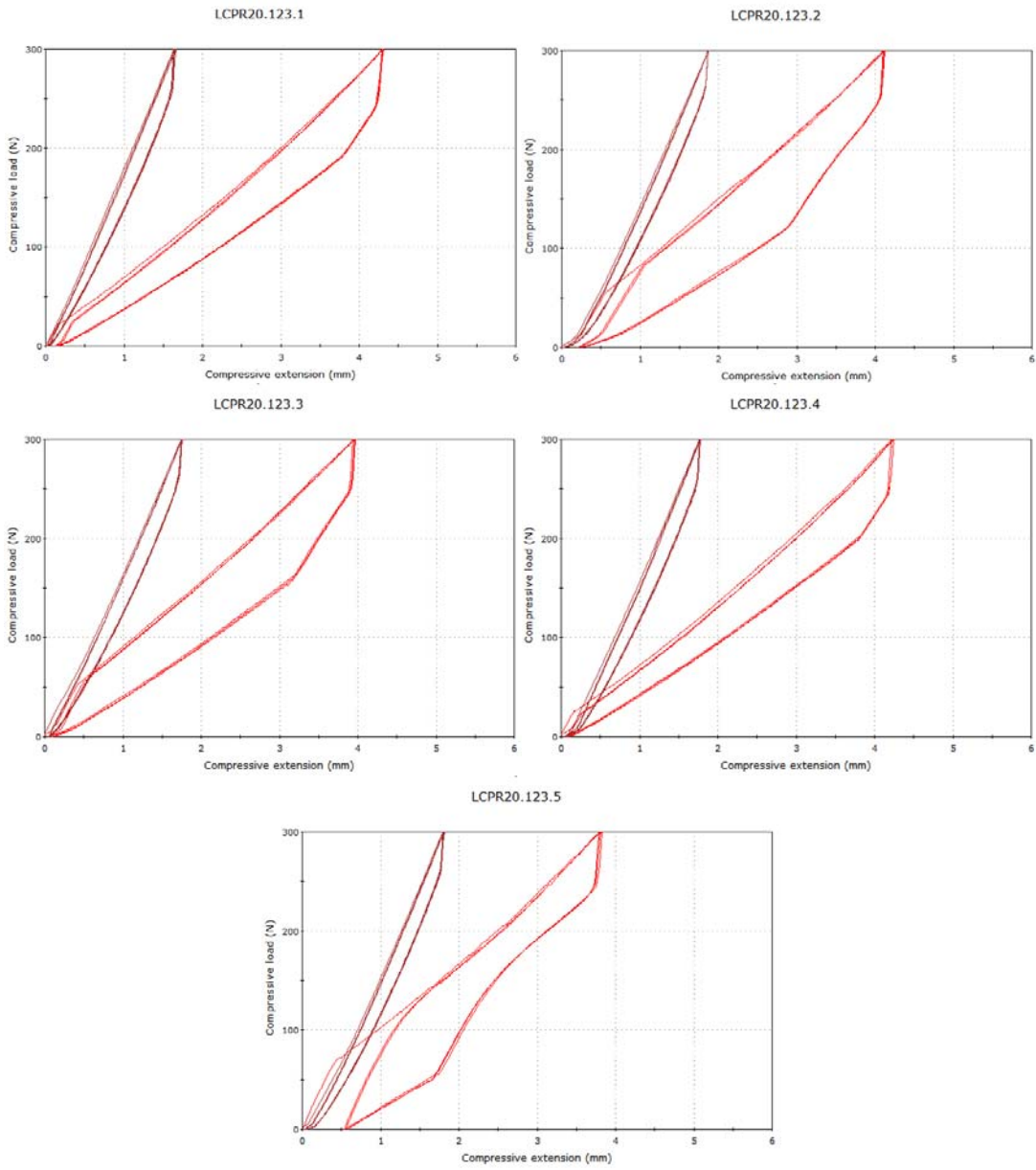
LCPR20.12 (5 replicates)



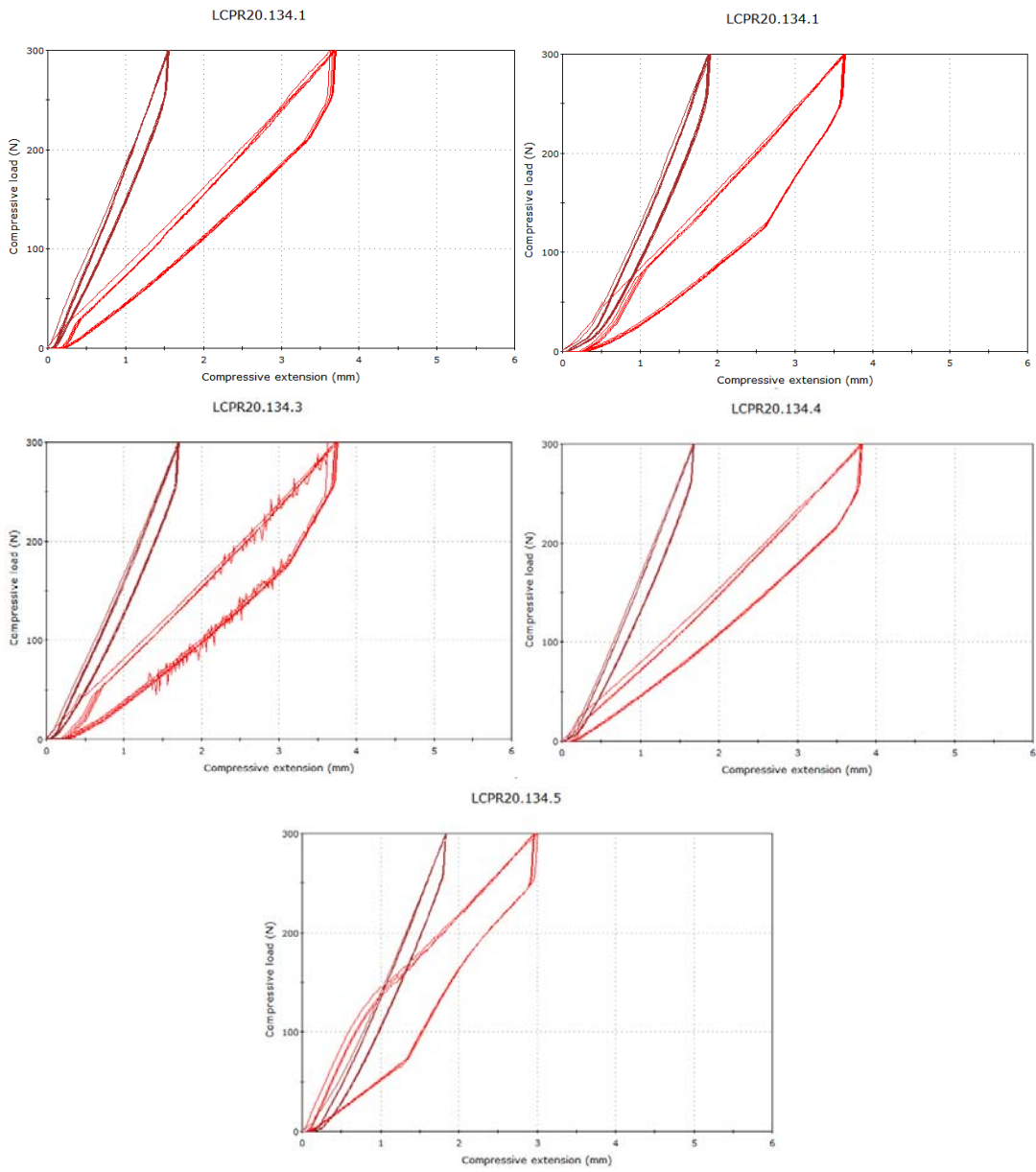
LCPR20.14 (5 replicates)



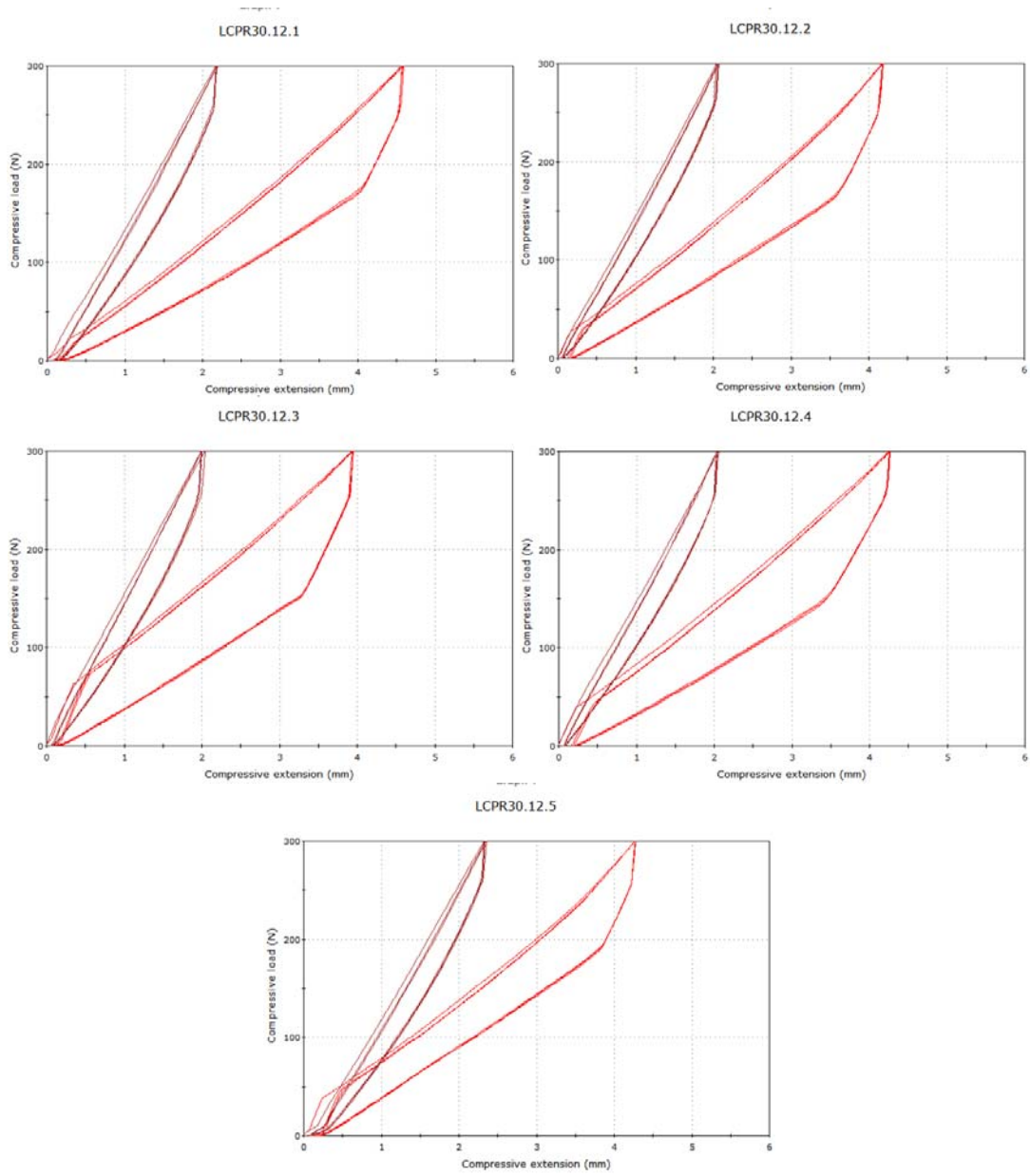
LCPR20.123 (5 replicates)



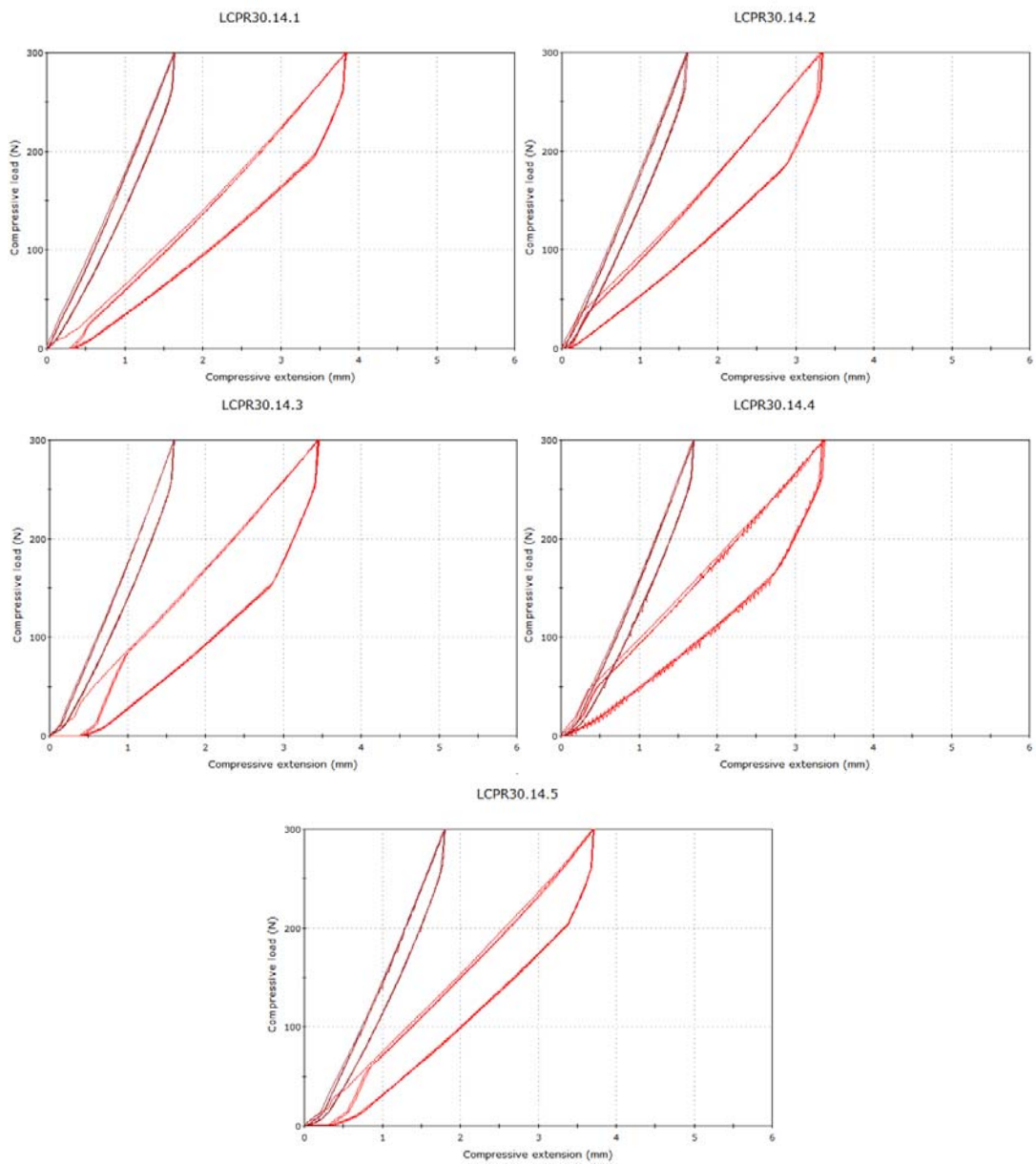
LCPR20.134 (5 replicates)



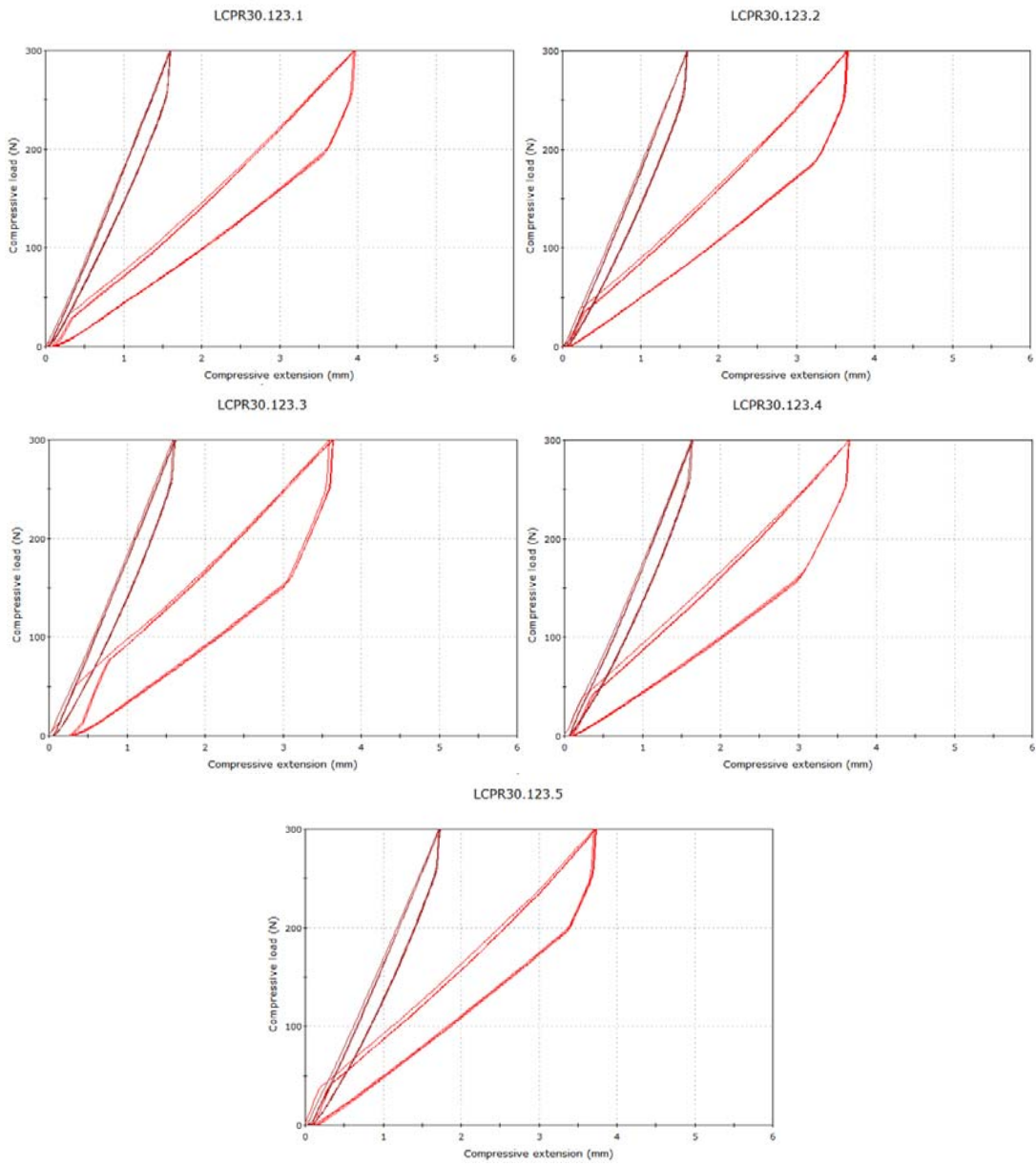
LCPR30.12 (5 replicates)



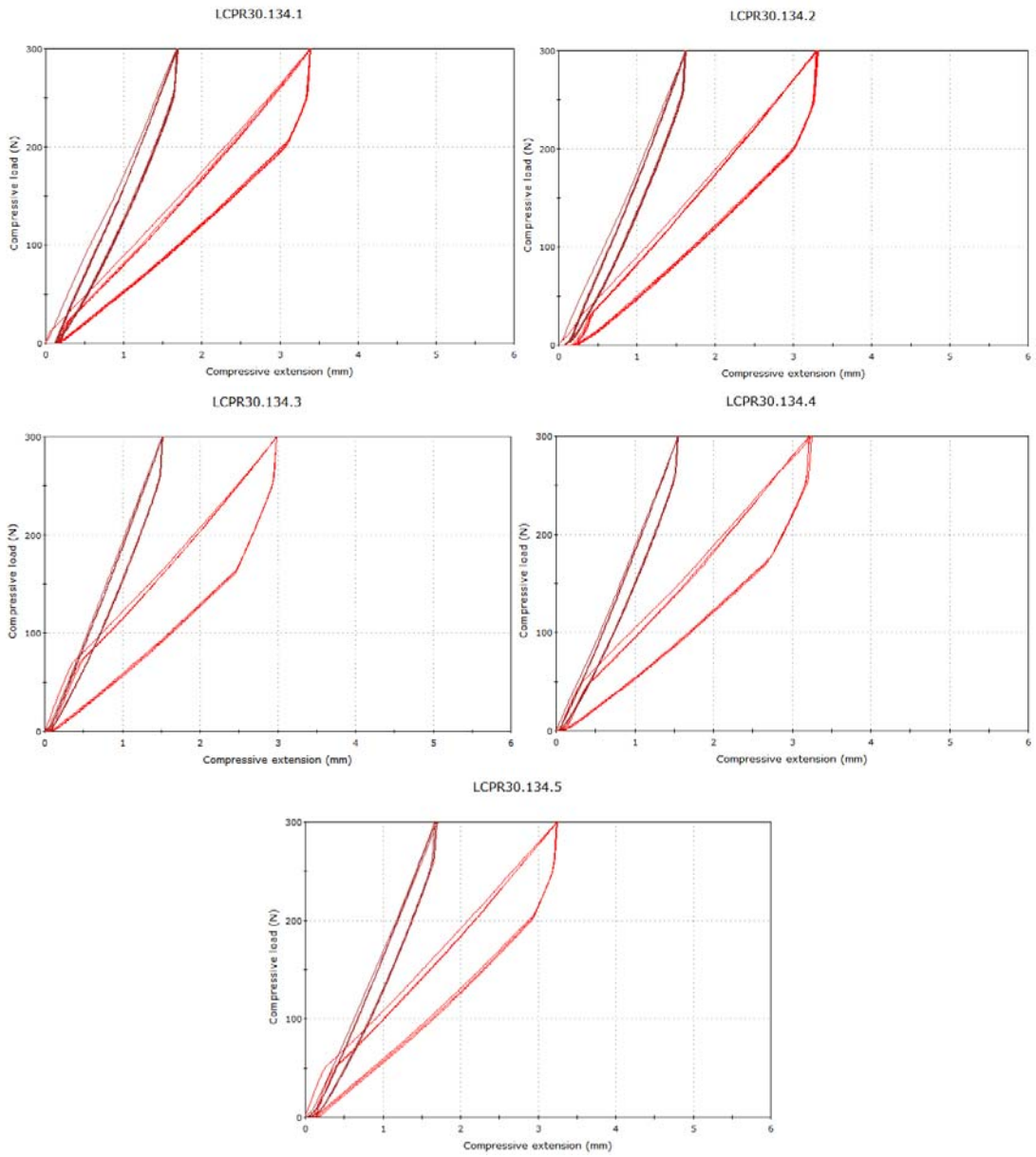
LCPR30.14 (5 replicates)



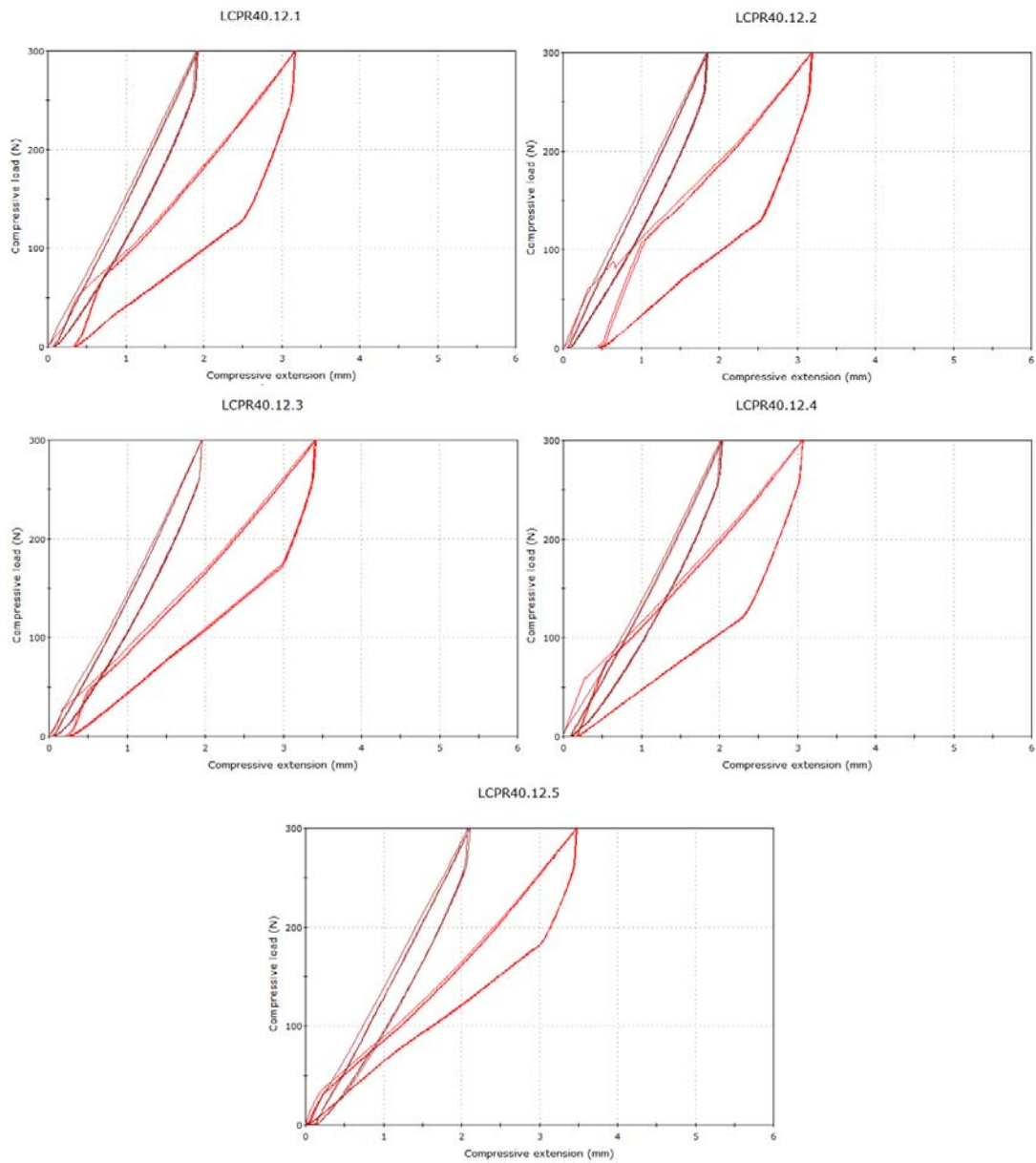
LCPR30.123 (5 replicates)



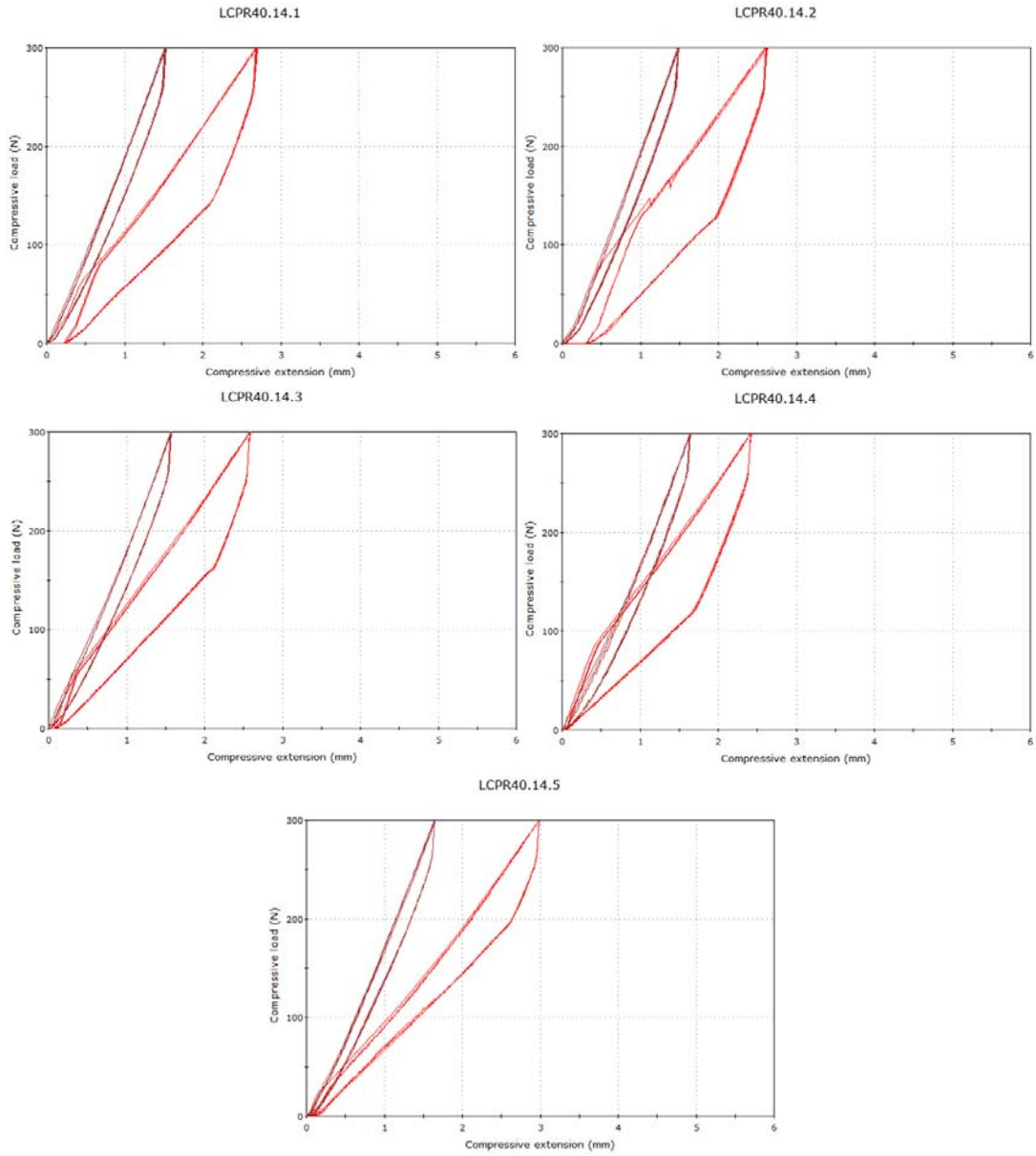
LCPR30.134 (5 replicates)



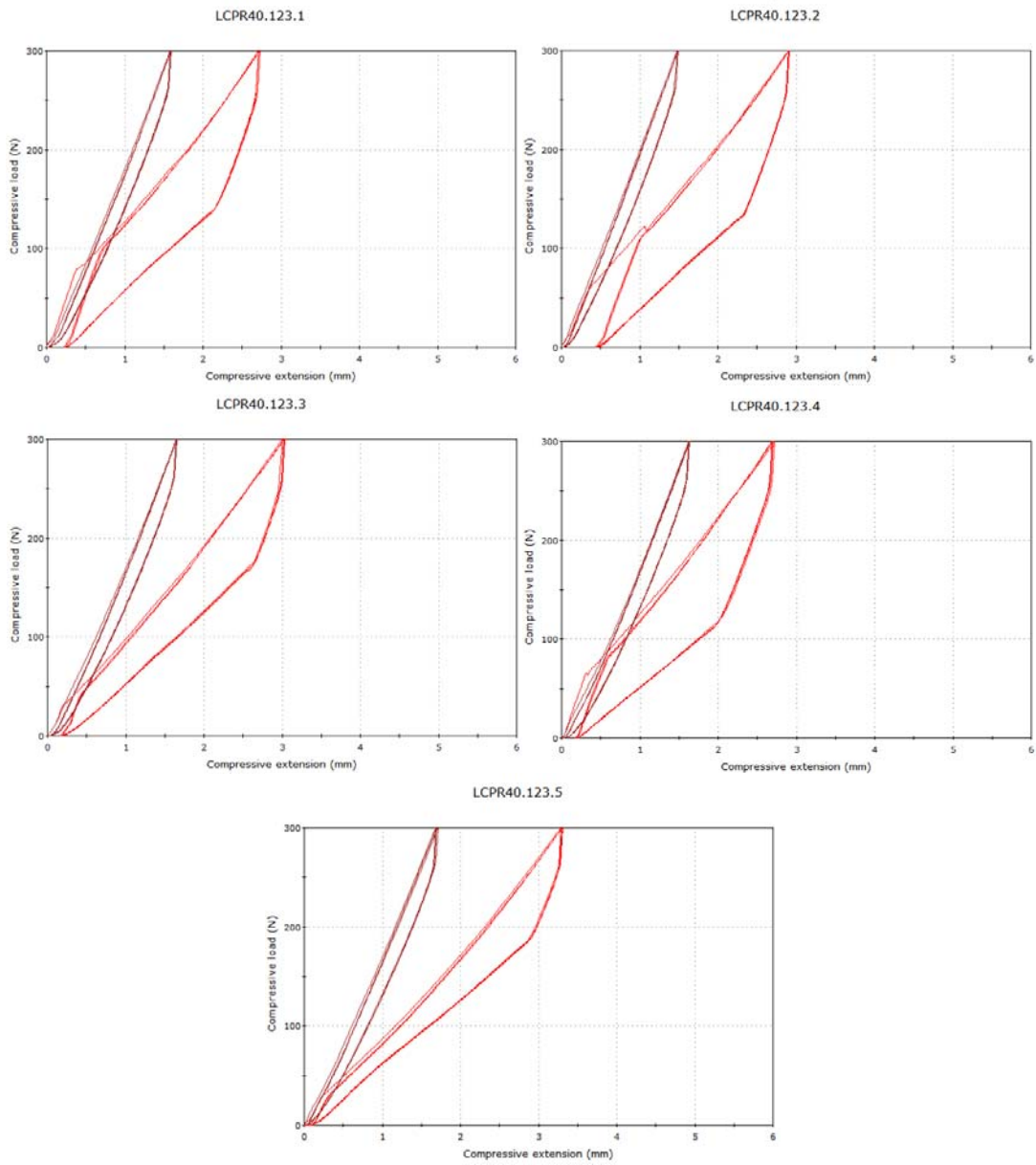
LCPR40.12 (5 replicates)



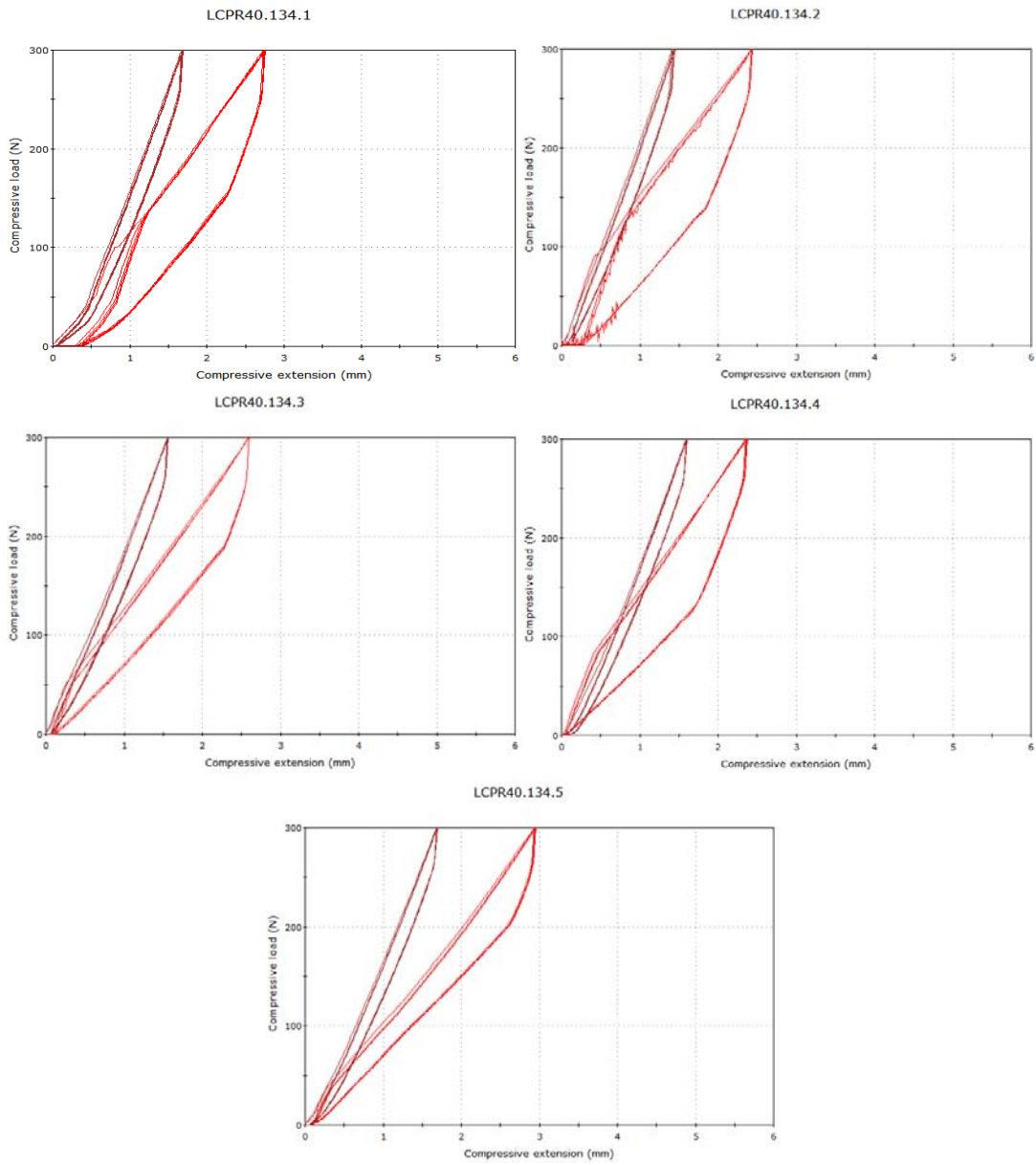
LCPR40.14 (5 replicates)



LCPR40.123 (5 replicates)



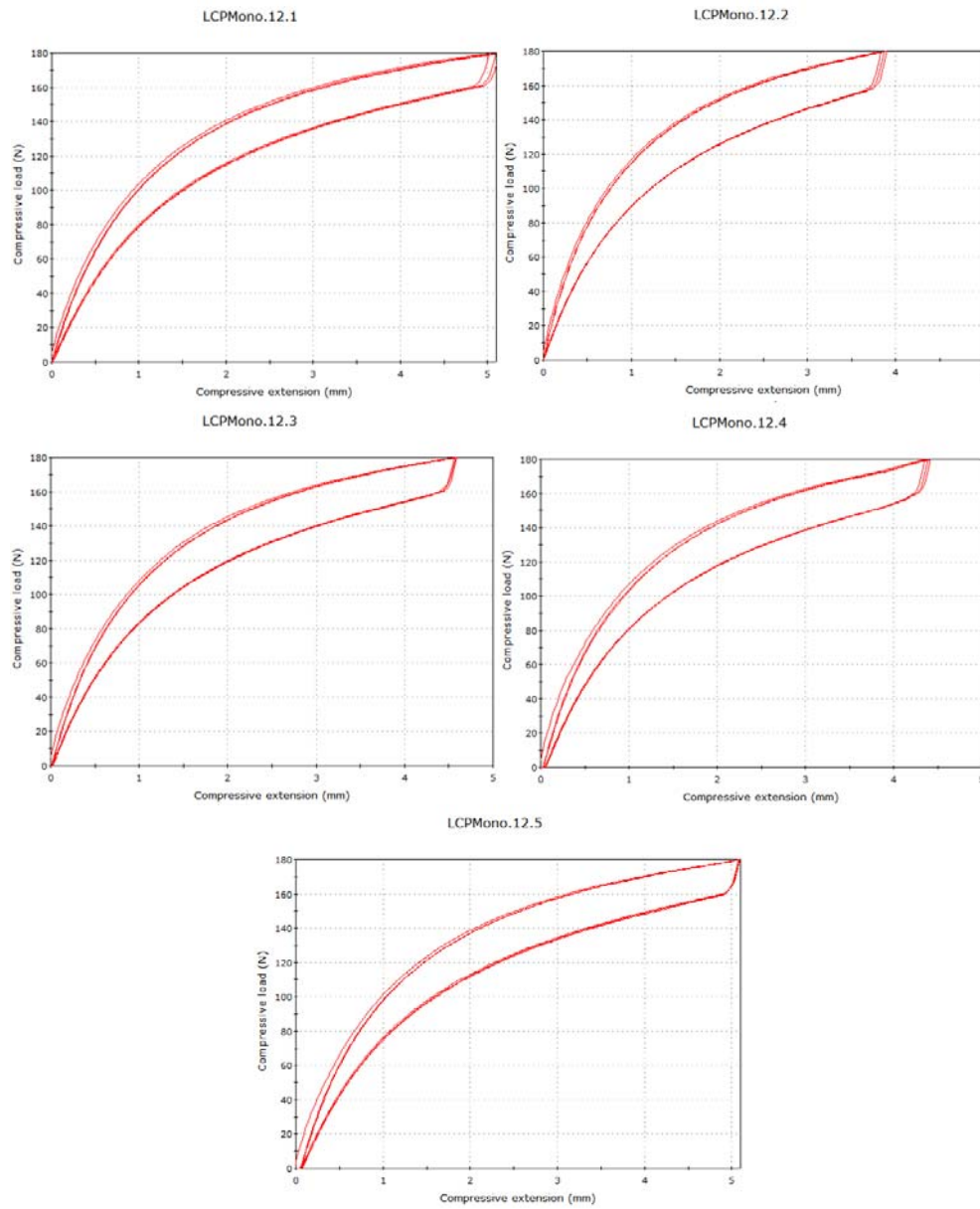
LCPR40.134 (5 replicates)



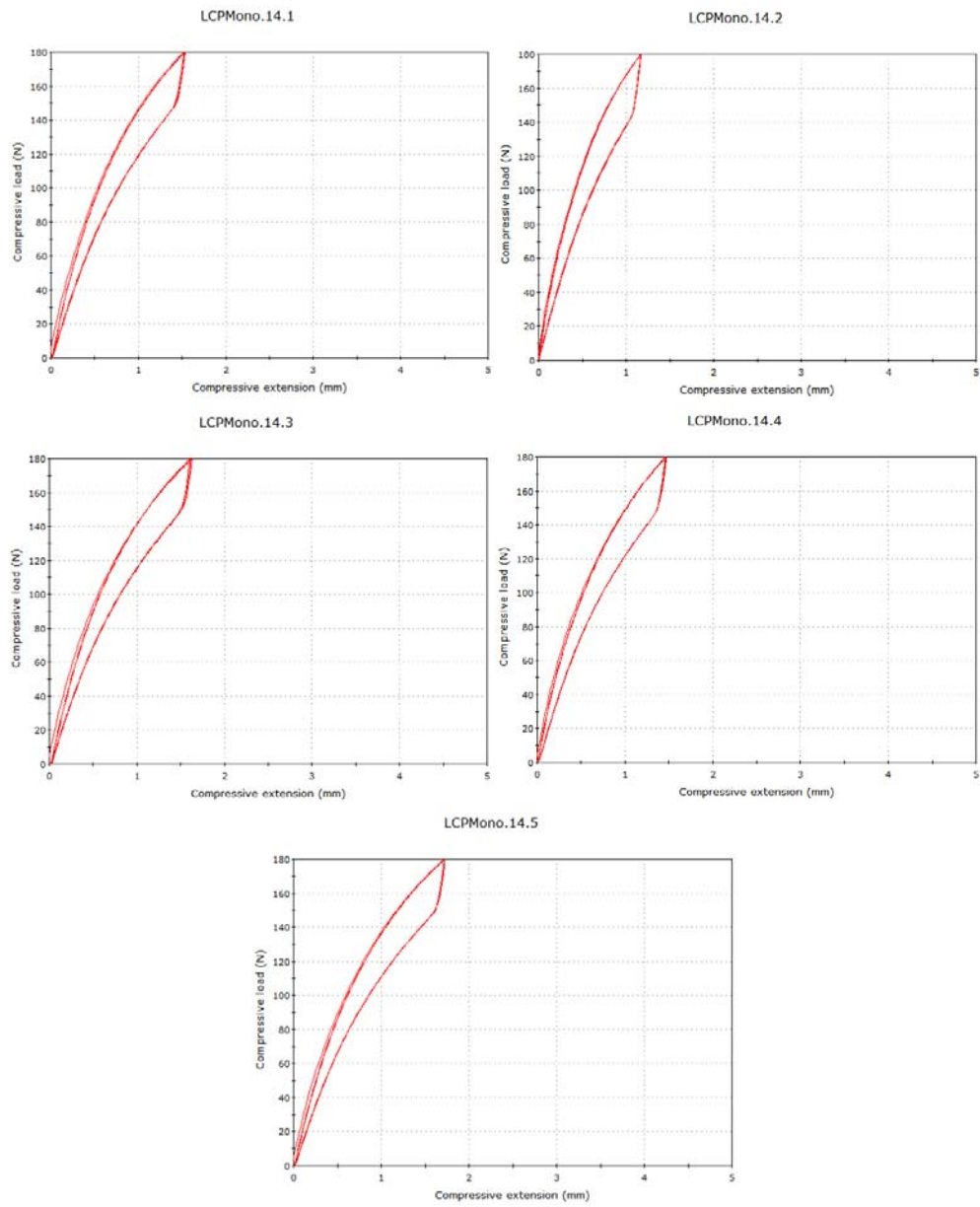
APPENDIX 2: LOAD DEFORMATION CURVES: AXIAL COMPRESSION.

Five different constructs were created; each with 5 replicates, making 25 specimens to be tested. **LCPMono** - LCP with monocortical screws, **LCPBi** - LCP with bicortical screws, **LCPR20** - LCP with monocortical screws + 20% IM pin, **LCPR30** - LCP with monocortical screws + 30% IM pin and **LCPR40** - LCP with monocortical screws + 40% IM pin. Screw configurations with 2 screws per fragment then modelled the longest (1.2) and shortest (1.4) plate working lengths. Screw configurations with 3 screws per fragment modelled the intermediate (1.2.3) and shortest (1.3.4) working lengths.

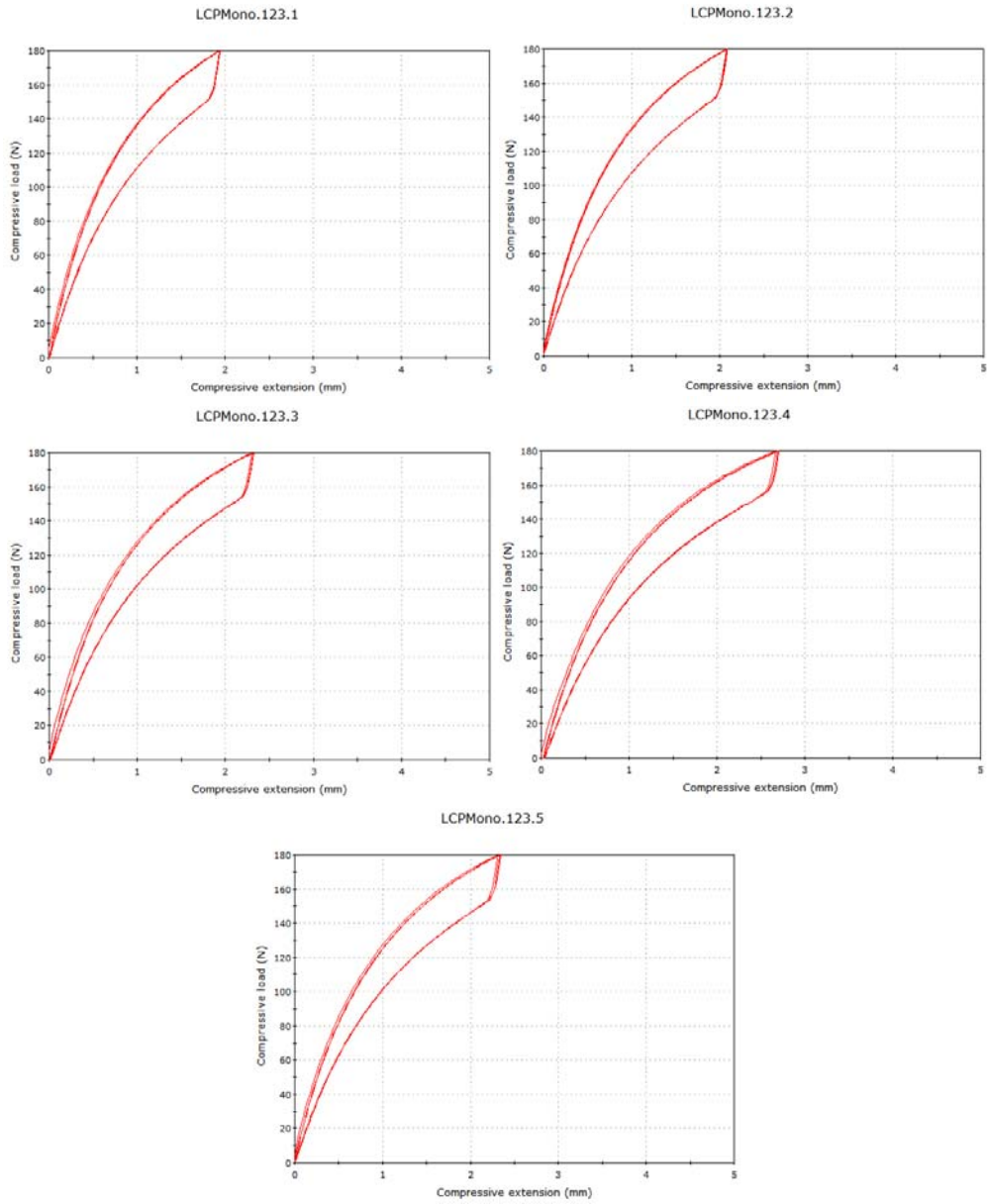
LCPMono.12 (5 replicates)



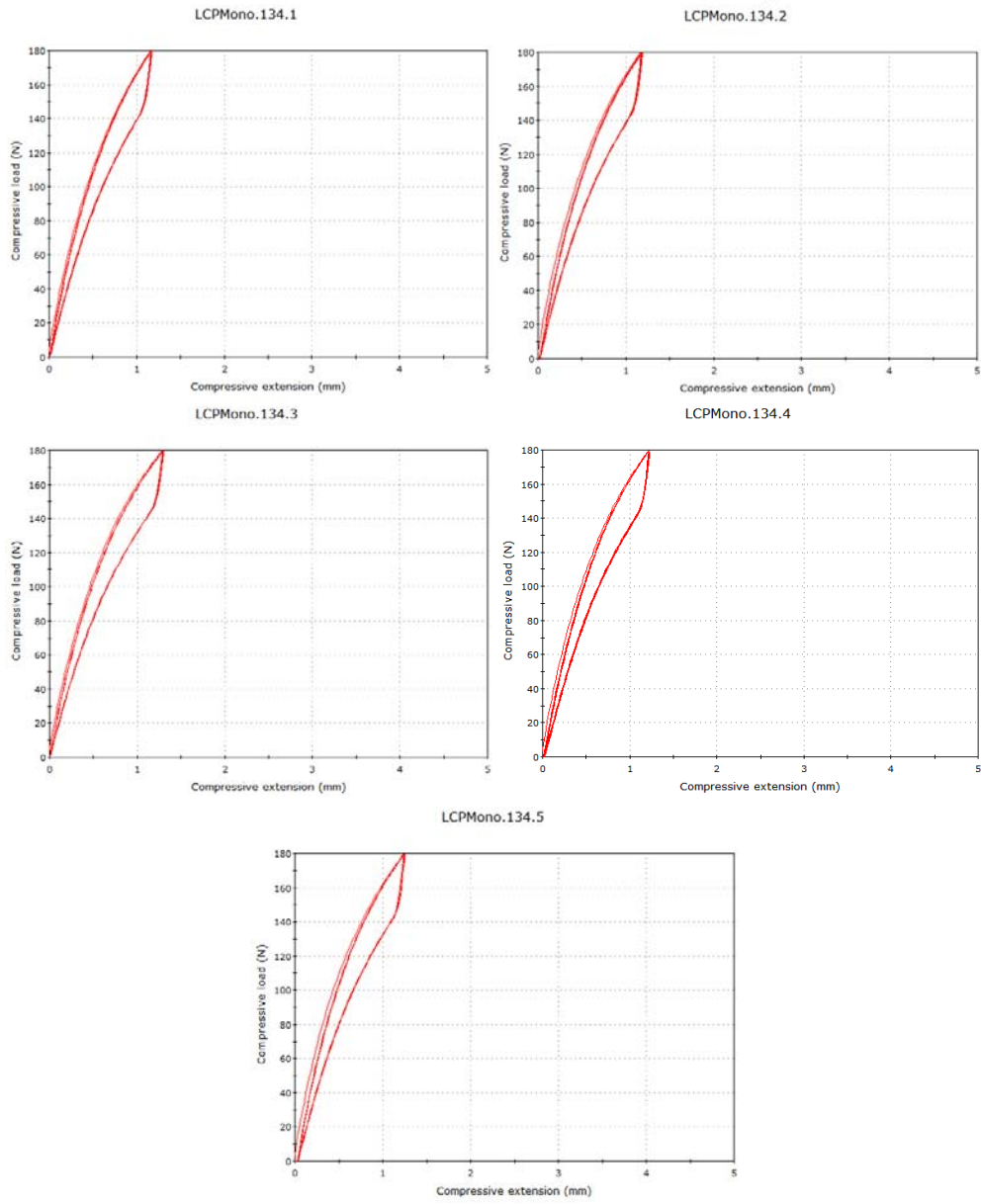
LCPMono.14 (5 replicates)



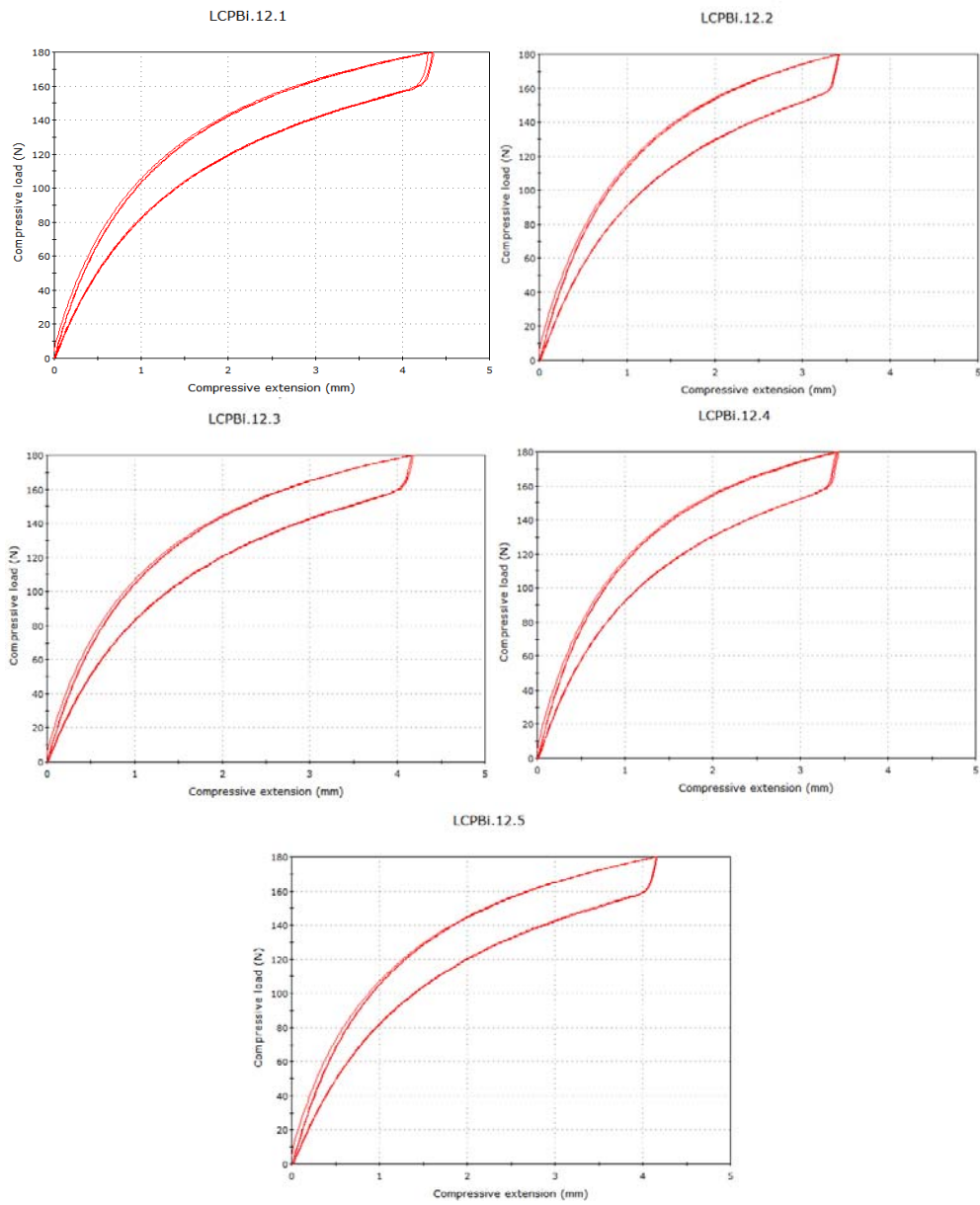
LCPMono.123 (5 replicates)



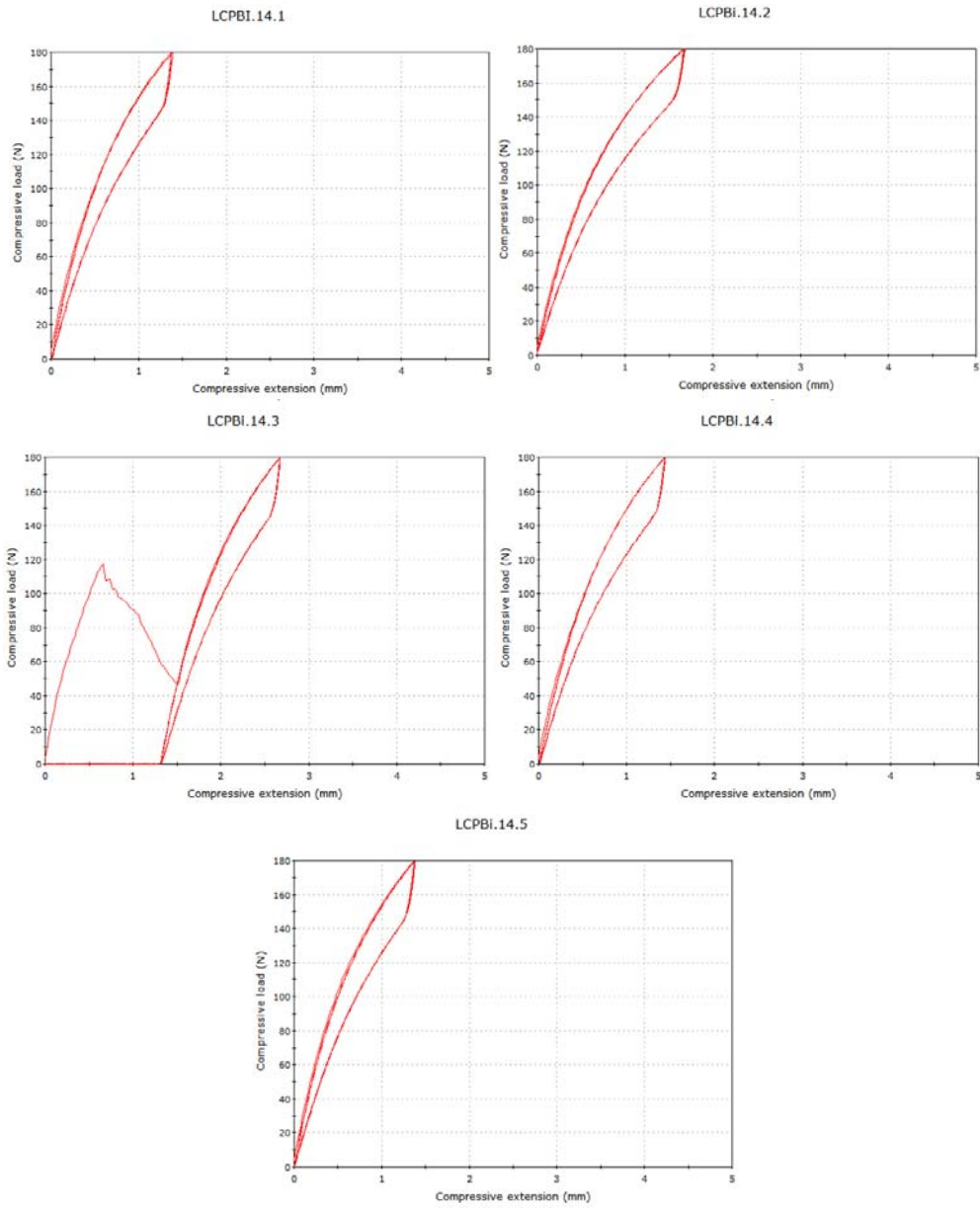
LCPMono.134 (5 replicates)



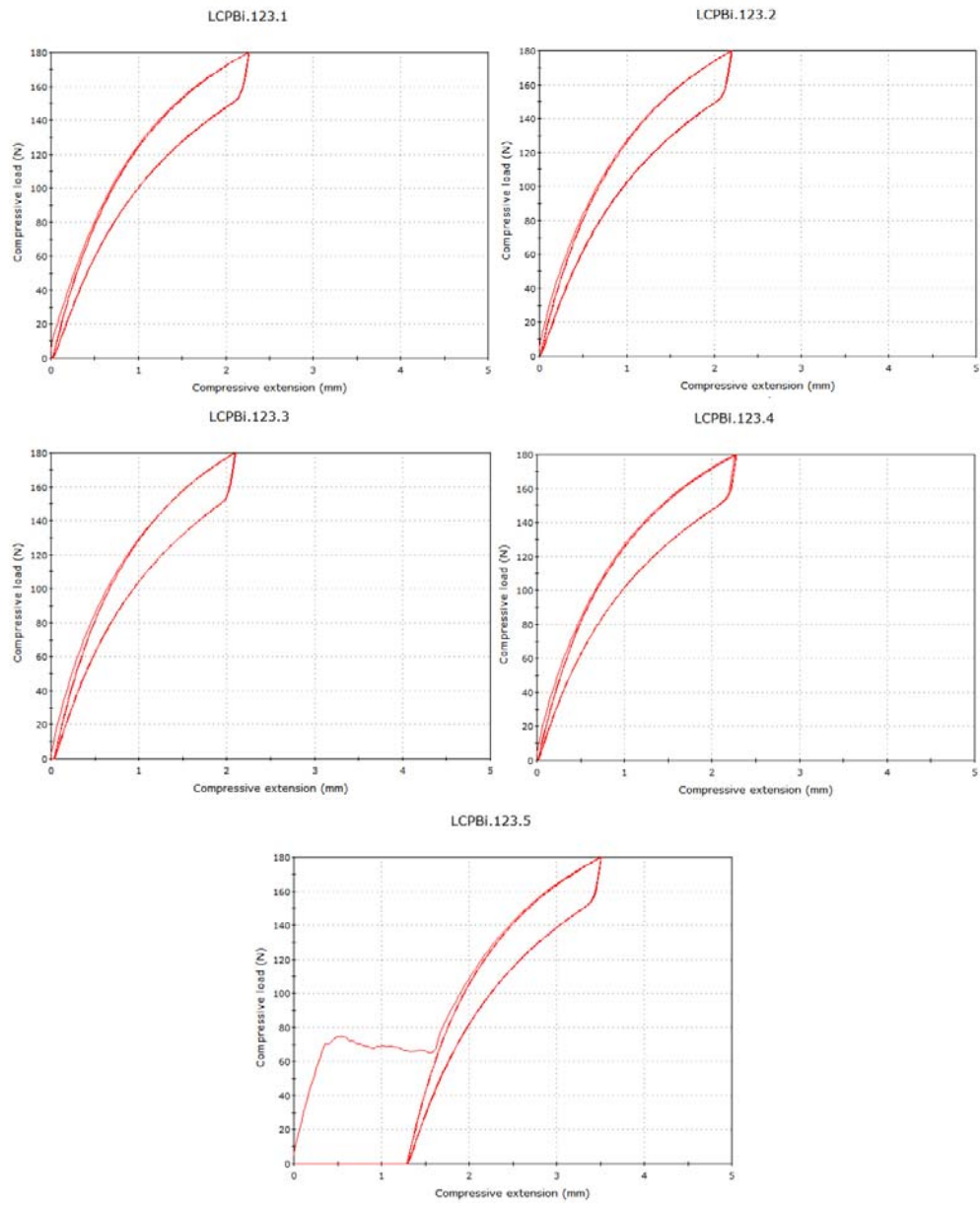
LCPBi.12 (5 replicates)



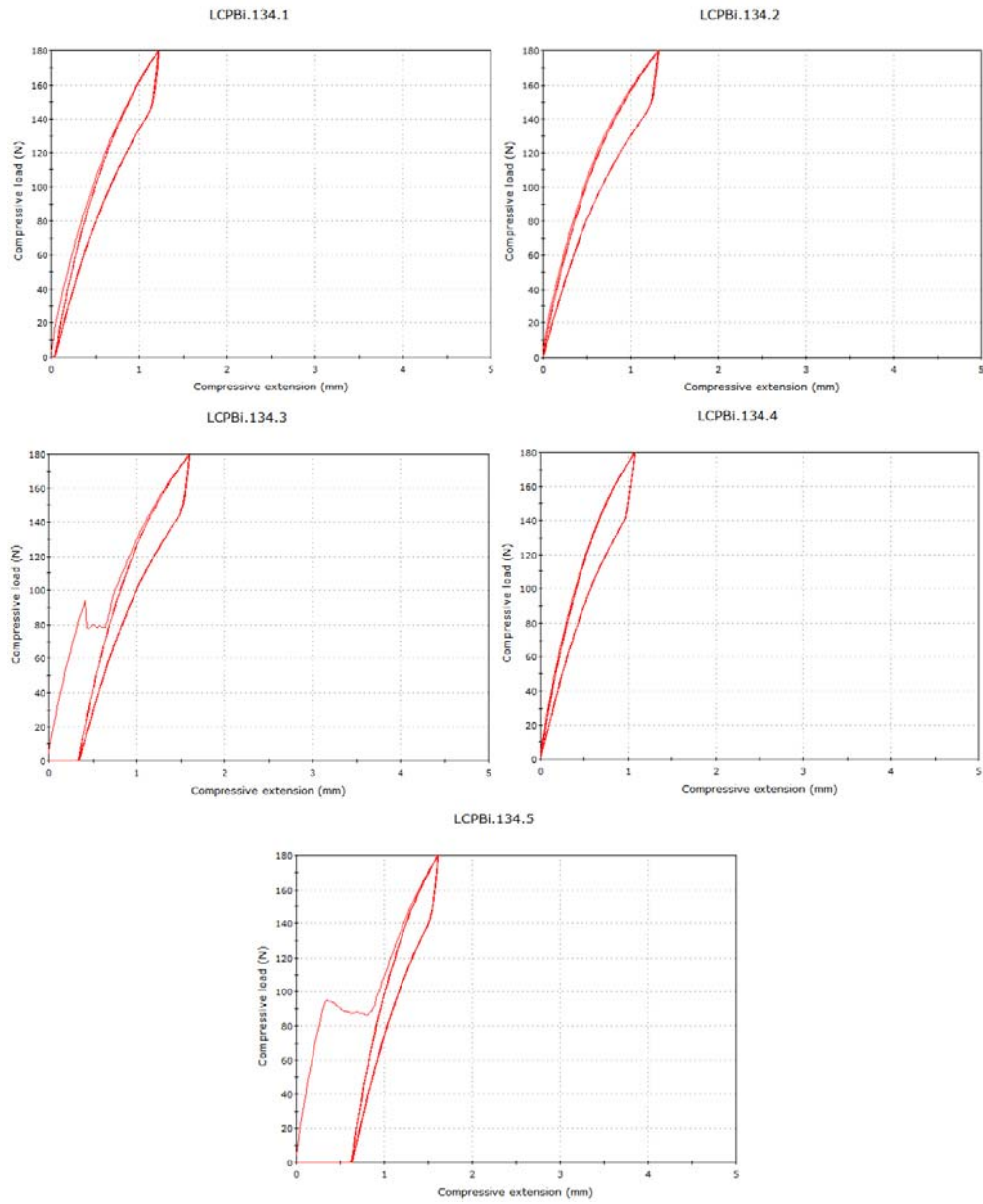
LCPBi.14 (5 replicates)



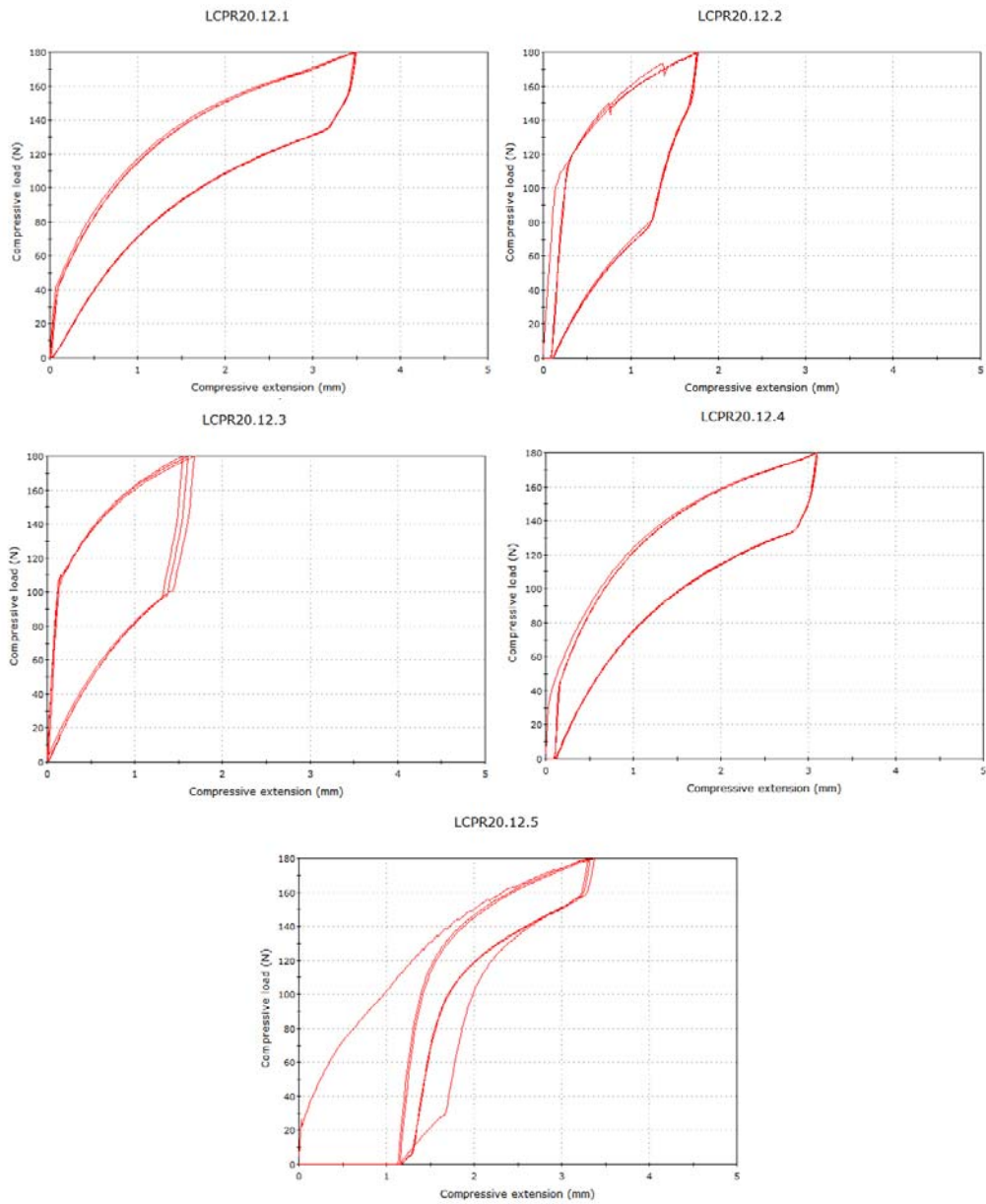
LCPBi.123 (5 replicates)



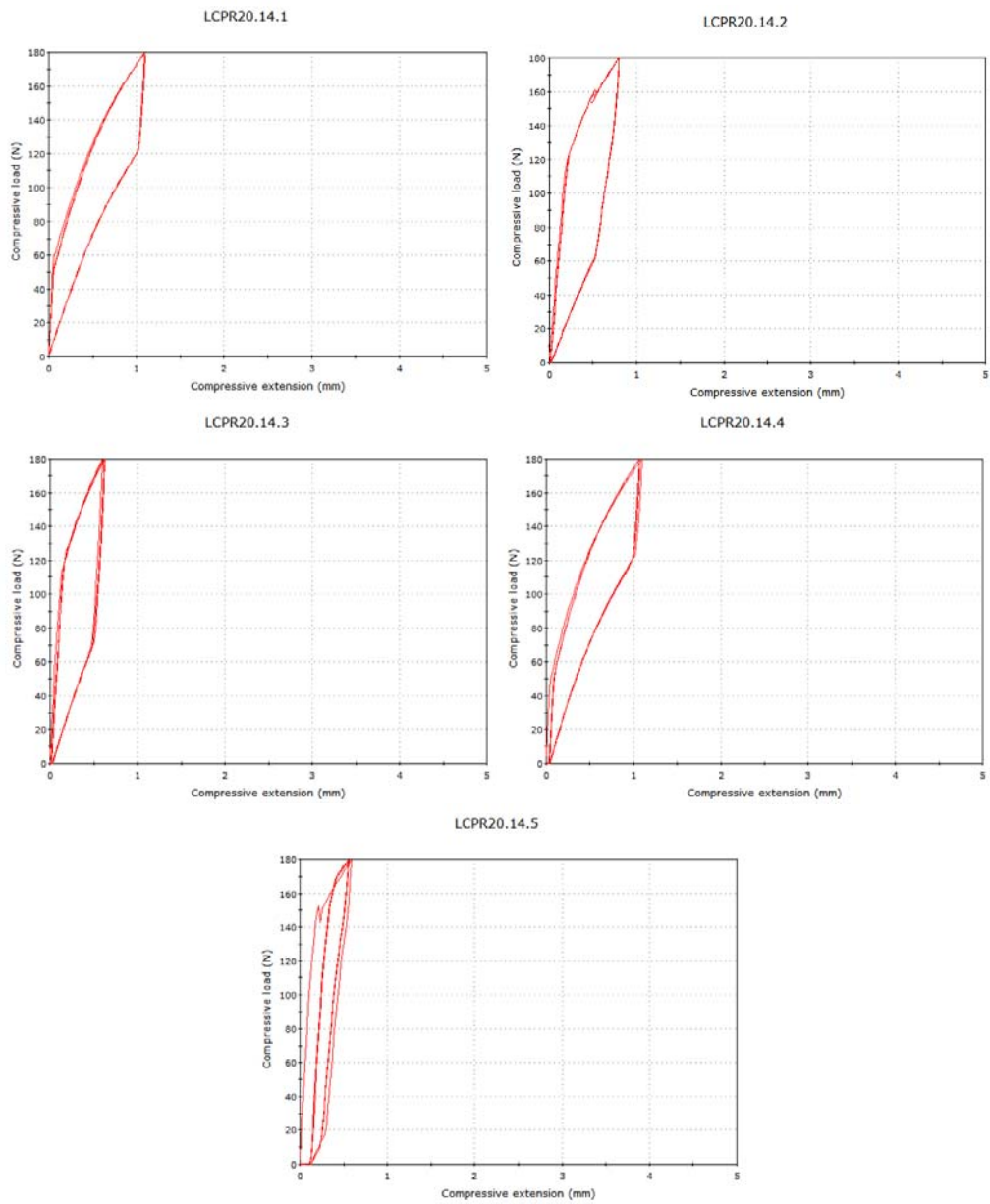
LCPBi.134 (5 replicates)



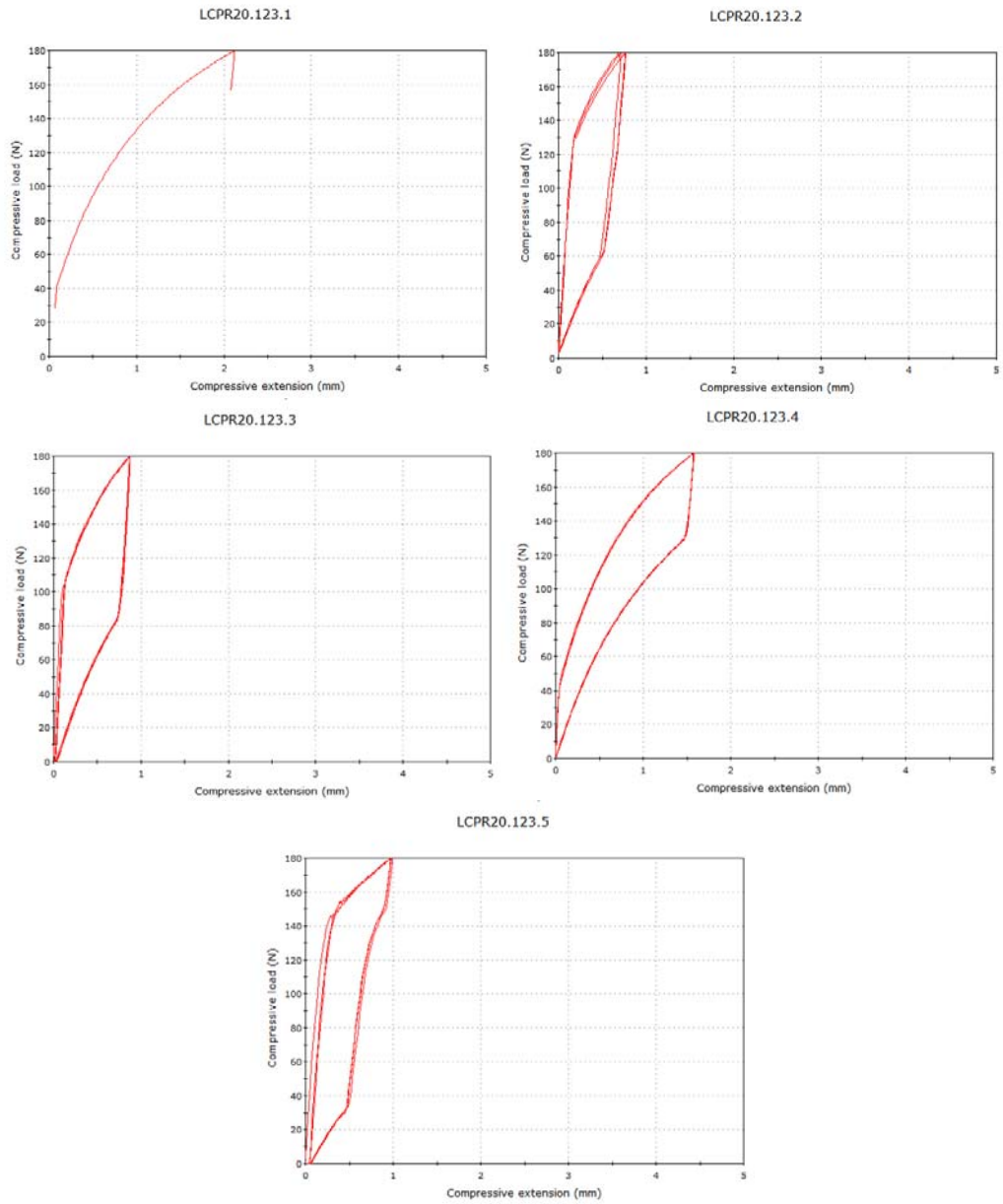
LCPR20.12 (5 replicates)



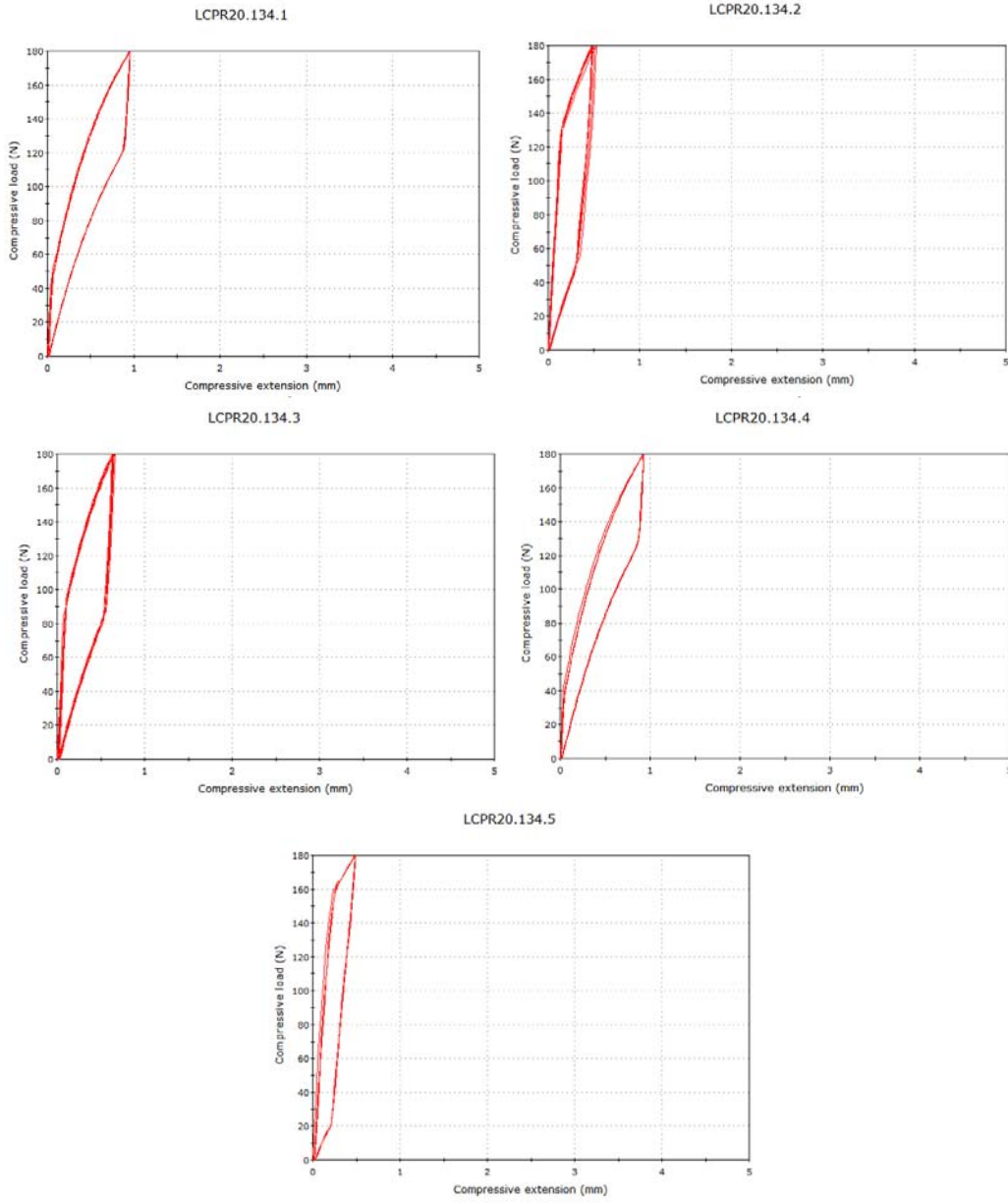
LCPR20.14 (5 replicates)



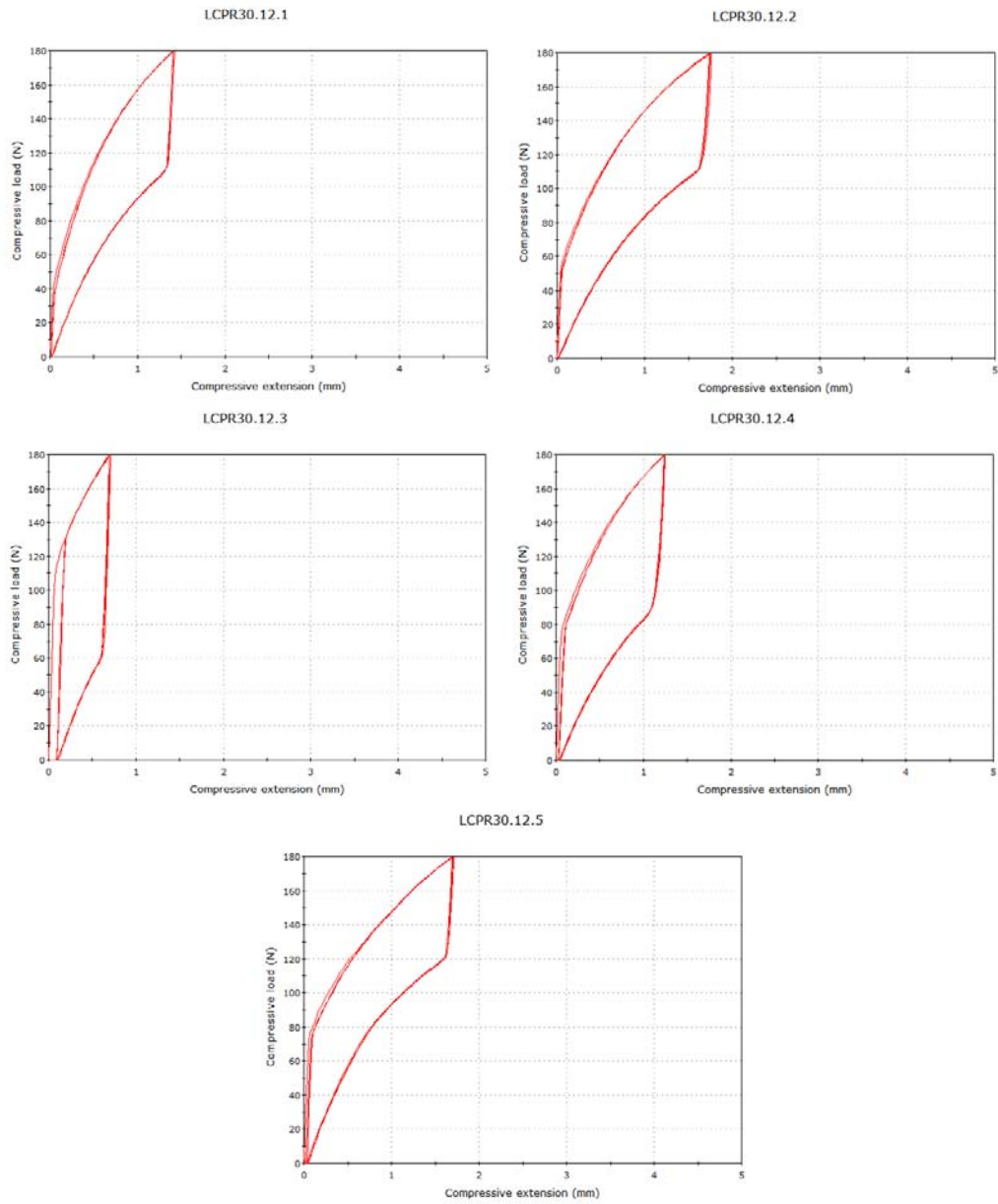
LCPR20.123 (5 replicates)



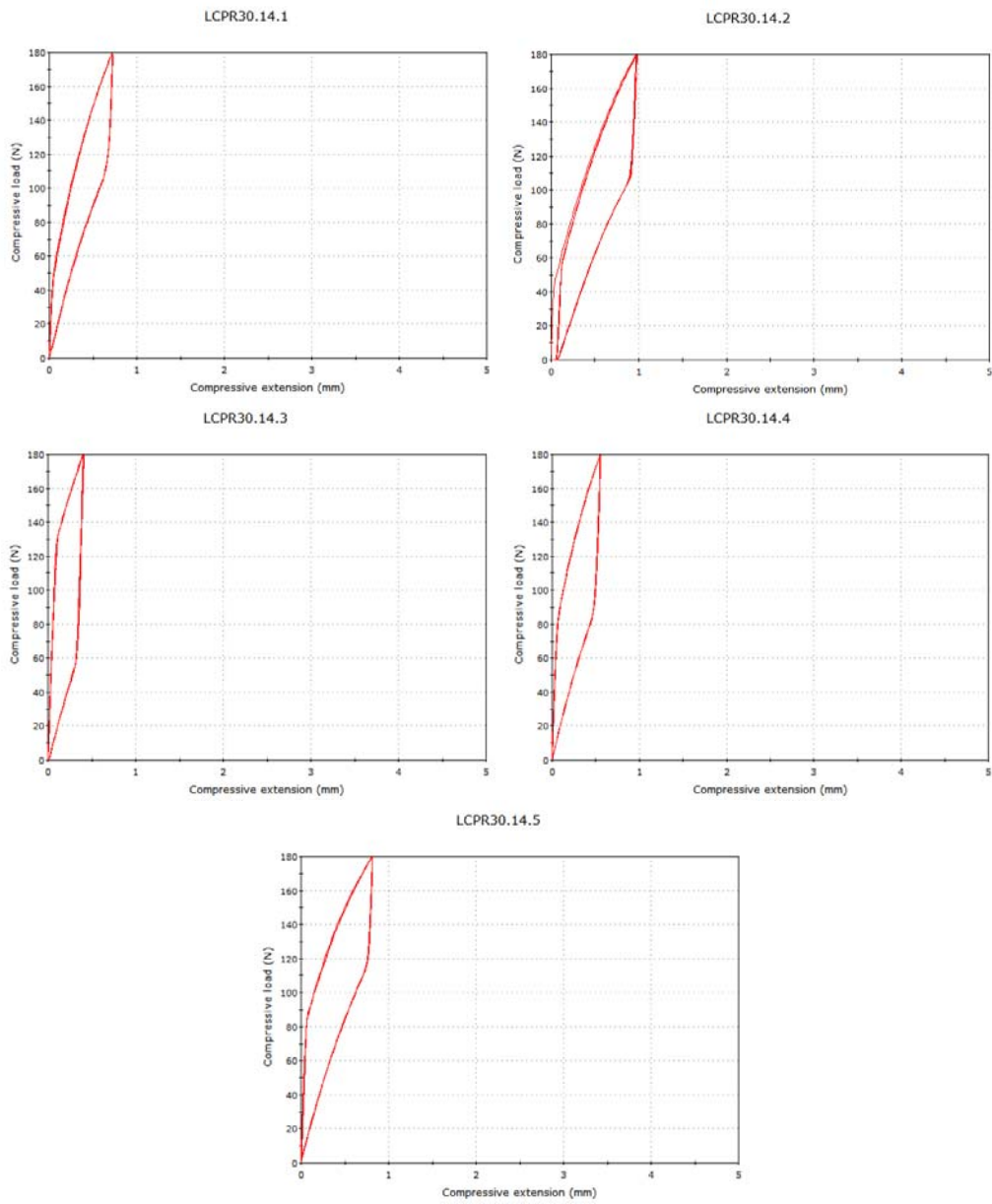
LCPR20.134 (5 replicates)



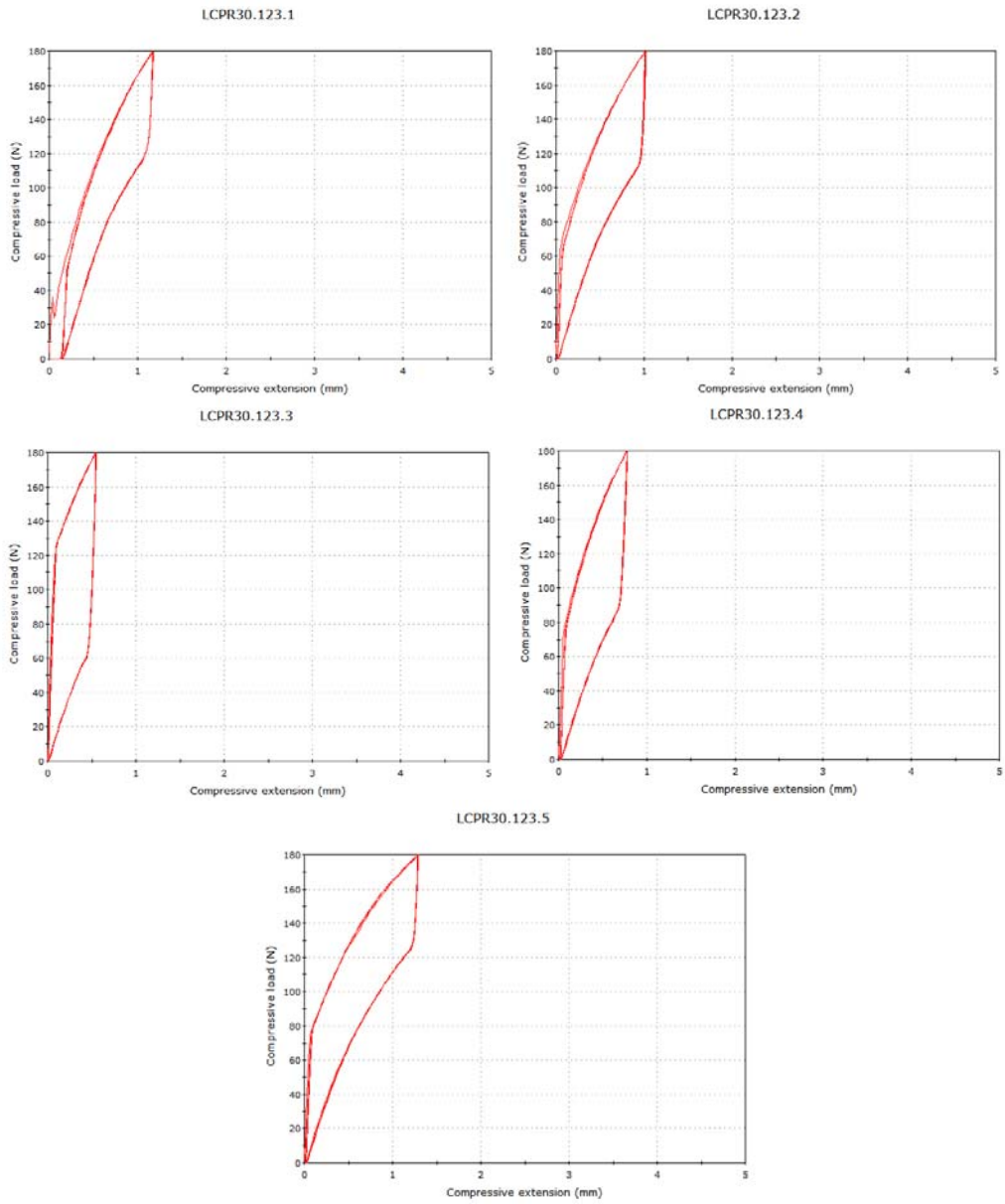
LCPR30.12 (5 replicates)



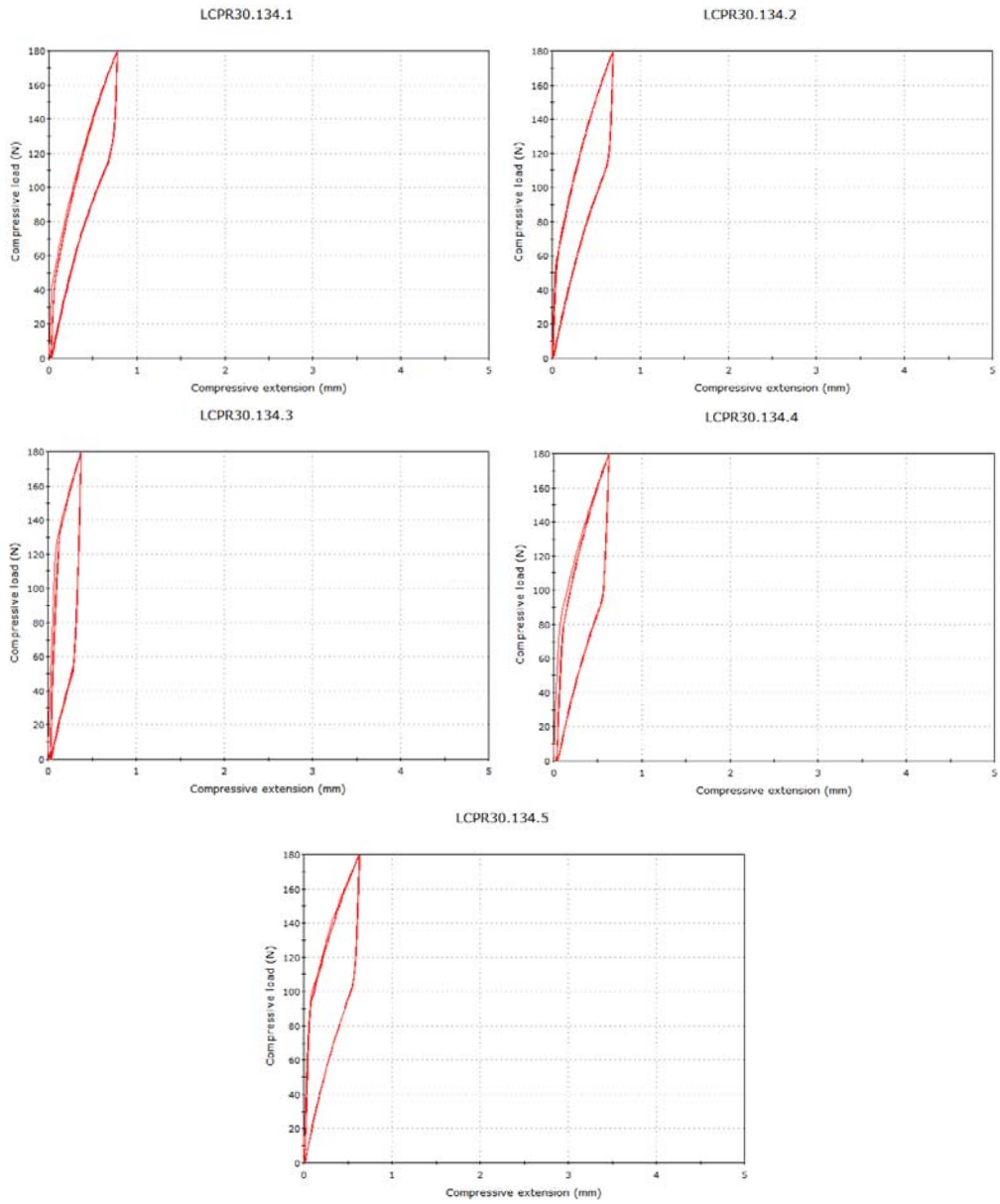
LCPR30.14 (5 replicates)



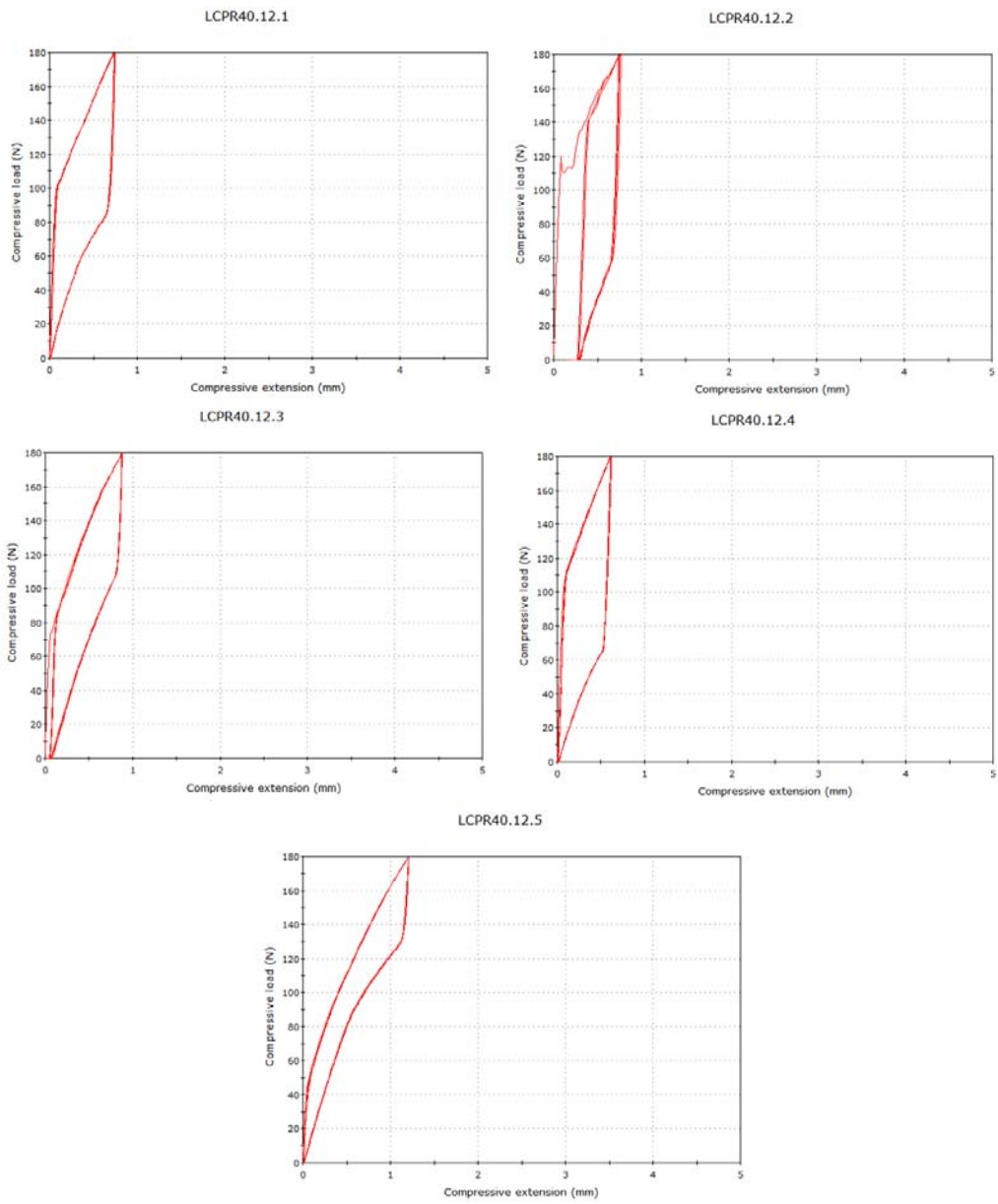
LCPR30.123 (5 replicates)



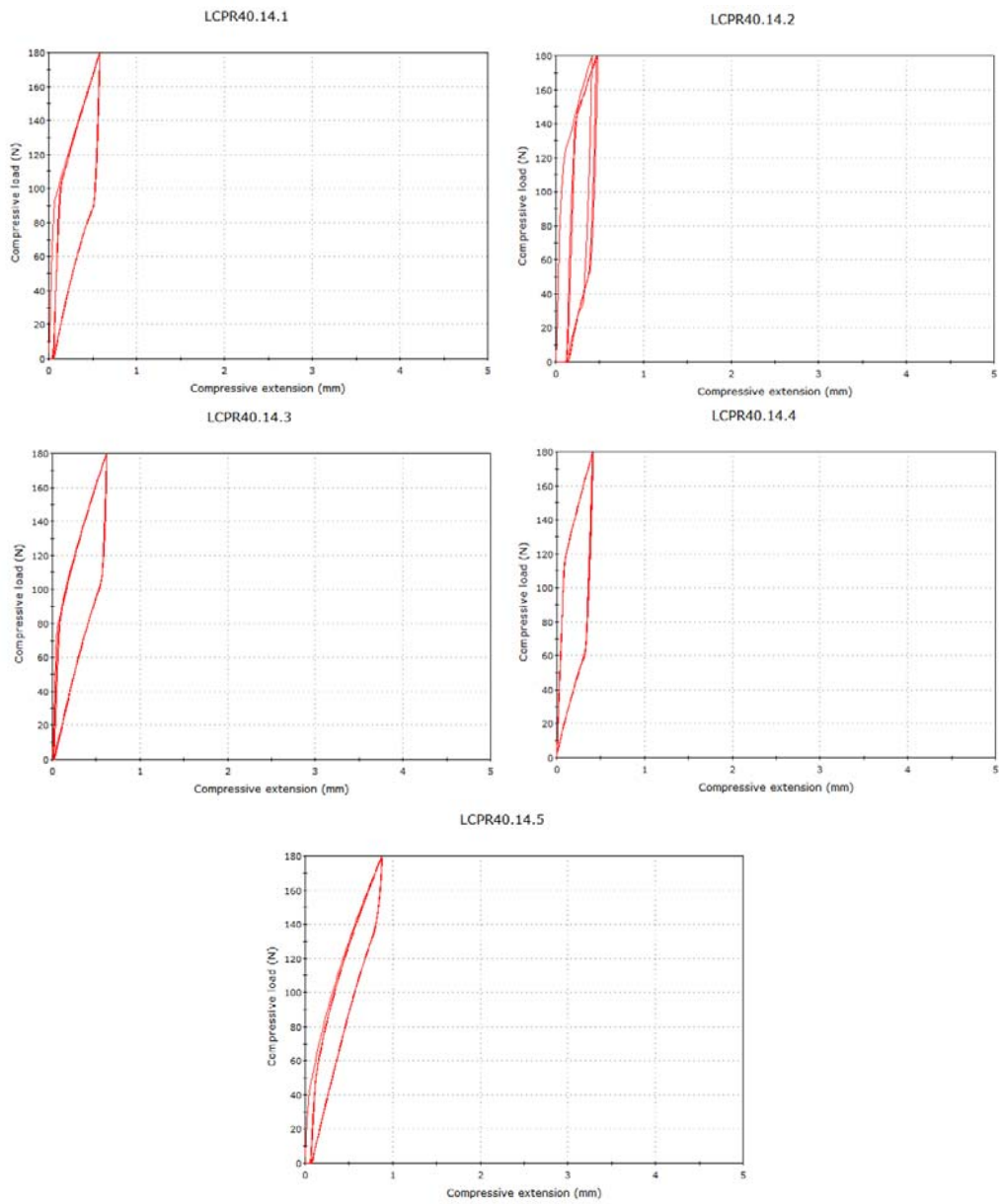
LCPR30.134 (5 replicates)



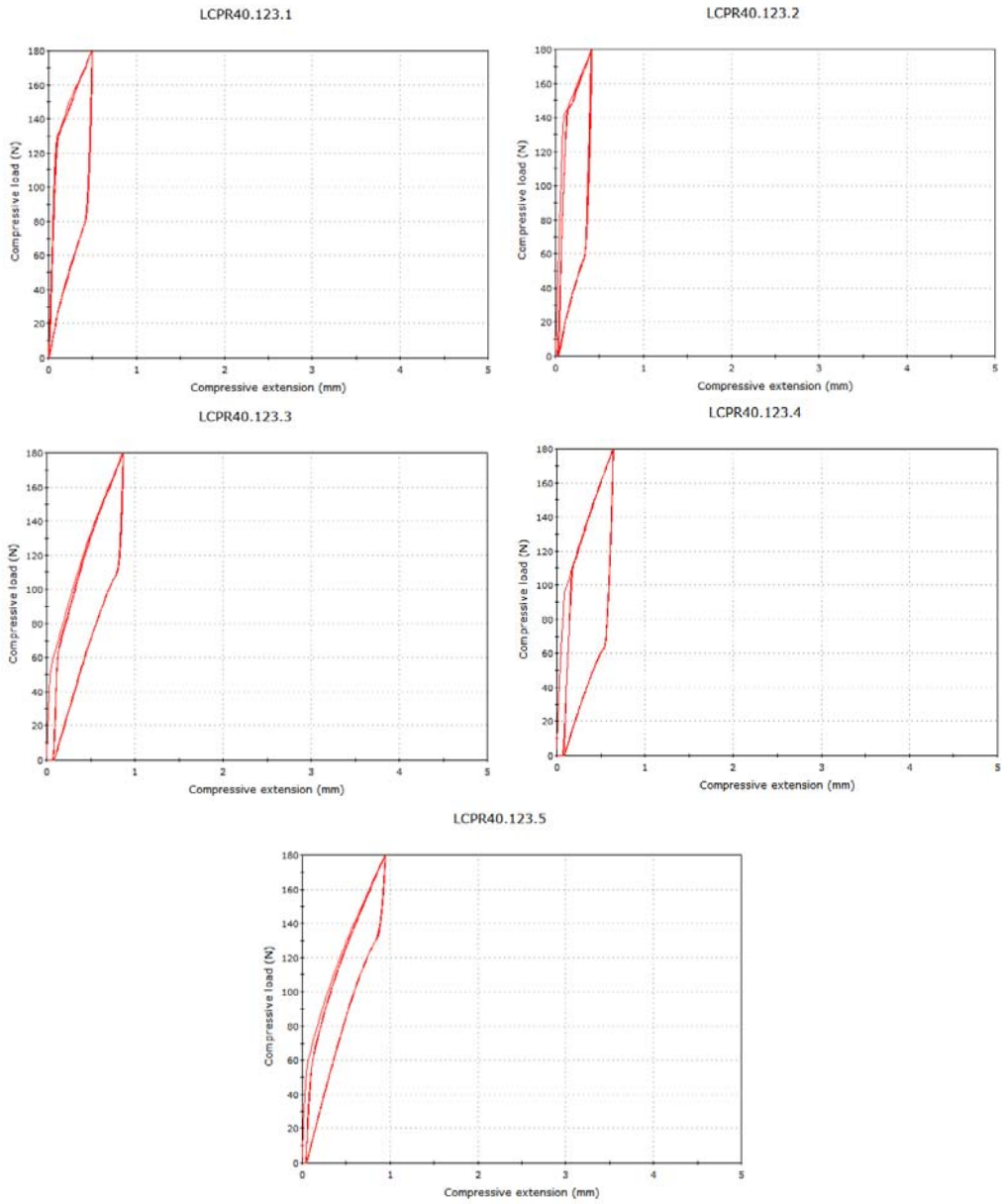
LCPR40.12 (5 replicates)



LCPR40.14 (5 replicates)

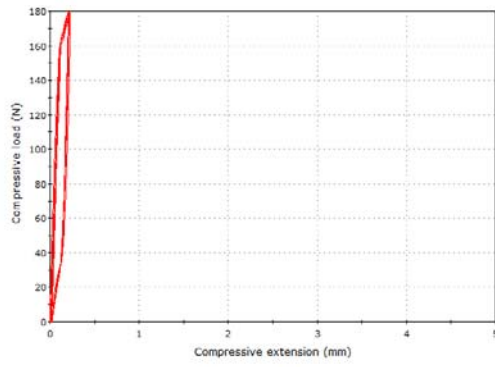


LCPR40.123 (5 replicates)

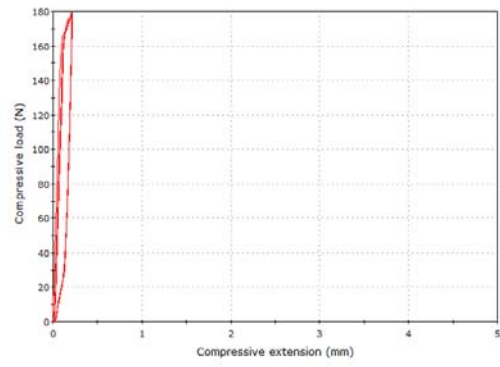


LCPR40.134 (5 replicates)

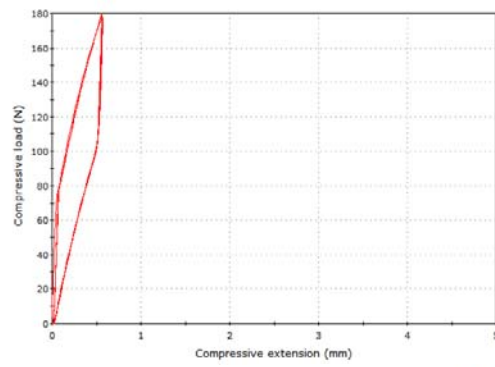
LCPR40.134.1



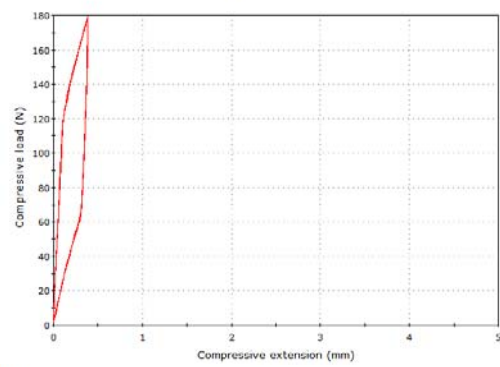
LCPR40.134.2



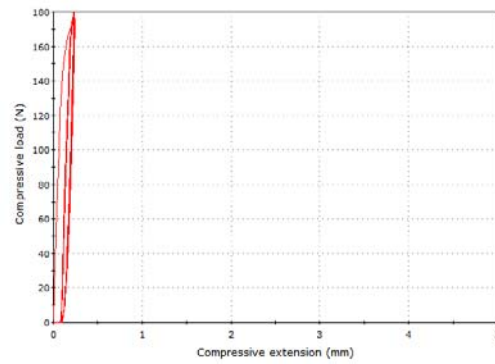
LCPR40.134.3



LCPR40.134.4



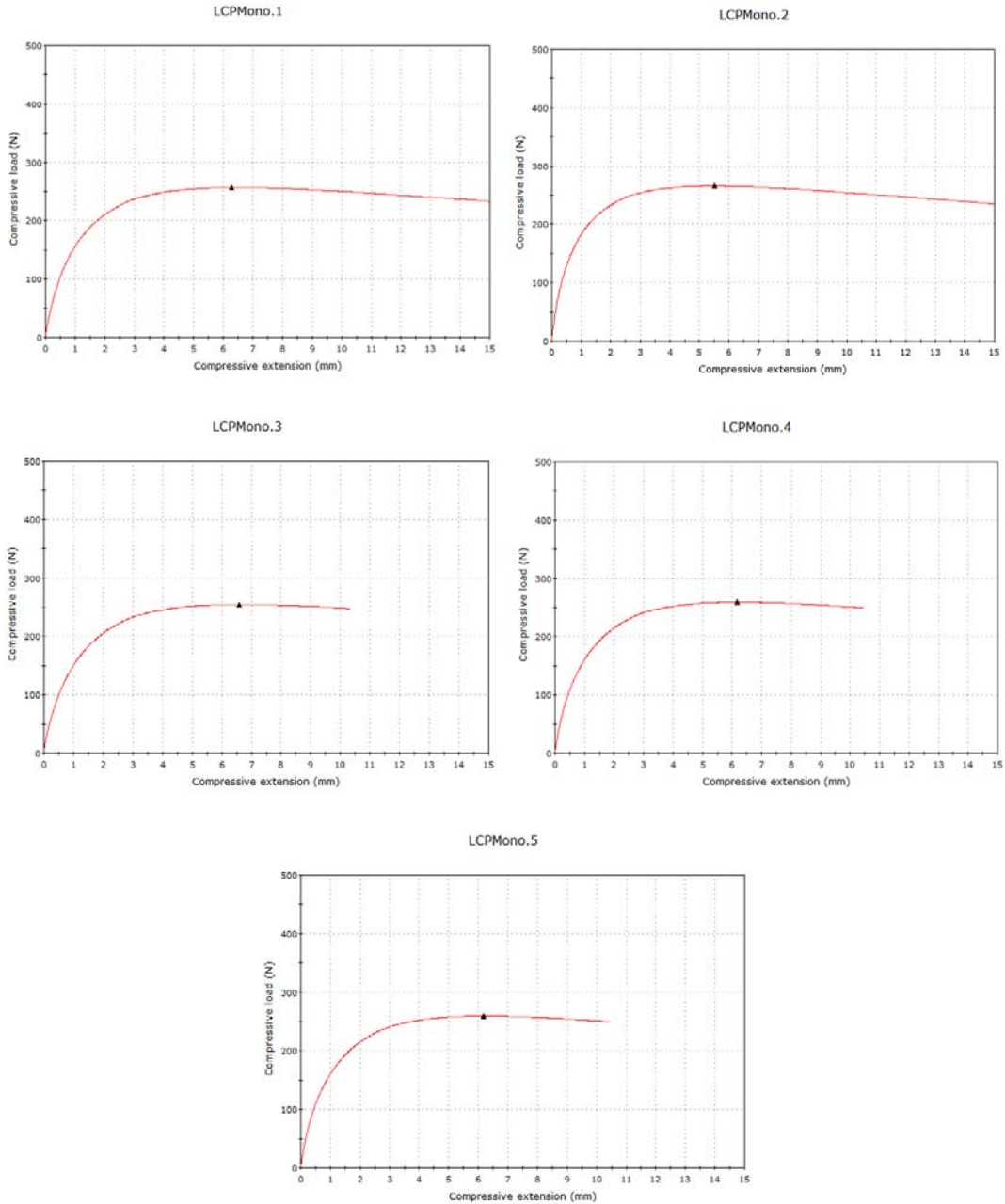
LCPR40.134.5



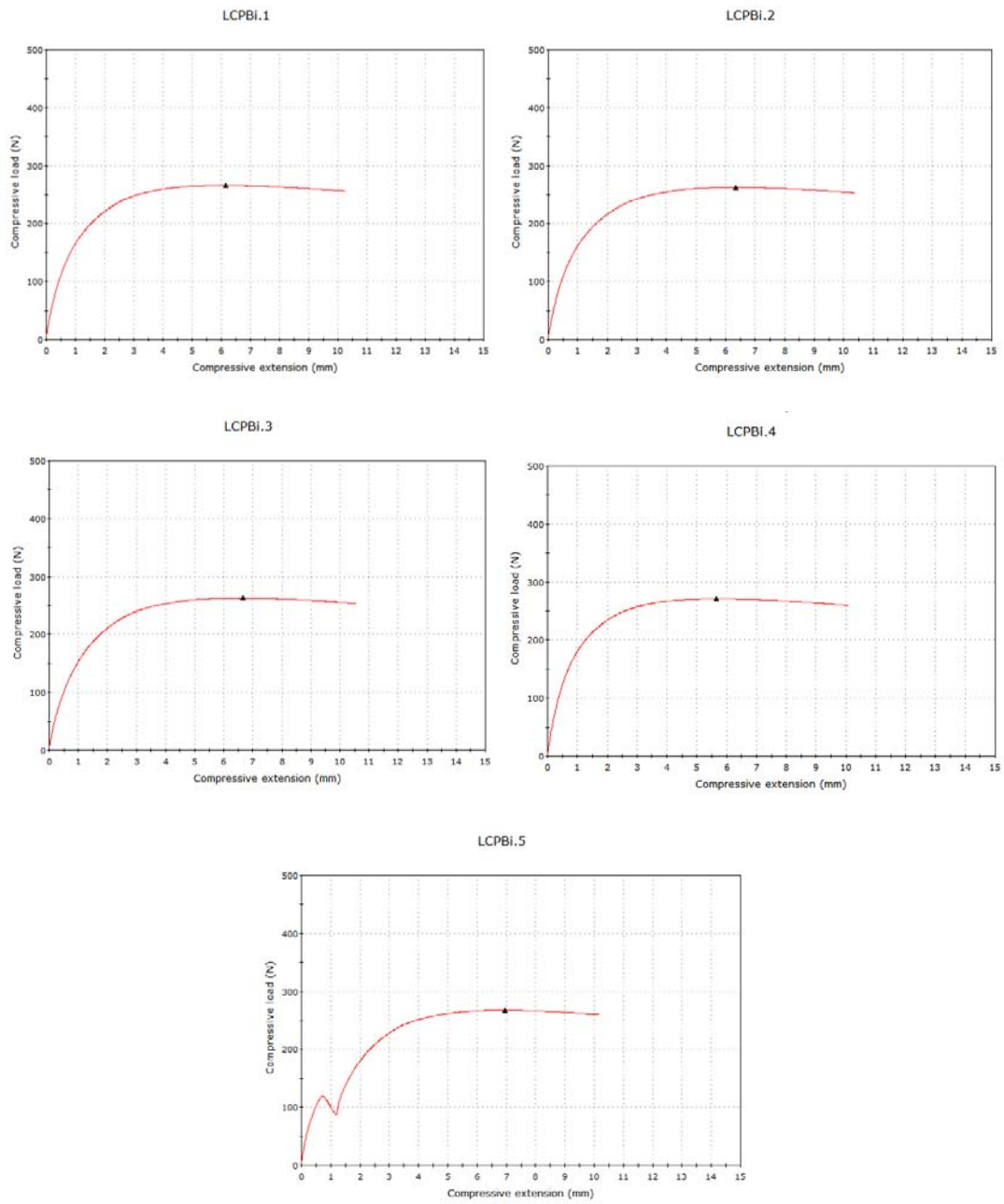
APPENDIX 3: LOAD DEFORMATION CURVES: AXIAL LOAD TO FAILURE

Five different constructs were created; each with 5 replicates, making 25 specimens to be tested. **LCPMono** - LCP with monocortical screws, **LCPBi** - LCP with bicortical screws, **LCPR20** - LCP with monocortical screws + 20% IM pin, **LCPR30** - LCP with monocortical screws + 30% IM pin and **LCPR40** - LCP with monocortical screws + 40% IM pin. Destructive testing was conducted with 3 screws per fragment and the shortest (1.3.4) working length.

LCPMono.134 (5 replicates)

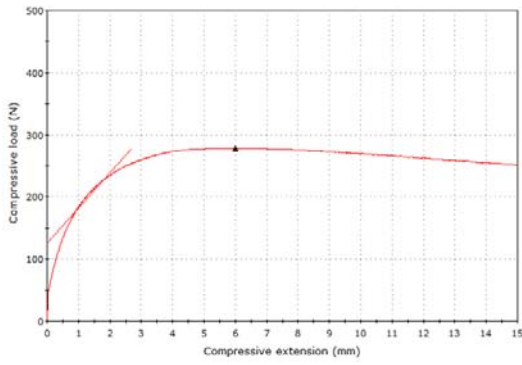


LCPBi.134 (5 replicates)

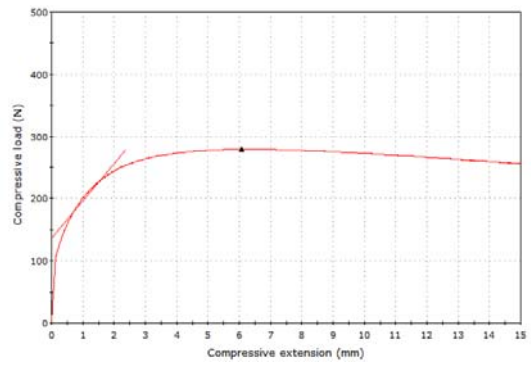


LCPR20.134 (5 replicates)

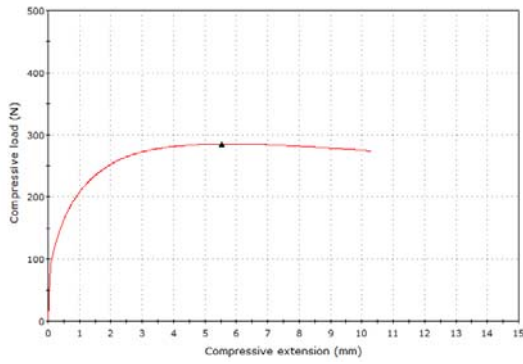
LCPR20.1



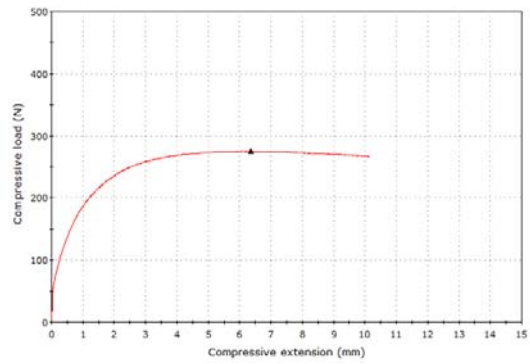
LCPR20.2



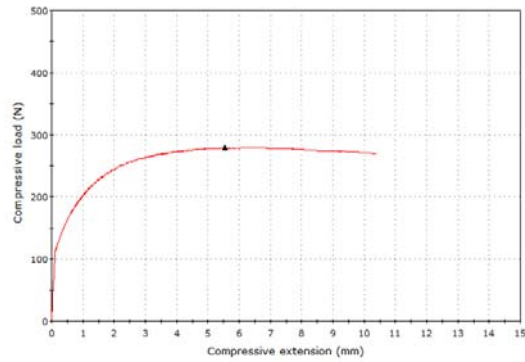
LCPR20.3



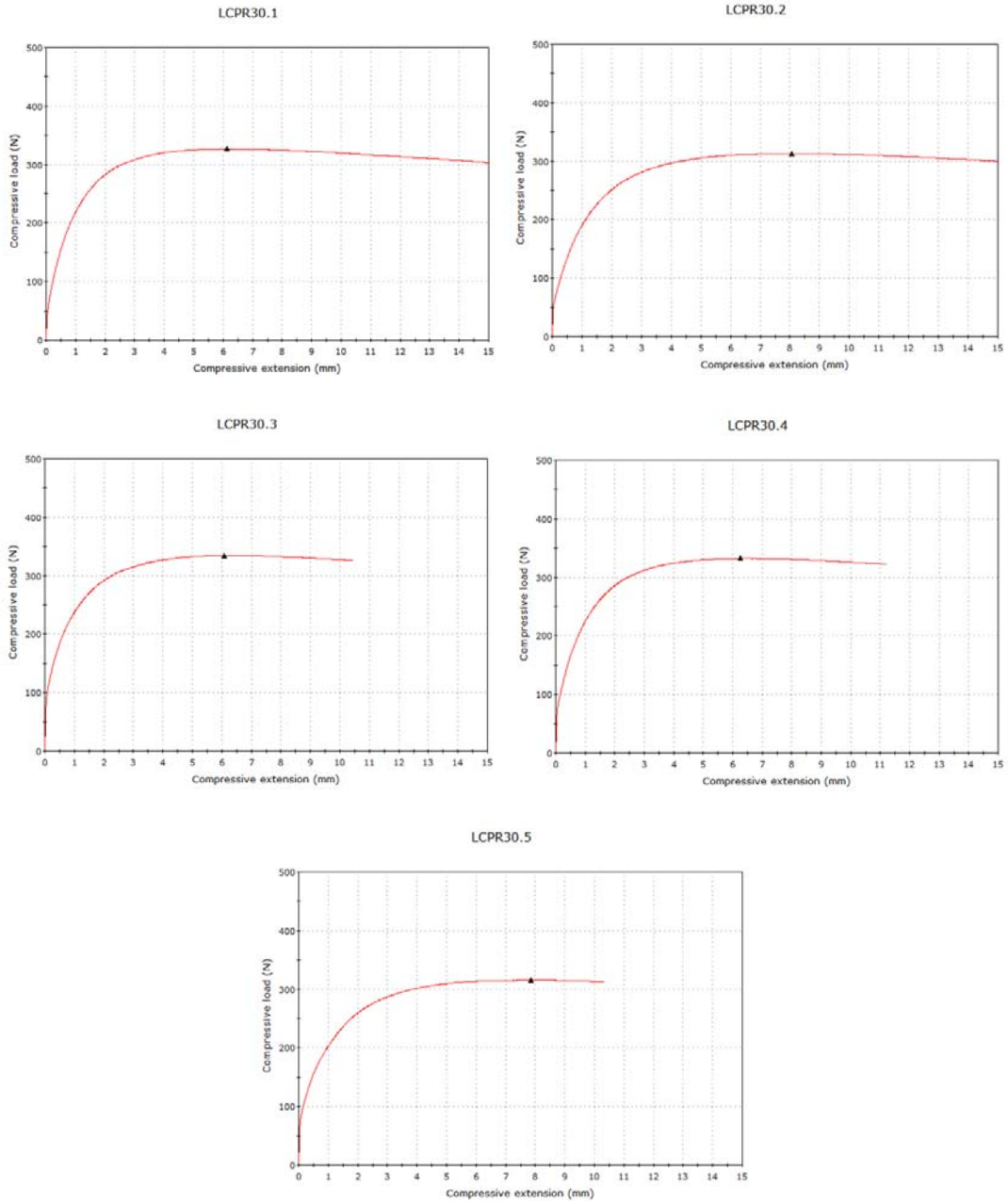
LCPR20.4



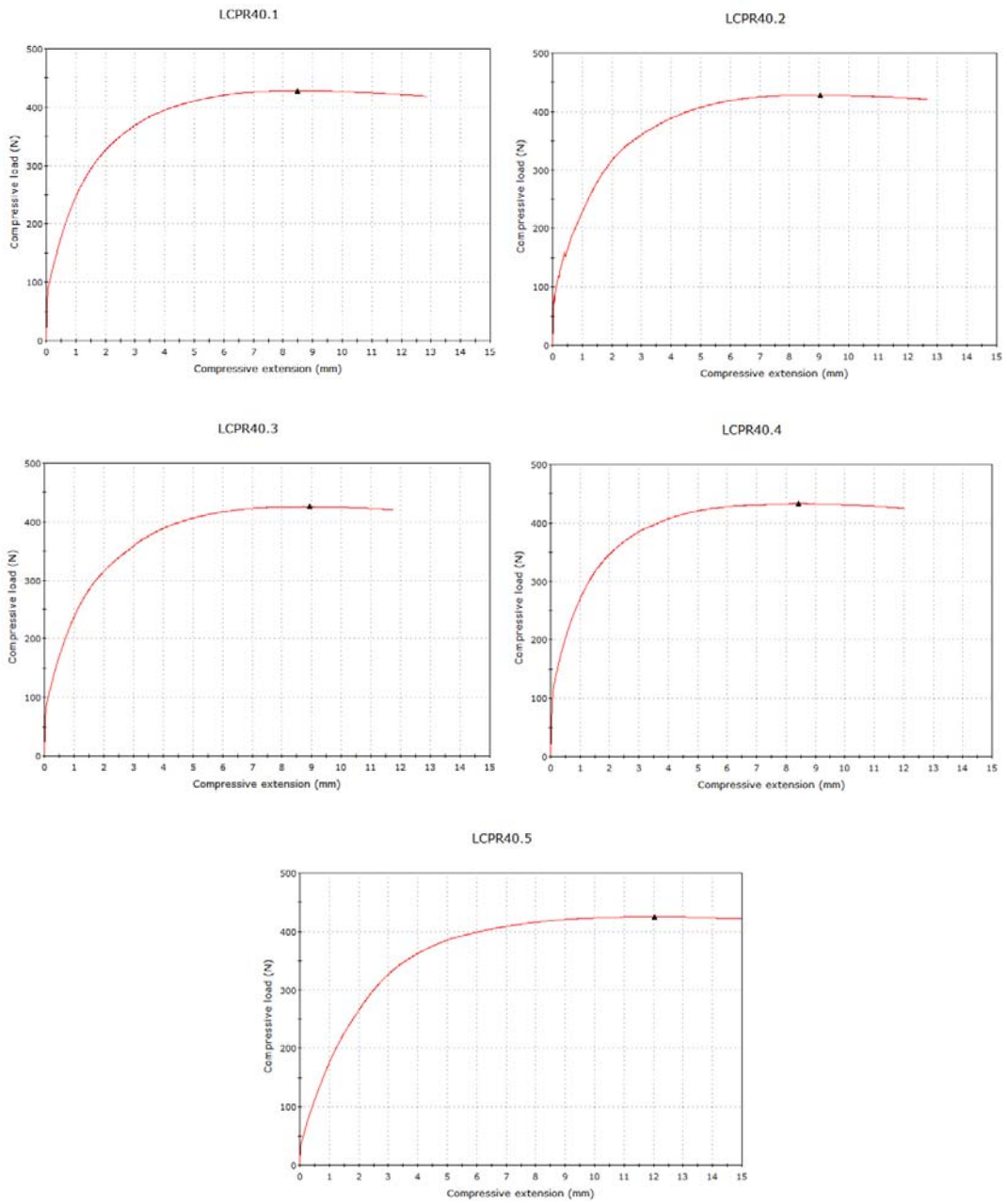
LCPR20.5



LCPR30.134 (5 replicates)



LCPR40.134 (5 replicates)



APPENDIX 4: PLATE STRAIN PLOTS

These plots graph Von Mises strain on the y axis against time (Video frames) on the x axis. A red dot is used to identify peak strain for each of the 3 cycles in each test. An average of these peaks were averaged using computer software to arrive at the raw data for statistical comparison between constructs.

Five different constructs were created; each with 5 replicates, making 25 specimens to be tested:

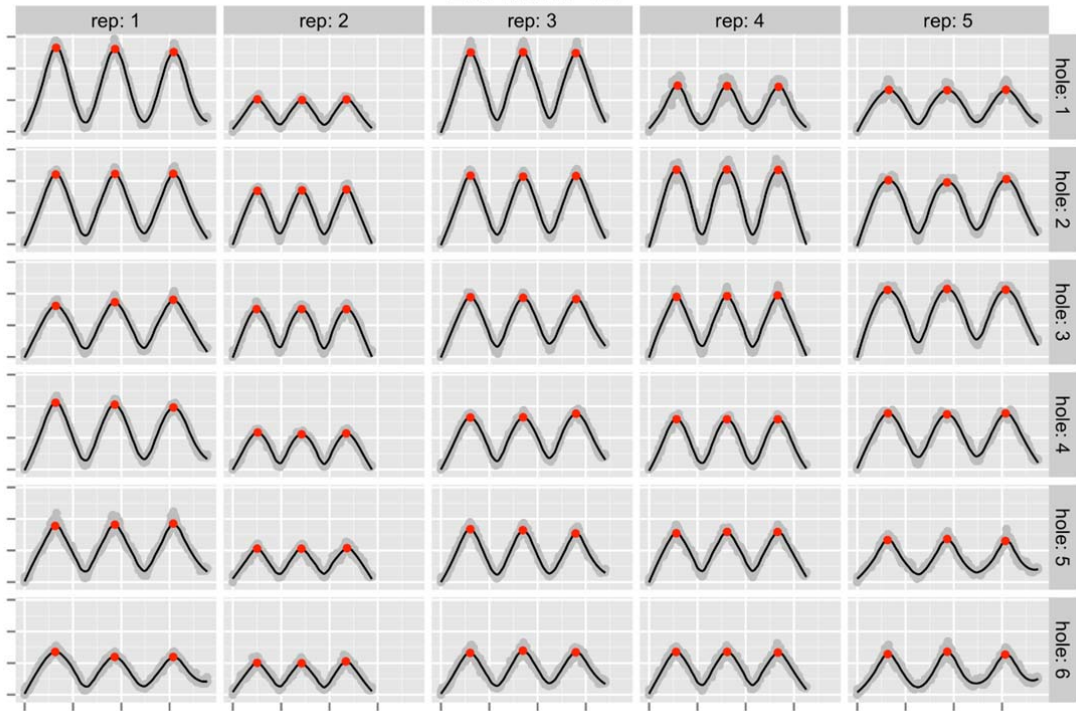
- **LCPMono** - LCP with monocortical screws
- **LCPBi** - LCP with bicortical screws
- **Mono20** - LCP with monocortical screws + 20% IM pin
- **Mono30** - LCP with monocortical screws + 30% IM pin
- **Mono40** - LCP with monocortical screws + 40% IM pin

Two screw configurations were tested:

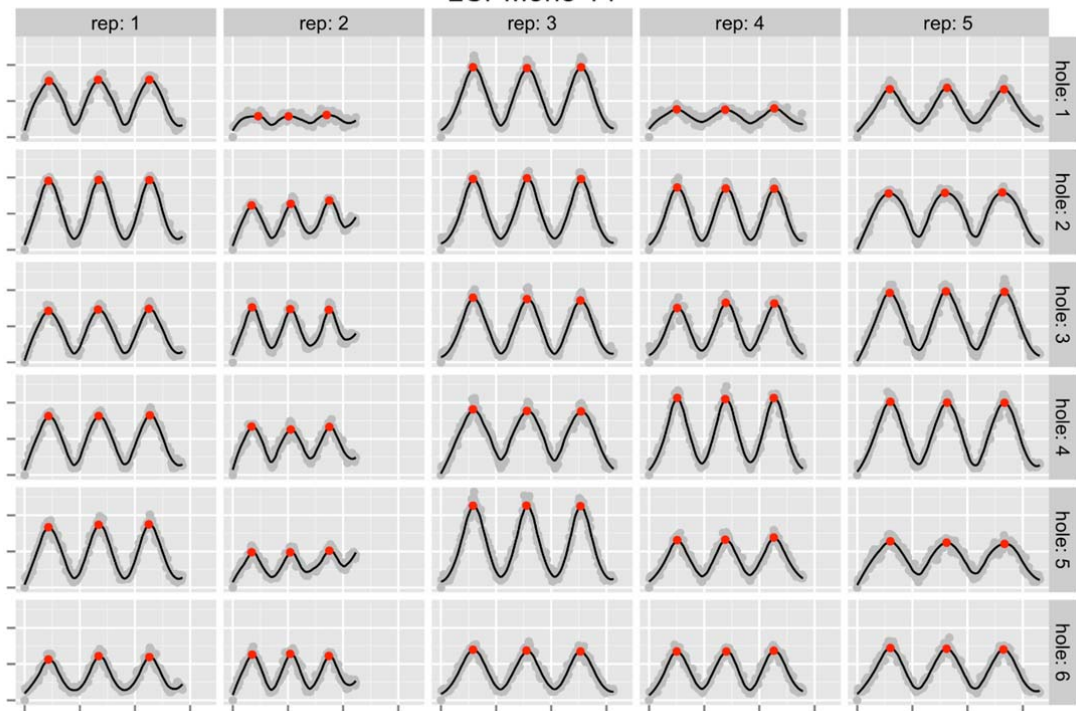
- screws at holes 1 and 2 modelling the long working length (1.2)
- screws at holes 1 and 4 modelling the short working length (1.4)

Six regions on the plate were chosen for measurement of plate strain corresponding to the segment of the plate between each screw hole with region 6 being the centre of the plate (Hole 1 to 6).

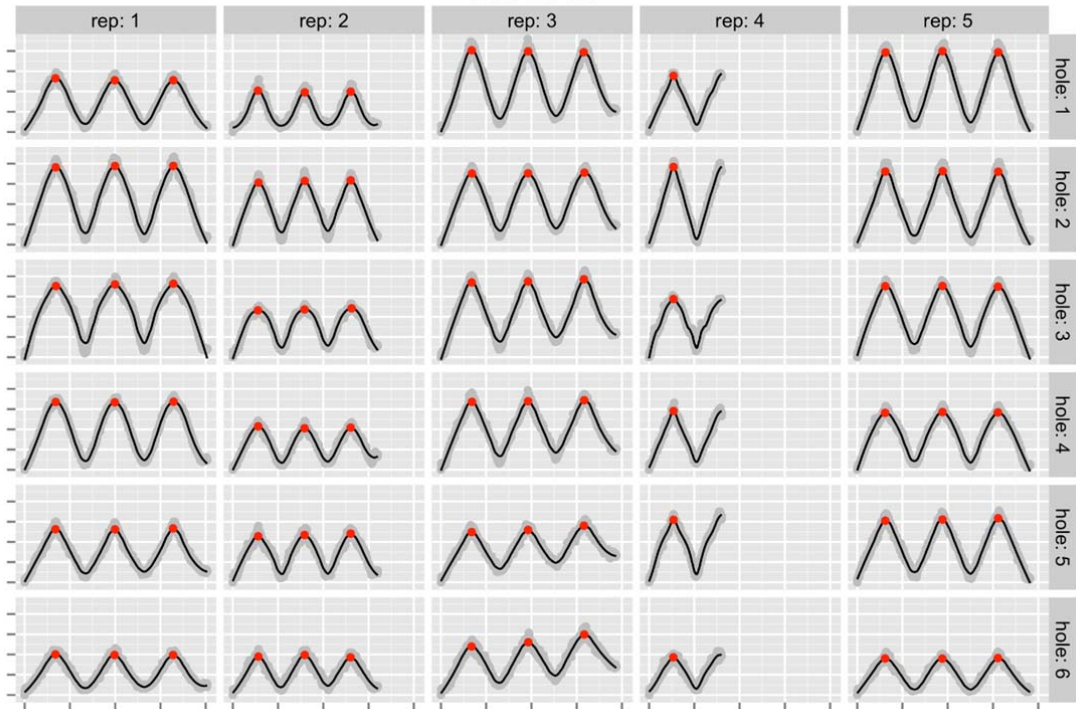
LCPMono 12



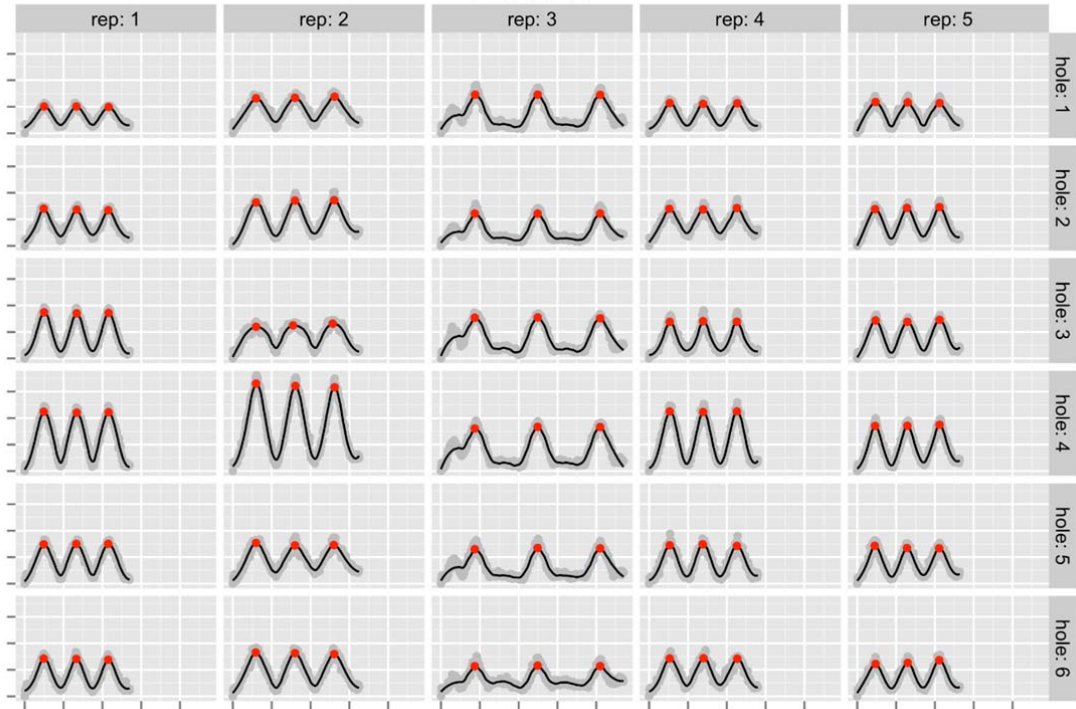
LCPMono 14



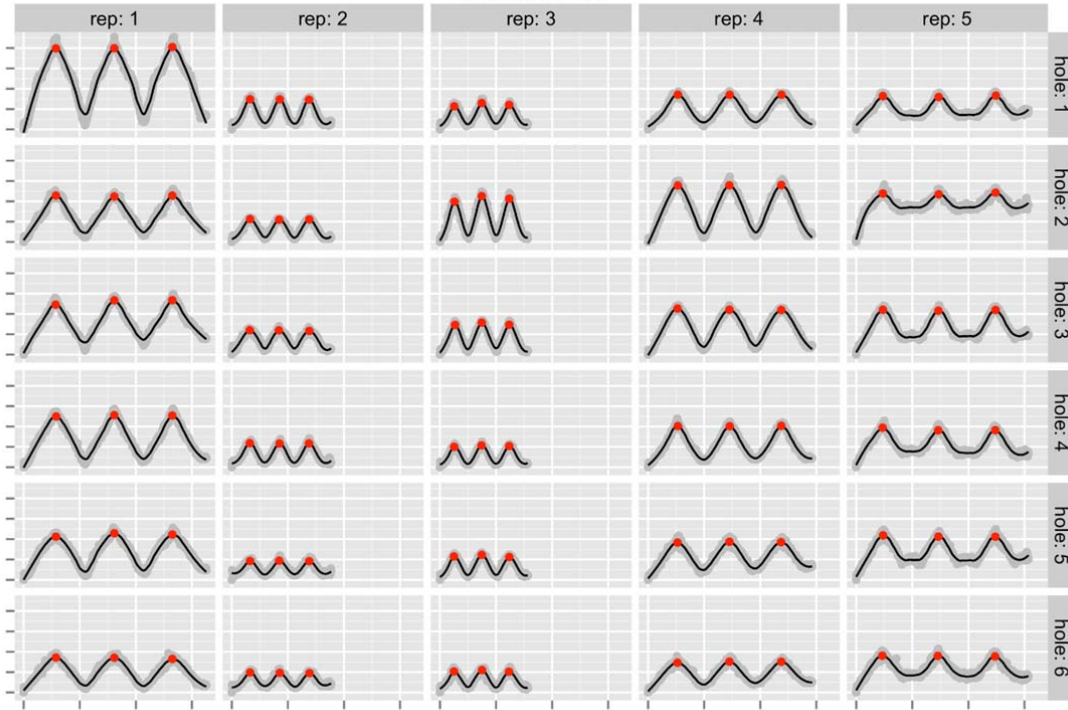
LCPBi 12



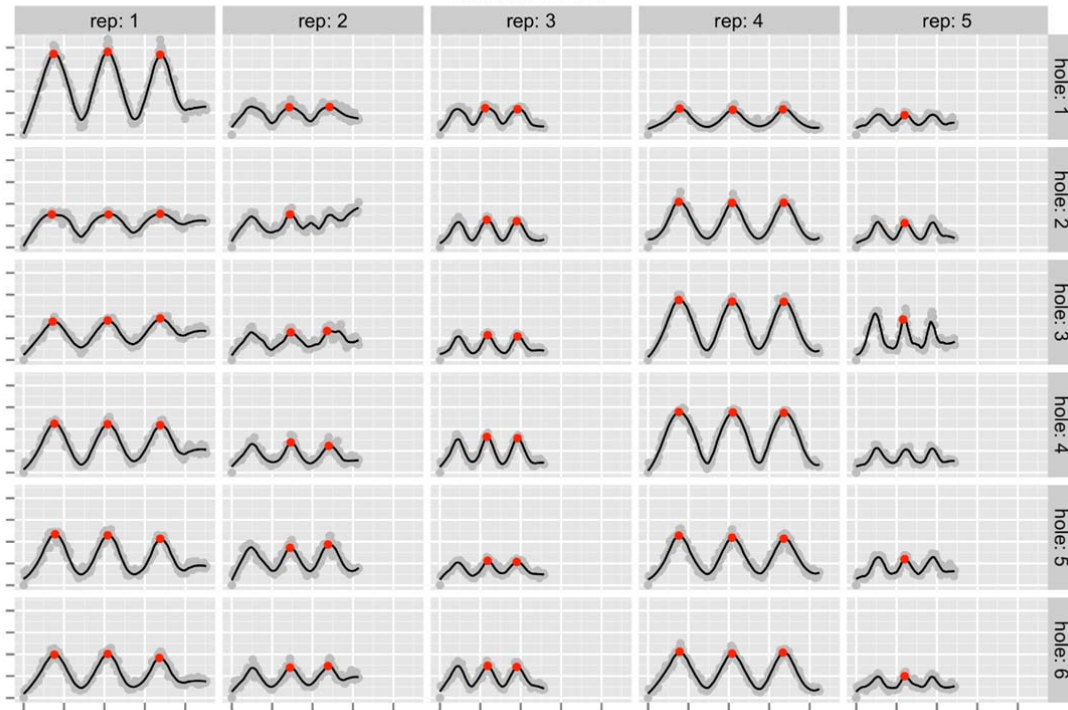
LCPBi 14



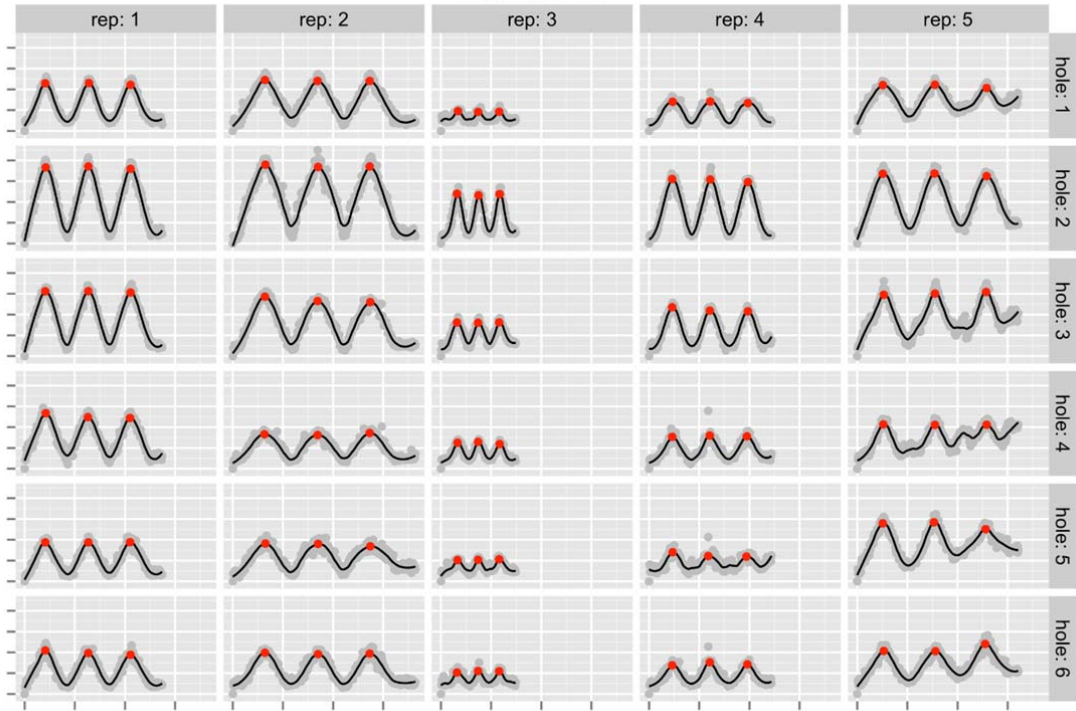
Mono20 12



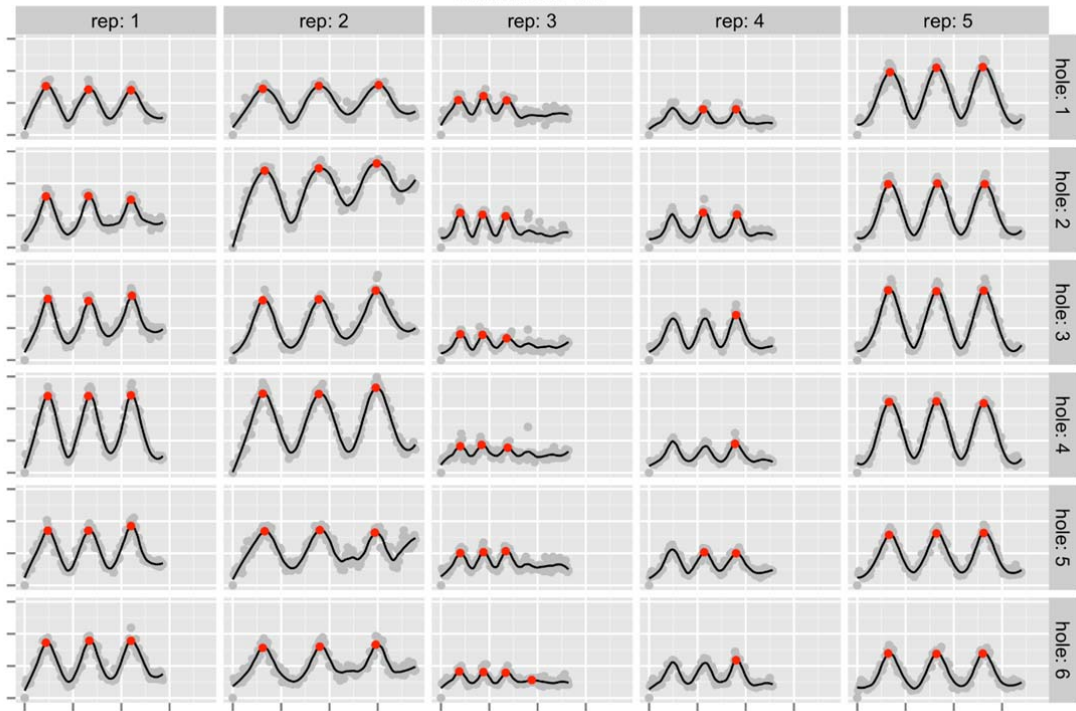
Mono20 14



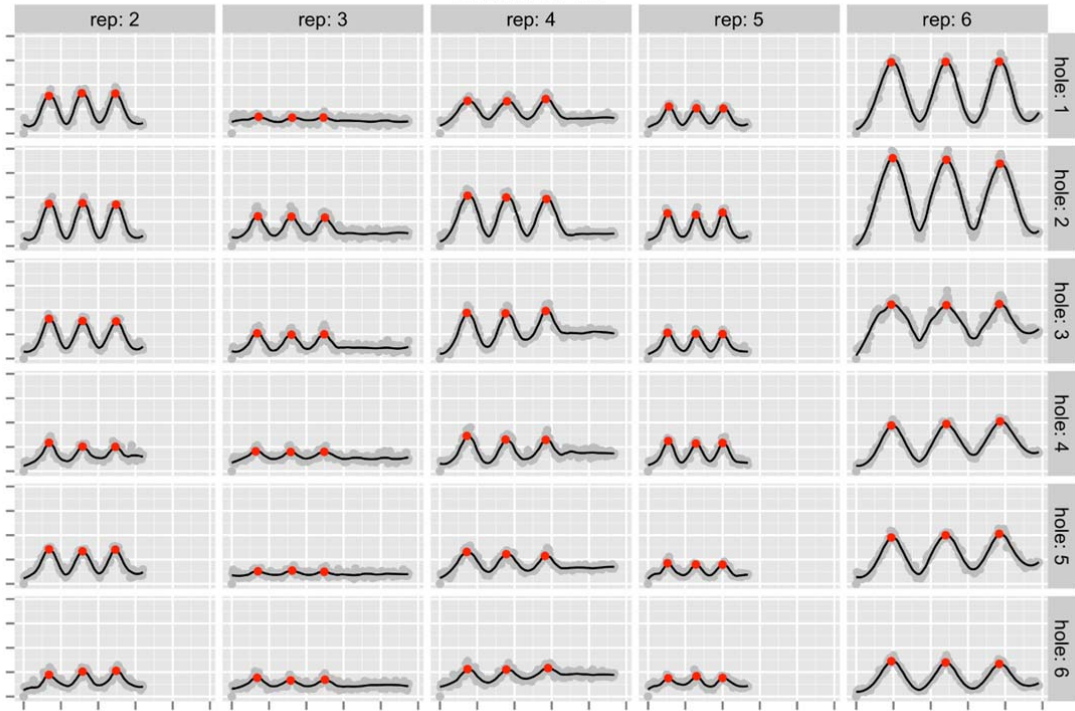
Mono30 12



Mono30 14



Mono40 12



Mono40 14

