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Abstract

Extramedullary devices that use screws, pins or wires are used extensively to treat fractures in normal and diseased bone. A common failure mode is implant loosening at the bone-screw/pin/wire interface before fracture healing occurs. This review first considers the fundamental mechanics of the bone-fixator construct with focus on interfacial strains that result in loosening. It then evaluates the time-independent and time-dependent material models of bone that have been used to simulate and predict loosening. It is shown that the recently developed time-dependent models are capable of predicting loosening due to cyclic loads in bone of varying quality.

Key words: locking plates; unilateral fixators; ring fixators; time-dependent behaviour; cyclic loading; inter-fragmentary motion; plasticity and viscoplasticity

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1 Introduction

Extramedullary devices that use screws, pins or wires are used extensively to treat fractures in normal and diseased bone. These devices carry most of the load, particularly in cases where there is a fracture gap, before callus formation occurs. The load is transmitted from the bone-screw/pin/wire interface to the plate or an external frame. It has been well documented that these devices need to fulfil three clinical requirements [1,2]: (a) they must support fracture healing; (b) they must not fail during the healing period; and (c) they should not loosen or cause patient discomfort. Requirement (a) depends on the stiffness of the bone fixator construct and the load applied by the patient, which determine the relative movement between fractured fragments or interfragmentary motion (IFM). Requirement (b) relates to stresses within the implant and potential failure before healing occurs. Strains at the bone-screw/pin/wire interface should not be too high to ensure that requirement (c) is met.

There have been a number of studies that have considered requirements (a) and (b) [3–10] and shown that fulfilment of these depends on factors such as fracture location, device used and its configuration (e.g. where the screws are placed in a locking plate or how much tension is applied to the wires in ring fixators). Interestingly it has been found that device stiffness (or resulting IFM) and stresses within the device are not strongly effected by bone quality [3–5,11]. In other words, if the aim of a biomechanical study is to determine IFM alone then bone quality does not have a significant role to play. Whereas, loosening at the bone-implant interface strongly depends on bone quality in addition to the factors that influence IFM [3,4].

Loosening is reported frequently as a complication in implant usage and some previous studies have noted that mechanical forces initiate it before any contribution from biological processes [12]. Since biomechanical prediction of loosening requires modelling the complex bone material, it is much more complicated; consequently, influence of bone properties to examine mechanical environment at interface has received relatively little attention [3,4,11].

The first aim of this review is to present the fundamental mechanics of the bone-fixator construct with focus on interfacial strains that result in loosening. The second aim is to consider the constitutive material models of bone used to predict loosening, in particular recently developed novel time-dependent models that are capable of predicting loosening due to cyclic loads [13–15]. While most discussion presented is in the context of extramedullary devices such as locking plates, unilateral fixators and Ilizarov rings, many of the concepts presented are equally applicable to other fixation devices.

2 The mechanics of extramedullary devices

2.1 Interfragmentary motion and stresses in the implant

We first consider the mechanics of extramedullary devices. Figure 1a shows a bone-locking plate construct, the mechanics of which is not too dissimilar to unilateral fixators. A number of biomechanical responses arise due to the application of load P (due to partial or full load bearing by the patient). Firstly load bearing causes interfragmentary motion (IFM) between the fractured fragments (Figure 1b) which is known to aid callus formation [16,17] – too much or too little inhibits fracture healing [2]. IFM can vary across the thickness of the bone; for example from Figure 1a and

1b it can be seen that the largest IFM is at the far cortex and given by x-x'. Secondly the plate and screws experience bending causing stresses within the implant. The amount of bending and IFM depend on factors such as dimensions and materials of the locking plate, bone-plate offset, load applied and the manner in which bone experiences load and screw configuration particularly the working length (also known as the bridging span and defined as the distance between the two innermost screws on either side of the fracture). In cases with a fracture gap, higher working length results in larger plate stresses (primarily in the plate portion bridging the fracture) and larger IFM [2,4]. Some studies have incorrectly reported larger stresses with shorter working lengths [18], but the reasons for this erroneous interpretation have been discussed in Macleod and Pankaj [2]. Plate bending also results in pull-out and push-in forces as shown in Figure 1b; these have been previously discussed in the context of unilateral fixators [11]. As the applied load increases the lever arm d (Figure 1a) increases to $\Delta > d$ (Figure 1b) which increases the bending forces even further. In engineering mechanics this is often referred to as P - Δ effect and causes the relationship between load and IFM to become nonlinear [19]. Nonlinear load-displacement behaviour also arises in Ilizarov fixators (Figure 2a) due to sagging wires [3]. Studies on locking plates [4], unilateral fixators [5,11] and Ilizarov fixators [3] have shown that bone quality has a relatively small influence on IFM and implant stresses.

2.2 The mechanics of loosening

Let us now consider strains at the bone-screw interface due to forces along the axis of the bone (as shown in Figures 1a and 2a); these strains are responsible for loosening, which is the primary focus of this review. It is important to note that we deliberately employ the response parameter strain rather than stress for three reasons. Firstly it is now well recognised that bone fails due to strain rather than stress [20]. Secondly, failure strain does not vary significantly with bone quality or its anisotropy (this is further discussed later in this review). Lastly, while stresses have peak values beyond which they cannot rise due to yielding/failure, strains can continue to increase. Typical large strain regions for locking plates are shown in Figure 1c and for Ilizarov fixators in Figure 2b. It has been shown that the maximum bone strains at the interface of the screw/pin/wire closest to the fracture (e.g. screws 2 and 3 rather than screws 1 and 4 in Figure 1a) [3–5,11,21]. For locking plates and unilateral fixators the strains are the largest at the periosteum of the near cortex and progress towards the endosteum with increasing load [11]. The volume of bone that goes beyond the yield level increases considerably with poor bone quality [3,11]. The pattern of bone yielding is different between unilateral and Ilizarov fixators. For unilateral fixators and locking plates bone yielding can progress through the full cortex as shown in Figure 1c for screw 2, where bone superior to the screw experiences large strains. If the depth of yielded bone is greater than thread height, then loosening can be initiated due to loss of screw thread purchase. For Ilizarov fixators, on the other hand, bone yield remains concentrated separately at the periosteum and endosteum, superior and inferior to the wire, respectively [3] as shown in Figure 2b. This is a possible reason for Ilizarov wires being associated with lower rates of loosening than half pins [22,23].

It has also been shown that reduced stiffness (or increased flexibility) of the bone fixator construct, which increases IFM, also results in larger interfacial strains [3,4,11]. Flexibility can be increased by using materials with lower elastic modulus (e.g. titanium rather than steel), smaller plate or screw dimensions, larger working length or in case of Ilizarov fixators smaller wire tensions. So flexibility is detrimental from the point of view of large strains at the interface but it may result in an IFM that causes faster healing before any ill effects of high interfacial strains come to the fore. Thus need for maintaining adequate IFM needs to be balanced with the risk of loosening. It is also important to note that compressive and tensile strains often occur simultaneously as shown in Figure 1d for the near cortex of screw 2. In this case compressive strains due to screw pushing up in the radial direction are accompanied by tensile strains in the circumferential direction due to screw hole being enlarged.

Figure 1

It is also important to note that drilling (prior to screw insertion) causes interfacial damage which has been estimated to extend up to 300 µm around the circumference [24]. Moreover, large interfacial strains also result from an interference fit when the drilled pilot hole has a smaller diameter than the screw being inserted [19].

Figure 2

Push-in and pull-out forces discussed in the context of unilateral fixators and locking plates can cause loosening which is resisted by screw threads. It has been shown that the bone at the interface of the first thread from the screw entrance carries the largest load [6] and this load carrying demand decreases for screws deeper inside the bone. As bone is not homogeneous, local microarchitecture can play an important role in determining whether the device may become loose [25].

3 Material models of bone to predict loosening

As discussed above bone quality (varying from healthy to osteoporotic) plays a major role in the distribution of strains at the bone-screw/pin/wire interface. In order to predict loosening using principles of biomechanics it is important to use appropriate material models of bone. The most commonly used mechanical models of bone are time-independent i.e. they assume that any deformation due to loading occurs instantaneously. Almost all research on bone-implant systems assumes bone behaviour to be time-independent [26] though it is well recognised that bone deformation on load application increases with time or is time-dependent [13–15,27,28] In the following sections we first discuss time-independent models that have been employed to examine loosening; these include use of elasticity and elastoplasticity. We then go on to consider time-dependent models that have been recently developed by the authors and employed to evaluate fixator loosening.

3.1 Modelling bone as an elastic material

In computational biomechanics the most common assumption for modelling bone is that it is linear, isotropic and elastic. The term elastic implies that any deformation experienced by the material on application of forces is fully recovered when the forces are removed. Addition of the term linear means that the mechanical response (e.g. deformation) is proportional to the load applied and isotropic material is one which has the same mechanical properties in all directions and requires two elastic constants to relate stresses to strains (e.g. Young's modulus and Poisson's ratio). In most computational studies with generic bone geometries it is a common practice to further assume that the material is homogeneous (i.e. properties do not vary from point to point), though distinctly different regions (e.g. cortical and trabecular) may be assigned different properties [29]. In subject-specific studies for which CT data is available inhomogeneous material properties are often assigned [30,31] by empirically converting CT attenuations to Young's modulus. It is arguable as to whether answers obtained from subject- or patient-specific models have a limited applicability and whether generic or "average" models are more suitable for answering general questions.

While the assumption of isotropy serves well for many biomechanical studies, it is well recognised that both cortical and cancellous bone are better represented by orthotropic or transtropic elasticity [32] requiring many more properties for relating stresses to strains. Materials that are not isotropic do not have the same properties in all directions. For example, orthotropic materials have three orthogonal planes of elastic symmetry and stress-strain relations are defined by using 9 elastic constants. Orthotropic properties of bone have been determined using experimental [33] and numerical approaches [34,35].

In computational modelling to evaluate loosening of fracture fixation systems two questions arise. The first is whether an isotropic bone model is adequate for obtaining reasonable answers and the second is whether elasticity can be used to predict loosening. Let us consider each of these questions in turn.

To our knowledge there have been no studies that have compared isotropic and anisotropic models in fracture fixation studies. It can be argued that the use of orthotropic material properties increases the complexity of the model, and if these are not accurately assigned, they may introduce more prediction errors than a simple assumption of isotropy. However, Young's moduli for both cortical and cancellous bones in one principal orthotropic direction can be around three times the other direction [35]. Therefore, same force acting in one direction will cause much larger strains than in the other. Donaldson et al. [35] showed that in the femoral mid-shaft the elastic modulus of cortical bone in the proximal-distal direction was not only higher than that for endosteum-periosteum direction but also decreased less rapidly with age i.e. bone became more anisotropic with age. Considering this finding in conjunction with the mechanics of unilateral and locking plate fixation in which axial loading of bone is accompanied by pull-out and push-in forces it can be concluded that half-pin or screws apply forces in the direction least adapted to loading, and therefore most at risk of failure in patients with osteoporosis [11].

Let us now consider use of elasticity in the estimation of loosening. It has been suggested that loosening is caused by large irreversible strains at the bone implant interface that enlarge the screw/pin/wire hole [3,11]. Since elasticity implies that deformations are recovered on load removal it is argued that it cannot be used to model loosening. However, researchers often use elasticity wherein they assume a threshold output variable (e.g. yield strain in compression) and evaluate the volume of material that exceeds this threshold value, which is then taken as an estimate of the volume susceptible to yielding [4,36,37]. In reality, when a small region bone goes beyond its yield limit and cannot carry additional loads, considerable redistribution of stresses occurs resulting in the yield region becoming localised; these phenomena cannot be captured by elasticity. In spite of this shortcoming, it has been shown that in the case of hip screws prediction of regions likely to yield using elasticity are similar to those obtained from more complex models [38]. MacLeod et al. [4] used orthotropic elasticity with equivalent strain threshold to examine screw placement to reduce loosening risk in locked plating. They found that the use of titanium in comparison to steel increased the volume of bone exceeding the threshold; results similar to those obtained with plasticity models [11]. MacLeod et al. [4] also showed that larger working lengths increase the predicted volumes of bone above the threshold (Figure 3). Therefore, simple elastic models can be successfully used to, at least, ascertain trends, though they are unable to predict propagation of yielding or damage.

Figure 3

3.2 Modelling bone as an elastoplastic material

It has been shown that load bearing causes strains at the bone-screw/pin/wire interface that are larger than the elastic limit for bone [3,11] resulting in irreversible deformations and these are responsible for loosening. Simulation of this irreversible deformation response requires inclusion of post-elastic material behaviour for bone which has been most commonly modelled using elastoplasticity. Elastoplasticity implies that the material remains elastic when loaded up to a certain limit (yield value defined in terms of stresses or strains) and has irreversible deformations when loaded beyond this limit. A wide range of yield criterion are available in commercial finite element codes and several of these have been used for bone [26], often with little thought to their suitability. Most models available in commercial codes are based on stress i.e. a material is considered to have yielded when a combination of stress components reaches a yield value (i.e. elastic limit). In addition to anisotropic elasticity, bone is also anisotropic in terms of yield strength, which varies with bone quality. So, specifying yield parameters for stress-based criteria cannot be readily achieved. Interestingly relatively recent experimental [39] and computational [40] research has shown that bone yields at relatively isotropic strains and yield strain is not dependent on apparent elastic stiffness or density. In other words, it is much simpler to model bone of varying quality and microstructure using strain-based criteria in comparison to stress-based approaches. Strain-based plasticity was first discussed about four decades ago by Naghdi and Trapp [41] but has received little attention in comparison with stress-based theories. Algorithms to achieve these are now available [42].

Donaldson et al. [3] used orthotropic elasticity in conjunction with strain-based plasticity to determine loosening in Ilizarov fixators. They used asymmetric yield strain limits, 0.5% in tension and 0.7% in compression, and showed that the pattern of yielding in ring fixators was as shown in Figure 2. They found that: increasing wire tension reduces volume of yielded bone and the volume increases as the bone quality decreases; and that there is significant reduction bone yield volume when the number of wires on either side of the fractures are increased.

3.3 Bone modelled as a time-dependent material

As discussed loosening at the bone-screw/pin/wire interface has been considered by examining strains on load application using time-independent elastic or elastoplastic constitutive models for bone. A number of studies [43,44,45] have shown that loosening of connecting screw/pin is a function of loading cycles. Time-independent models are unable to capture this phenomenon as cyclic loading (with the same magnitude and direction) merely reproduces the mechanical response from the first cycle. Here we consider a recently promulgated theory which explains loosening due to cyclic loading via time-dependent behaviour of bone [46].

Bone is recognised as time-dependent material and its time-dependent properties have been measured experimentally using: creep tests [13–15] in which time-varying strain due to applied constant load is measured over time; relaxation tests [47,48] in which time-varying force due to applied constant deformation is measured over time; and dynamic tests [49,50] in which the lag between sinusoidal stress and strain is measured over a frequency range. Although time-dependent behaviour of bone has been studied extensively, most experimental studies were not developed into computational models or employed in modelling of bone-implant systems. Recently studies employed multiple-load-creep-unload-recovery experiments [13] to characterise time-dependent behaviour of trabecular bone, and developed BV/TV-based linear viscoelastic [14], nonlinear viscoelastic [15] and nonlinear viscoelastic-viscoplastic [51] constitutive models – models with increasing complexity and consequent accuracy.

Xie et al. [46] considered the influence of cyclic loading in an idealised unicortical bone-screw system (Figure 4a and 4b). In this the screw was subjected to 500 cycles of lateral loads (Figure 4c) with loading frequency f = 1 Hz followed by 1000 sec recovery. The trabecular bone modelled as time-dependent material. The study examined the accumulation of strain at the bone-screw interface with increasing number of cycles and after recovery.

Figure 4

Figure 5 shows the minimum (compressive denoted negative) and maximum (tensile denoted positive) principal strain contours from the symmetry surface (Figure 4a) and Section A-A (Figure 4b). Figures 5a and 5b show the compressive strain contours at time points when the load is at its peak and when it has been reduced to zero respectively at different loading cycles. Similarly, Figures 5c and 5d show the tensile strain contours at time points when the load is at its peak and when it has been reduced to zero respectively at different loading cycles. Figures 5e and 5f show the compressive and tensile strain contours respectively after 1000 sec of recovery following 500 cycles of loading. It is clear that the strain experienced by bone increases with increasing number of cycles, similar to that reported in previous studies [43,44,45]. It is important to note that with time-independent models the variation with number of cycles cannot be captured. Moreover, time-independent elastic models will show zero strains upon unloading. For the nonlinear viscoelastic-viscoplastic simulation [46], not all of the strain is recovered upon unloading and the strain experienced by bone increases with applied loading cycles. A residual strain exists even after 1000s of recovery. This increase in strain with increasing number of loading cycles and residual strain indicates that the mechanical environment at the bone-screw interface will change as physiological activities are undertaken by the patient and will accentuate screw loosening.

Figure 5

By assigning time-dependent material properties for different bone densities based on recent experiential studies [14], permits simulation of bone-screw interface strain/micromotion similar to that reported experimentally [43]. This has only become possible recently.

A recent study has also shown that the strain/displacement experienced at the interface is also loading frequency dependent [51]. In the first few cycles the larger strain is observed if bone-screw system is loaded at a lower frequency; while the interface experiences larger strain at higher loading frequencies after a large number of loading cycles have been applied. In the first few cycles, a lower loading frequency has a relatively longer loading time and relatively smaller loading rate. Therefore, larger displacement occurs when bone-screw system is loaded at a lower frequency during the loading and unloading phases as the bone is provided more time to deform or recover. When the bone-screw system is loaded at higher frequencies, the loading/unloading time is shorter (in comparison to lower frequency loading) and the bone is loaded again by the next cycle before it can recover from its last loading cycle.

4 Conclusions

Implant loosening is initiated by strains at the bone-screw/pin/wire interface. These strains are generally larger in low density bone. The interfacial strains increase with decrease in the stiffness of the bone fixator construct which can be caused by features such as increased working length, use of implant materials with lower stiffness (e.g. titanium rather than steel) or reduced wire tension in ring fixators. The reduction of the construct stiffness also causes increased interfragmentary motions between fractured segments which may be beneficial for healing. Therefore, risk of loosening needs to be balanced by the need of maintaining adequate interfragmentary motion. Computational simulation/prediction of loosening requires appropriate models of bone behaviour. For this most previous studies have employed time-independent models. These are unable to capture loosening that is accentuated due to cyclic loading. Recently developed time-dependent models are extremely promising in this respect.

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***Highlights**

- Fundamental mechanics of the bone-fixator construct with focus on interfacial strains that result in loosening are discussed
- Bone models as time-independent and time-dependent material that have been used to simulate and predict loosening are reviewed
- Capability of time-dependent models to capture cyclic accumulated deformation at bone-pin/ interface is highlighted

Figure 1 Locking plate used for mid-shaft fracture fixation: prior to load application (a) and after load application (b); pattern of large strains at the bone screw interface for screws 2 and 3 (c); compressive and tensile strain distributions for the near cortex for screw 2 (d). Unilateral fixators present similar strain patterns.

Figure 2 Ilizarov ring-wire external fixator construct (a); the deformed shape of bone-wire system with regions of large interfacial bone strains (b).

Figure 3 Predicted volumes of bone above 0.02% equivalent strain (EqEV) for different working lengths. (a) Screw arrangements C123; C234; and C345. EqEV values at different screw locations for (b) healthy bone and (c) osteoporotic bone. Load of 250N is applied to the bone-fixator construct. Reproduced from MacLeod et al. [4] (open access)

Figure 4 Geometry of the bone-screw system showing symmetry surface with location of load application (a); section A-A (b); load application - each model was subjected to 500 cycles of triangular load of 300 N amplitude followed by 1000 s of recovery (c). From Xie et al. [46] (open access)

Figure 5 Compressive (a, b and e) and tensile (c, d and f) strain (%) contours from the symmetry surface and Section A-A. Three representative cycles were selected to show the strain accumulation with increasing cycle number when load is at its peak (a and c); at the time points when load is zero (b and d); and recovery after 1000 s (c and f). Redrawn from Xie et al. [46] (open access)

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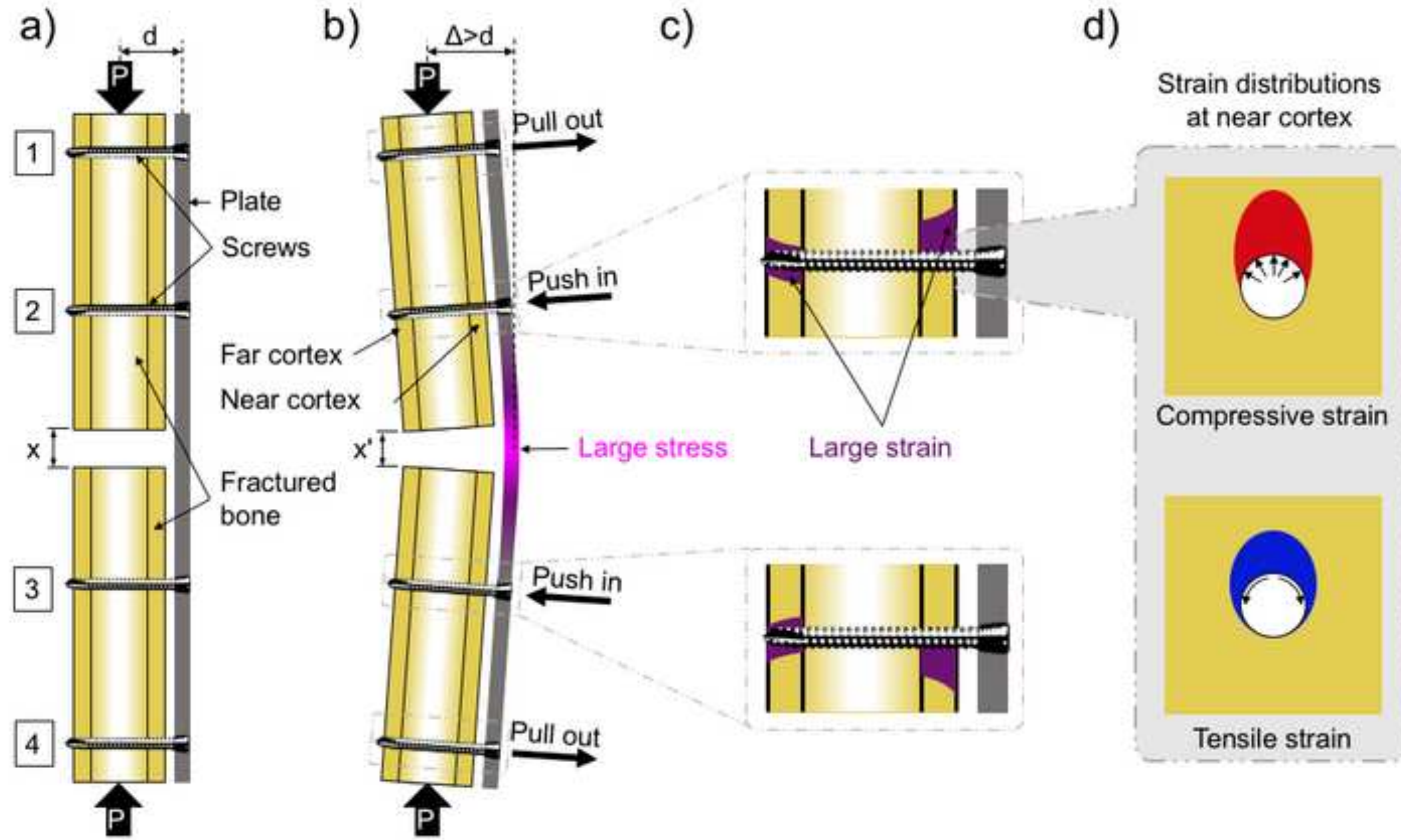

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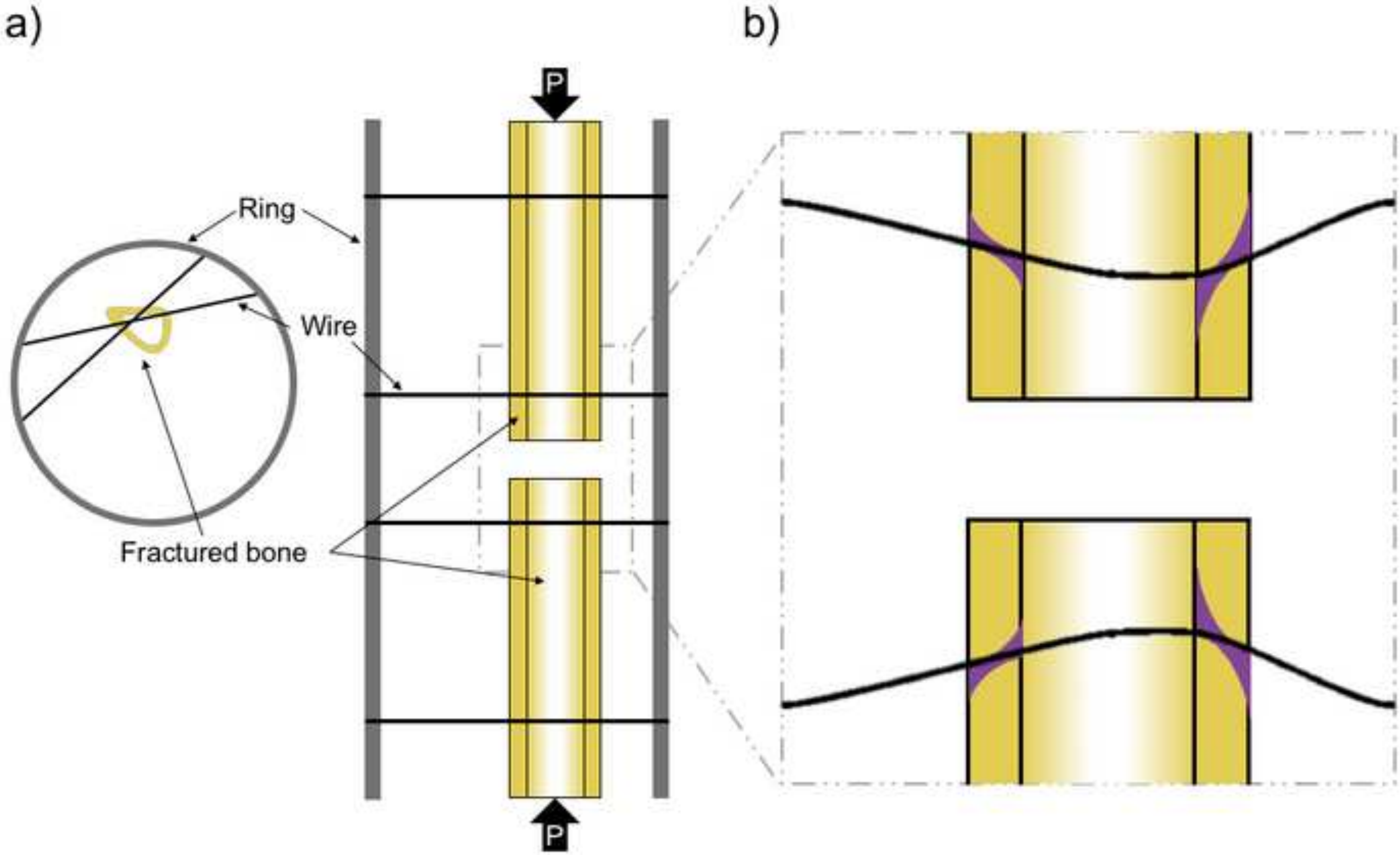

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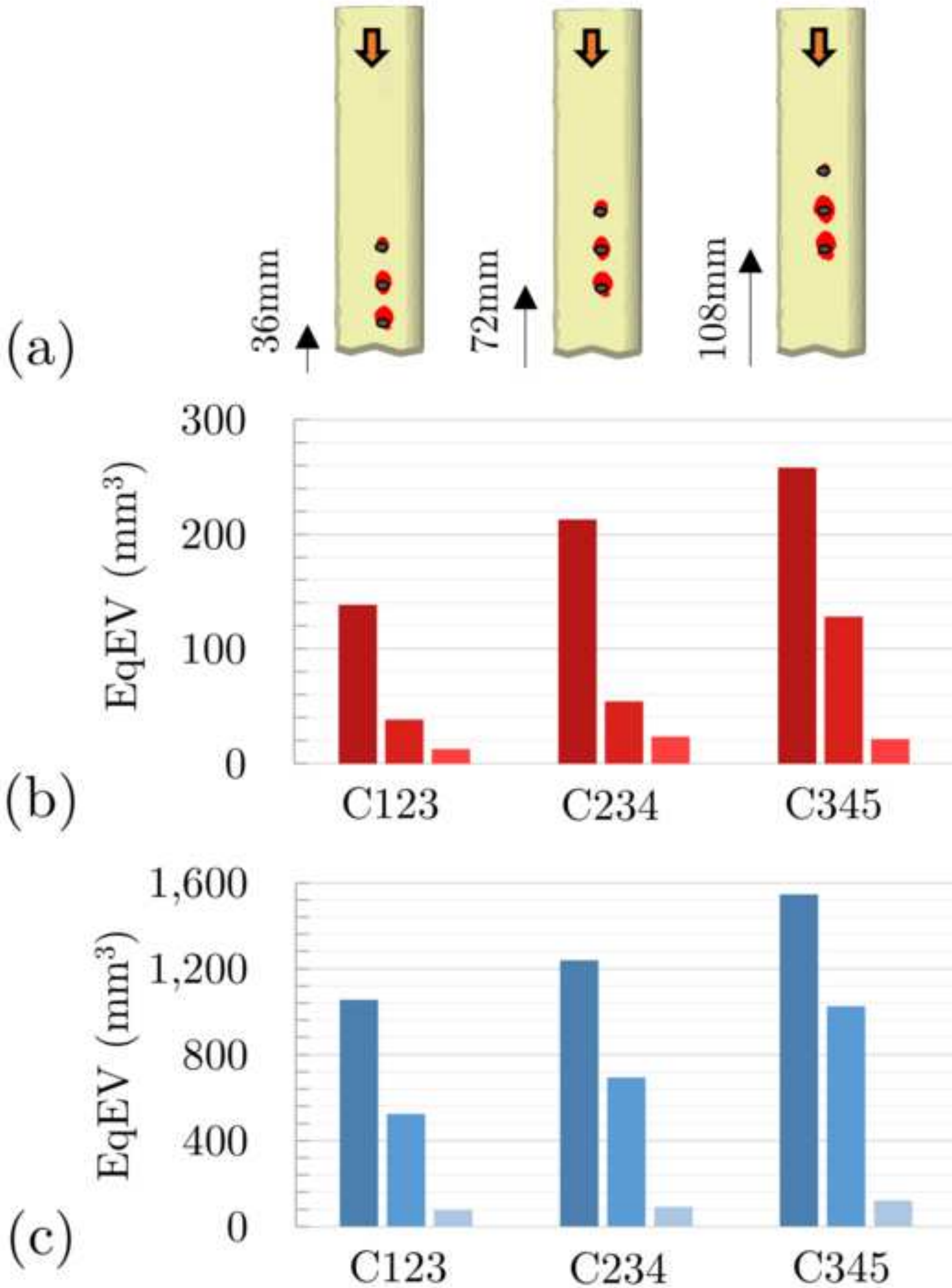

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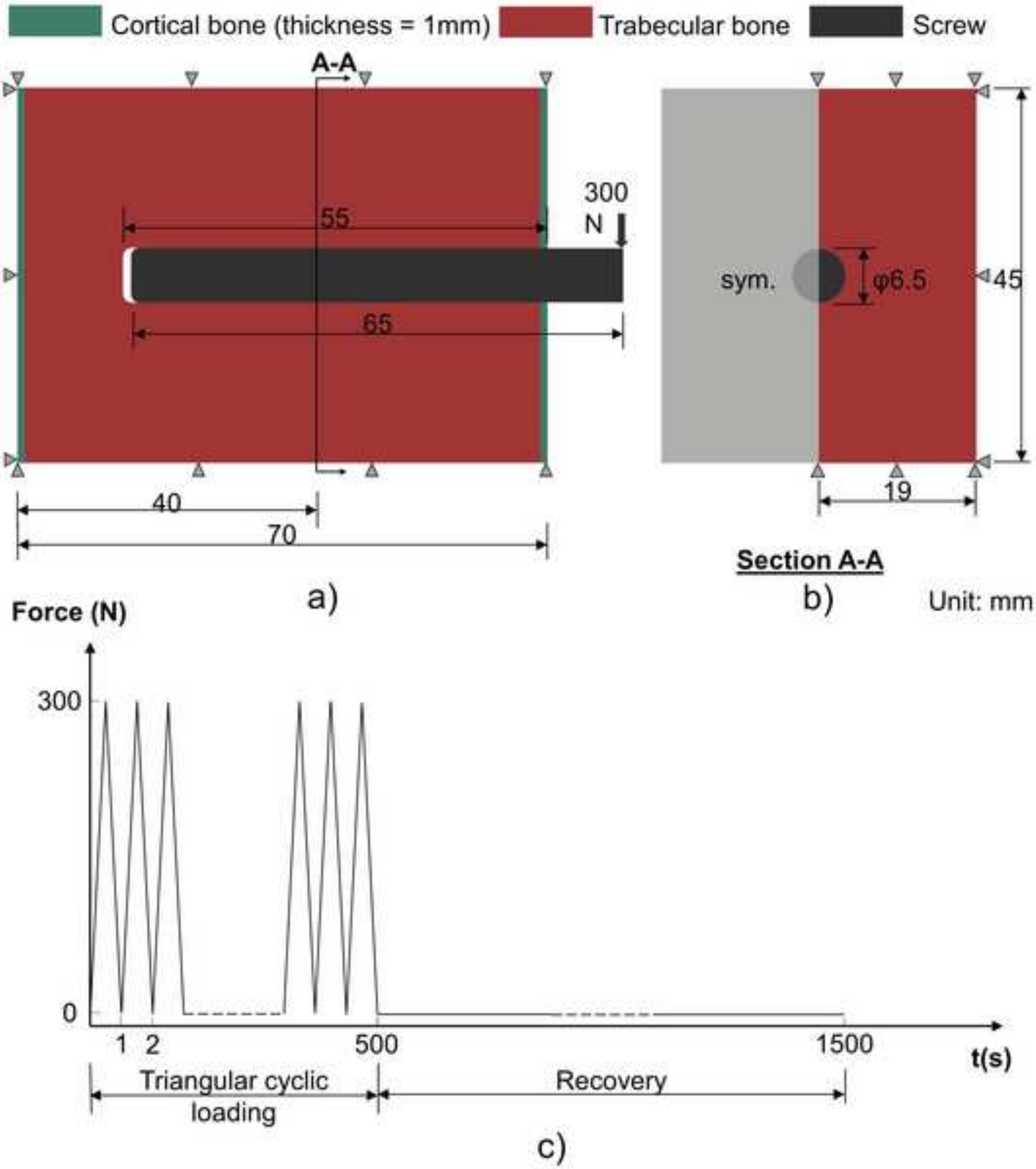

Figure 5

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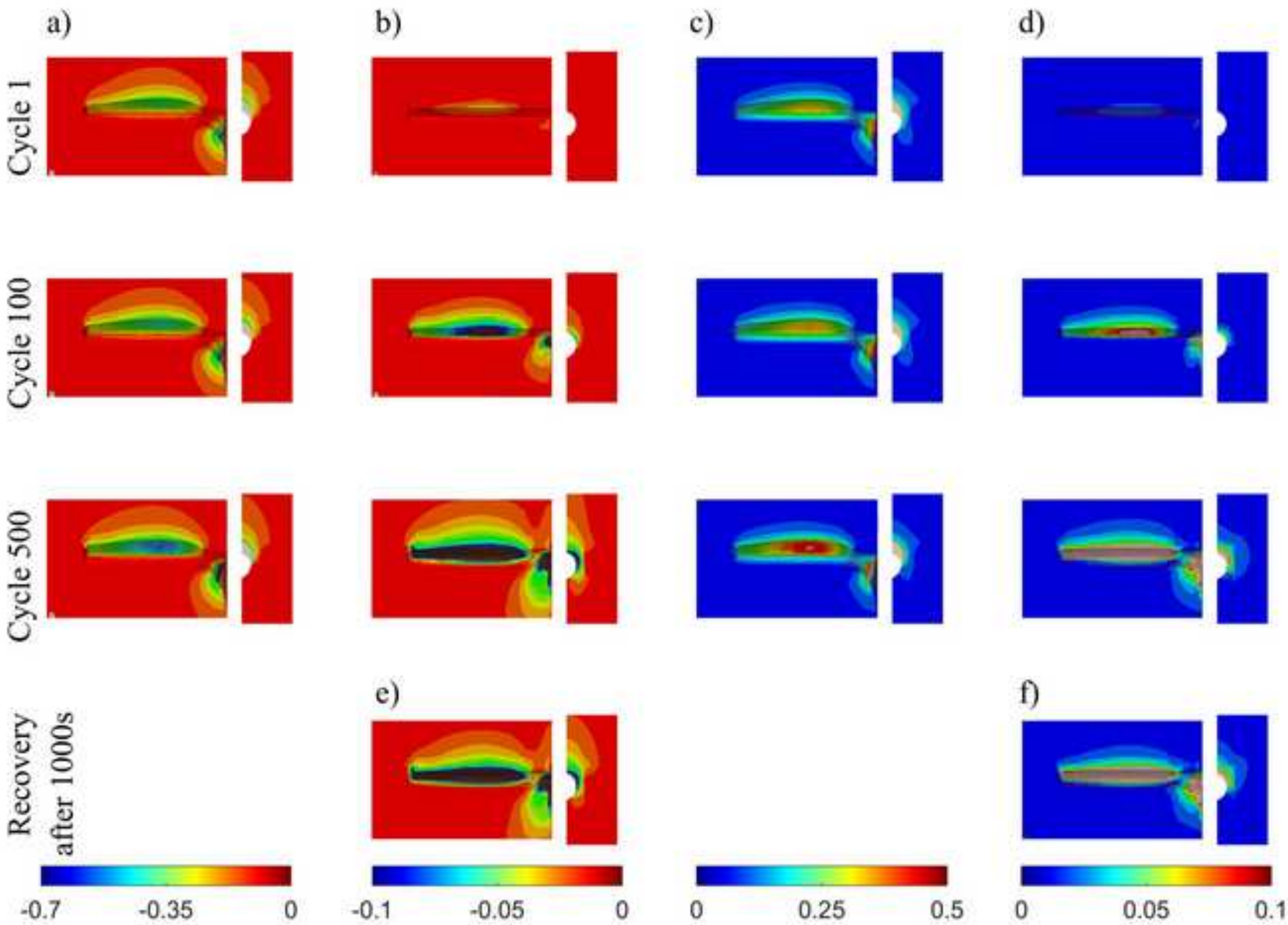

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