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Mechanical testing of internal fixation devices: A theoretical and practical examination of current methods

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ABSTRACT

Successful healing of long bone fractures is dependent on the mechanical environment created within the fracture, which in turn is dependent on the fixation strategy. Recent literature reports have suggested that locked plating devices are too stiff to reliably promote healing. However, *in vitro* testing of these devices has been inconsistent in both method of constraint and reported outcomes, making comparisons between studies and the assessment of construct stiffness problematic. Each of the methods previously used in the literature were assessed for their effect on the bending of the sample and concordant stiffness. The choice of outcome measures used in *in vitro* fracture studies was also assessed. Mechanical testing was conducted on seven hole locked plated constructs in each method for comparison. Based on the assessment of each method the use of spherical bearings, ball joints or similar is suggested at both ends of the sample. The use of near and far cortex movement was found to be more comprehensive and more accurate than traditional centrally calculated interfragmentary movement values; stiffness was found to be highly susceptible to the accuracy of deformation measurements and constraint method, and should only be used as a within study comparison method. The reported stiffness values of locked plate constructs from *in vitro* mechanical testing is highly susceptible to testing constraints and output measures, with many standard techniques overestimating the stiffness of the construct. This raises the need for further investigation into the actual mechanical behaviour within the fracture gap of these devices.

1. Introduction

It is understood that the mechanical environment (the amplitude of movement occurring within the fracture) influences its healing. When a fixation system has been used to stabilise the fracture, this movement is dictated by the behaviour of the whole construct under the observed physiological loads. Claes et al. (1997) have suggested that for optimum healing the range of motion observed should be between 0.2 and 1.0 mm within a 3 mm gap.

During the early phases of healing the behaviour of the bone–implant construct is primarily related to the physical characteristics of the fixator itself. The fixation type (plate, nail, external fixator), material (stainless steel, titanium), geometry (breadth, thickness and length), as well as the implanted configuration of screws and screw type; will all influence the deformation of the fracture under load. To determine the effect of each of these parameters on the mechanical environment, an appropriate set of loads and boundary conditions need to be defined that most closely reflect the observed mechanical environment *in vivo*. There is currently no standard test methodology which reflects this.

Previous mechanical testing has been conducted using a range of boundary conditions and loads, and using a variety of outputs for comparison (Table 1). Compression testing is commonly conducted on fracture fixation implants, as this is the primary mode of loading occurring physiologically. This compression is then converted into bending by the natural geometry of the bone.

Within the studies examining compressive loading of bone–implant constructs, the method of constraint of the sample varies considerably. Three methods of constraint are common, fixation of both translations and rotations at both ends of the sample (fully fixed), freeing the rotations at a single end of the sample while keeping the other fully fixed (fixed–free), and freeing rotations at both ends of the sample while keeping translations fixed (free–free). There has been no discussion however, as to which of these methods of constraint is the most appropriate for compression testing of bone–implant constructs, or if any of them allow the natural bending behaviour of the bone.

Additionally, the reported outcome measures from these studies vary and again there is little discussion of the advantages or disadvantages of using each parameter. Stiffness is commonly reported and can be calculated globally using the applied load and

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Table 1
A sample of published literature on mechanical testing of fracture fixation systems.

Authors and year	Constraint	Deformation capture	Load (N)	Sample type	Geometry	Fixators	Fracture gap (mm)
Duda et al. (1998)	Free–free	IFM	1377	Surrogate	Cylinder	External fixator	4
Gaebler et al. (2001)	Free–free	Global 1d	To failure	Surrogate	Other	Nail	55
Kassi et al. (2001)	Fully fixed	IFM	Unspecified	Surrogate	Cylinder	External fixator	Unspecified
Duda et al. (2002)	Fully fixed?	IFM	500	Human	Tibia	1 × 5 hole SS plate constructs	11
Stoffel et al. (2003)	Free–free	Global 1d	200	Sawbones	Cylinder	8 and 12 hole Ti plate constructs	6
Ahmad et al. (2007)	Fully fixed	Global 3d	250	Sawbones	Humerus	2 × 7 hole SS plates	10
Epari et al. (2007)	Fully fixed	IFM	Unspecified	Ovine	Tibia	4 × external fixator, 2 × nail	3
Meleddu et al. (2007)	Fixed–free	IFM	Unspecified	Surrogate	Cylinder	External fixator	Unspecified
Augat et al. (2008)	Fixed–free	Global 3d	100	Human	Tibia	Nail	8
Snow et al. (2008)	Fully fixed	Global 1d	450	Synbone	Cylinder	2 × 8 hole SS plate constructs	10
Uhl et al. (2008)	Fixed–free	90 and 160°	355	PU	Cylinder	3 × SS plate constructs	2
Bottlang et al. (2009)	Fixed–free	Near and far cortex	1000	Sawbones	Cylinder	2 × 11 hole Ti plate constructs	10
Fitzpatrick et al. (2009)	Fixed–free	IFM	1000	Surrogate	Cylinder	4 × SS plate constructs	10
Gardner et al. (2009)	Fixed–free	Global 1d	200	Sawbones	Cylinder	2 × 11 hole SS plate constructs	18
Penzkofer et al. (2009)	Fixed–free	IFM	100	Human	Tibia	Nail	8
Bottlang et al. (2010)	Fixed–free	Near and far cortex	400	Sawbones	Cylinder	3 × 11 hole Ti plate constructs	10
Gardner et al. (2010)	Unspecified	Global 1d	700	Surrogate	Cylinder	2 × 10 hole SS plate constructs	10

the global deformation. Increasingly though the stiffness of constructs is calculated using the Interfragmentary motion or IFM. This parameter describes the motion occurring at the centre of the fracture gap under load. Alternatively, Bottlang et al. (2010) and Bottlang and Feist (2011), expand IFM into movements on the near and far cortex with respect to the fixation and Uhl et al. (2008) tracked changes in height of the fracture gap under load, placed at 90° and 160° from the fixation.

From this review of current practices, it is evident that a standardised testing methodology is currently lacking in terms of both sample constraints and measurement outputs. Therefore, the aim of this study was to characterise, from a mechanical engineering standpoint, the existing compression testing methodologies and to determine the most relevant output parameter. Discussion of engineering bending theory and constraint mechanisms will be coupled with an example of each method and output using a standardised single fracture fixation plate sample. A standard protocol for comparative testing of these devices will then be suggested.

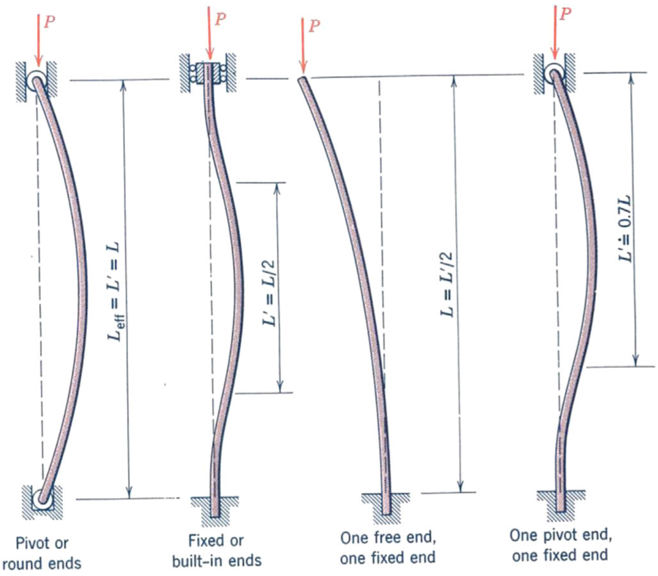

Fig. 1. The effect of end constraints on the effective length of simple beams under load. Adapted from Riley et al. (1995).

2. Methods theory

2.1. Boundary conditions

The three reported methods of constraint during compression testing were first assessed from an engineering perspective to determine their effect on the bending mode of the samples. As an initial simplification, the bone was assumed to be a solid without any fixation, in which case the effect of the three load cases on the deformation mode of the sample can be related to the bending modes of intact beams with the same end constraints (Fig. 1).

In the figure, the effect of the various end constraints on the effective length (L) of the beams can be seen. The only constraint system in which the effective length is equal to the true length is the case of two pivot or round ends allowing free rotation at each end. The other two common compression cases: fixed–fixed and fixed–free both result in a dramatic shortening of the effective length of the column to $0.5L$ and $0.7L$ respectively. Conversely, allowing free rotations and translations at one end results in a doubling of the effective length.

While the constructs of interest in this paper are more complex than simple beams, with both discontinuities (fractures or osteotomies), and additional high stiffness members applied off axis (fixators) the way in which they will bend under a compressive load will follow the same basic pattern as for these simple beams.

2.2. Outputs

The mechanical testing of bone–implant constructs lends itself to a range of different output parameters. The global stiffness or the response of the entire system to load is a commonly reported parameter as it allows simple comparison between constructs based on a single number. This value is typically calculated from the load *vs.* deformation behaviour as recorded by the mechanical testing machine. However, there are a number of issues with the usage of this parameter, it is highly dependent on the constraints on the system, making samples within a study comparable but diminishing its use across studies.

Another increasingly common output measure is the movement within the fracture gap, but even within this one parameter there are differences in definition and reporting. The initial definition of interfragmentary motion, IFM, was as the movement at the centre of the fracture gap, calculated as the difference in the new position of this point as seen by the upper and lower segments under load (Duda et al., 1998). This was then coupled with the calculation of the relative rotations of the fragments from attached optical marker rigid bodies. While the definition of this seems reasonable the calculation generates a number of problems.

Examining the translational aspects, calculation only at the centre of the fracture gap, results in reporting the median deformation and not the full range experienced. The limited scope of this result is shown schematically in Fig. 2 for the case of looking at the vertical translations only. Three hypothetical cases of deformation within the fracture gap are shown (A, B and C), in each case the original location of the bones are outlined in black and the resultant deformed locations shown outlined in red. The centre of the fracture gap about which the IFM is calculated is indicated by a star. In each case the deformation is highlighted in grey, the sum of the deformation of the upper and lower fragments is then shown in the cumulative deformation plots at the bottom of the figure. The location of the centre of the fracture gap (star) is shown for reference. Cases A and B, both result in the same value of IFM (dotted red line in the cumulative deformation plots), and yet their near and far cortex deformations are very different. Case C, shows the case of zero IFM, with large near and far cortex movements (though small movements are equally possible). This case reflects simply that the instantaneous centre of rotation of the two fracture surfaces happens to be at the location about which the IFM is