



**A New Design of External Fixator
for Long Bone Fracture Management**

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Thesis submitted for the degree of Doctor of Medicine
In the University of Adelaide

TABLE OF CONTENTS

SUMMARY	i
DECLARATION	iv
ACKNOWLEDGMENTS	v
AWARDS	viii
LIST OF FIGURES	vii
LIST OF TABLES	xiii
LIST OF ABBREVIATIONS	xvi
GLOSSARY	xvii
CHAPTER ONE: INTRODUCTION	1
CHAPTER TWO: LITERATURE REVIEW	4
2.1 Introduction	4
2.2 Fracture healing	4
2.2.1 Histological description	5
2.2.2 Biomechanical description	10
2.2.3 Biochemical description	11
2.2.4 Physiological description	14
2.2.5 The control of fracture healing	16
2.2.6 Factors influencing fracture healing	18
2.2.7 Summary	18
2.3 Treatment of fractures by external fixation	22
2.4 The influence of applied loads on bone formation and fracture healing	23
2.4.1 The effect of removal of mechanical loads from bone	23
2.4.2 The effect of cyclic mechanical loads on intact bone	26
2.4.3 The effect of static mechanical loads on intact bone and fractures	27

2.4.4 The effect of cyclic mechanical loads on fractures	28
2.5 Dynamisation: The concept	29
2.6 Summary	31
 CHAPTER THREE: MECHANICAL EVALUATION	 33
3.1 Introduction	33
3.2 Evaluation of laboratory testing procedures	36
3.2.1 Mathematical analysis	43
3.2.2 Results	45
3.2.3 Discussion	46
3.3 Mechanical tests of the Orthofix fixator	47
3.3.1 Introduction	47
3.3.2 Materials and methods	49
3.3.3 Results	54
3.3.4 Discussion	57
3.4 Mechanical tests of the Lazo rod	58
3.4.1 Introduction	58
3.4.2 Materials and methods	62
3.4.3 Results	77
3.4.4 Discussion	84
3.4.5 Conclusions	87
3.5 Mechanical test of sliding rods made of dissimilar metal	88
3.5.1 Introduction	88
3.5.2 Materials and methods	89
3.5.3 Results	94
3.5.4 Discussion	95
3.5.5 Conclusions	97

3.6 Cyclic tests of a metal on polymer sliding rod	98
3.6.1 Introduction	98
3.6.2 Materials and methods	98
3.6.3 Results	104
3.6.4 Discussion	106
3.7 Comparative tests: Metal on polymer vs. Lazo rod	112
3.7.1 Introduction	112
3.7.2 Materials and methods	112
3.7.3 Results	114
3.7.4 Discussion	118
3.8 Discussion	121
 CHAPTER FOUR: THE RIGIDYNE FIXATOR	 123
4.1 Introduction	123
4.2 Performance requirements and design specifications	123
4.2.1 Biomechanical factors	124
4.2.1.1 Rigidity	125
4.2.1.1.1 Frame stiffness	125
4.2.1.1.2 Fracture biomechanics	126
4.2.1.1.3 The pin-bone interface	126
4.2.1.2 Dynamisation	128
4.2.1.3 Versatility	130
4.2.1.3.1 Anatomical constraints	131
4.2.1.3.2 Fracture configuration	137
4.2.1.3.3 Soft tissue injuries	140

4.3 Design	144
4.4 Mechanical testing	149
4.4.1 Introduction	149
4.4.2 Testing procedure	149
4.4.2.2 Cyclic tests	150
4.4.2.1.1 Materials and methods	150
4.4.2.1.2 Results	153
4.4.2.1.3 Discussion	155
4.4.2.1 Stiffness tests	157
4.4.2.2.1 Materials and methods	157
4.4.2.2.2 Results	162
4.4.2.2.3 Discussion	164
4.5 Comparative studies	167
4.5.1 Introduction	167
4.5.2 Methods and materials	167
4.5.3 Results	169
4.5.4 Discussion	172
4.5.5 Conclusion	173
 CHAPTER FIVE: PRELIMINARY CLINICAL TRIAL	 174
5.1 Introduction	174
5.2 Materials and methods	174
5.3 Results	176
5.4 Discussion	180
5.5 Conclusions	182

CHAPTER SIX: DESIGN ASSURANCE	193
6.1 Failure Mode Effects Analysis	193
6.1.1 Introduction	193
6.1.2 Methods	194
6.1.3 Results	194
6.1.4 Discussion	195
6.2 Torque Failure Tests of Socket Head Screws	202
6.2.1 Introduction	202
6.2.2 Method	203
6.2.3 Results	203
6.2.4 Discussion	204
6.3 Sterilisation Tests on the Rigidyne External Fixator	206
6.3.1 Introduction	206
6.3.2 Methods	207
6.3.3 Results	208
6.3.4 Discussion	209
6.4 Failure Mode Solutions	210
6.4.1 Introduction	210
6.4.2 Results	210
6.4.3 Discussion	210
6.5 Conclusions	213
CHAPTER SEVEN: DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS FOR FUTURE WORK	215
BIBLIOGRAPHY	217
APPENDIX 1 ENGINEERING DRAWINGS	
APPENDIX 2 PROVISIONAL PATENT	
APPENDIX 3 STRESS ANALYSIS REPORT	

SUMMARY

This thesis examines the sliding capability of external fixators under load and describes the development and testing of an external fixator capable of providing axial cyclic motion to a fracture site while a patient is walking.

Fracture healing by external callus formation or by modelling and remodelling is dependent on the rigidity of fracture fixation and is influenced by the application of mechanical loads through the fractured limb. Excessive mobility or rigidity of fracture fixation may adversely affect fracture healing. The importance of micromotion at a fracture site in promoting healing is now appreciated and there is considerable interest in the effects of controlling axial cyclic motion with external fixators during the early stages of fracture healing.

Others have shown benefits of axial cyclic loading forces applied at a later stage of fracture healing when greater mechanical stability has been regained and when there is little resultant movement at a fracture site. The relative benefits of early axial cyclic motion and later axial cyclic loading are unknown and further research is required.

A unilateral external fixator, used to provide micromotion by known displacements at a fracture site, must have a sliding mechanism capable of withstanding lateral bending moments under offset loading conditions when a patient is walking. Further, the fixator must be sufficiently stiff to insure that micromotion is provided by the sliding mechanism and not by instability of the fixator.

The mathematical concepts underlying mechanical bench testing of external fixators

were reviewed and a laboratory fracture model was developed that was suitable for testing the sliding properties of external fixators. Using this fracture model, laboratory tests showed that commercially available sliding fixators could not deliver consistent axial cyclic motion.

The absence of an appropriate commercially available external fixator necessitated the development of a suitable custom-made device. Sliding rods utilising different bearing surfaces were therefore made and tested. Metal on metal sliding parts were found to be unsuitable, but a bearing of polished stainless steel on Ertacetal, a plastic polymer, was shown to be capable of providing controlled axial displacements under offset loading conditions. Existing commercially available pin clamps were known to be mechanically inadequate for use with these custom made sliding rods, necessitating the design of a new clamp assembly. These combined requirements meant that a completely new external fixator had to be designed.

A design assurance pathway was used to design a new external fixator. The essential performance requirements of an ideal unilateral external fixator were identified as the capacity to apply known displacements and loads, rigidity, and versatility. Design specifications to achieve these requirements were identified and incorporated into the design of a new external fixator for long bone fracture management. Stiffness and cyclic testing confirmed that the performance of the fixator met the requirements for further investigation of the effects of modifying fracture healing by applying known loads and displacements to a healing fracture through an external fixator by the process of walking.

A preliminary clinical trial was conducted and a failure mode effects analysis was performed to identify possible failure modes. Failure mode solutions and tests were

successfully implemented, completing the fixator design.

The new external fixator described in this thesis is suitable for clinical use and provides the means for further investigation of the modification of fracture healing by applying known displacements and loads to a healing fracture.