INGLE, NILESH P. Prototyping and Finite Element Analysis of Tissue Specific Barbed Sutures. (Under the direction of Dr. Martin W. King and Dr. Elizabeth G. Loboa).

The project titled 'Prototyping and Finite Element Analysis of Tissue Specific Barbed Sutures' is focused on understanding the relationship between barb geometry and mechanical behavior of barbed sutures. In this study size '0' polypropylene monofilament sutures of diameter 0.4mm were used for creating bars at 150°, 160° and 170° cut angles and 0.07, 0.12 and 0.18mm cut depths. A new prototyping method was developed to create barbed sutures with precisely controlled geometries which used tMTS tensile testing machine to control cut depth. The cut samples were then characterized by image analysis to assess the reproducibility and the variability associated with the barbs geometric dimensions. Tensile testing and stress and bulk relaxation experiments were performed to obtain viscoelastic constants for finite element modeling. An experiment was run to quantify the peeling properties of a barb under point-pressure load by attaching a metal wire to the end of the barb. Suture/tissue pullout experiments were also performed using bovine tendon and porcine skin tissues. The finite element simulation of the point-pressure loading of a barb tip in ANSYS was validated by experimental results of the same materials by a margin of only 4%. Three sets of FEA simulations were then performed for each of the nine blocks of combination of barb geometries. The same three levels of cut angle and three levels of cut depth were selected. In addition point-pressure loading simulations were run and experimental suture/tissue pullout tests were performed on tendon and skin tissues. The experimental results revealed that since tendon tissue has a higher modulus than skin it needs a more rigid barb to penetrate and anchor into the surrounding tissue. A cut angle of 150° and 0.18mm cut depth are recommended. On the other hand for the softer skin tissue a cut angle of 170 degrees and 0.18 mm cut depth provided a more flexible barb that gives superior skin tissue anchoring. The simulations helped identify the areas of stress concentration. The cut line at the base of the cut appears to be the weakest part of the barb. So the geometry or design should be modified so that the stresses generated are lower. A new design with a circular cut line has been virtually prototyped and tested in ANSYS. This new and improved design helps to redistribute the stresses along the barb and its cut line so that peeling is initiated at higher stresses and improved anchoring performance.
DEDICATION

Dedicated to my mother and father.
BIOGRAPHY

Science has been my passion and driving force in my life. After school I am looking forward to applying my knowledge and enthusiasm to develop medical devices for better health care in this world.
Firstly, I wish to sincerely thank my advisor Dr. Martin W. King for everything. For his profound interest and unwavering support and guidance in prototyping, experimentation and finite element analysis. This project would not have been successful without him. Even in times of extreme difficulty, he has always been the guiding light to inspire and to motivate throughout the entire project to move a step further. He has always been a mentor and a teacher. Under his sound guidance and teaching, in addition to barbed sutures, I have learned a lot about other implantable and non-implantable medical devices. He has been extremely encouraging even in the face of many experimental failures during barbed suture prototyping. And in times of success he never forgot to celebrate.

I wish to thank my co-advisor Dr. Elizabeth Loboa for her deep interest in the barbed suture technology and all help in understanding the behavior of the barbed sutures and the effect their tissue specificity in a pullout test.

I wish to thank Dr. Mohammed A. Zkiry for teaching finite element analysis in his course. And his continued interest and help to successfully apply this knowledge to the barbed surgical sutures.

I wish to thank Dr. Mansoor Haider for teaching advanced mathematics in his course that helped me understand various constitutive equations of tissues. And his continued interest in the barbed suture project to understand viscoelasticity.

I wish to thank Dr. Bhupender S. Gupta for teaching fiber physics in his course. And his continued interest and help in understanding the viscoelastic behavior of the barbed sutures. And his unwavering support and help to allow access to his laboratory to use the microscopes for sample preparation and early image analysis.

I wish to thank Dr. Benham Pourdeyhimi for his interest and help in understanding the effect of polymer properties on the mechanical behavior of the barbed suture.

I wish to thank Dr. Peter L. Mente for his continued interest in the barbed suture project and his help and guidance in the experiments with uni-axial and bi-axial mechanical behavior of cartilage tissue.

I wish to thank Dr. Melissa A. Pasquinelli for her unwavering help and all her support to allowing access to her blades on the HPC server, which made it possible to run and successfully complete the simulations in parallel in the very short amount
of time available. I wish to thank Mr. Syamal Tallury his help and accommodating the simulations in this project with his ongoing computational modeling on HPC.

I wish to thank Dr. Gary Howell for all his quick and timely help and all his support in every aspect of remote HPC access and providing additional space and licenses to make it possible to run large simulations.

I wish to thank Dr. Moon W. Suh for all his help with the design of experiments part of this project.

I wish to thank Dr. Joseph Hotter, Covidien, Tyco Healthcare, New Haven, CT for providing us with the polypropylene monofilament suture samples required for prototyping the barbed sutures.

I wish to thank Dr. Gregory Ruff, Dr. Jeffrey Leung and Mr. Stan Batchelor for helping us in the initial part of the project and the stimulating discussions on the future possibilities of the barbed suture technology.

I wish to thank North Carolina State University for all the support during the entire course of my studies here. I wish to thank University of North Carolina and North Carolina State University for making it possible to do a co-major in Biomedical Engineering.

I wish to thank Ms. Carolyn Krystoff and Ms. Nancy McKinney for their help in co-ordinating my plan of work across the NCSU and UNC campuses.

I wish to thank Mr. Hai Bui for all his help in the mechanical workshop to make fixtures. I wish to thank Mr. William Barefoot, Mr. Timothy Pleasants, Mr. Stanley R. Long for all their help in prototyping vascular grafts. I wish to thank Dr. Jan. E. Pegram and Ms. Teresa J. White and for all their help in the Physical Testing Laboratory.

I wish to thank everybody from our Biomedical Textiles Laboratory: Ms. Genevieve Samson for all her help in designing and solid modeling the fixtures for cutting barbs and in barbed suture prototyping and keeping me inspired. Ms. Jessica Gluck for all her help in getting the tissue samples and the barbed suture project and keeping me inspired. Ms. Sangwon Chung, Ms. Sarah Spinella, Mr. Joshua Yoon, Ms. Huijing Zhao, Ms. Yongfang Qian, Ms. Juliette Henon, Ms. Emily Blair, Dr. Hoonjoo Lee, Mr. Matt Crutchfield, Mr. Mohamad Widodo for keeping me hopeful and inspired, even in times of difficulty and giving me tips to find a way to solve a particular problem. I wish to thank Dr. Ajit Moghe, Dr. Narahari Kenkare and Mr. Rahul Vallabh for all their help and keeping me inspired and hopeful during the project. You all are the
best. Finally I would like to thank everybody who has directly or indirectly helped me throughout the project.
TABLE OF CONTENTS

LIST OF TABLES ......................................................... x

LIST OF FIGURES ......................................................... xii

1 Introduction ......................................................... 1
  1.1 Background ..................................................... 1
  1.2 Objectives ..................................................... 2
  1.3 Outline of Thesis ............................................... 3
  1.4 Abbreviations .................................................. 4

2 Review of Literature .............................................. 5
  2.1 Brief History .................................................. 5
  2.2 Suture Biomaterials ............................................ 8
  2.3 Classification of Sutures ....................................... 13
  2.4 Comparison of Knotted and Knotless Sutures .................. 14
  2.5 Types of Knotless Sutures ..................................... 14
  2.6 Methods of Creating a Barb on a Monofilament Suture ...... 18
  2.7 Suturing Techniques ........................................... 23
  2.8 Image Analysis of Barbed Sutures ............................. 26
  2.9 Mechanical Properties ......................................... 28
    2.9.1 Tensile ................................................... 28
    2.9.2 Suture/Tissue Pullout Test ............................... 31
    2.9.3 Stress Relaxation ......................................... 32
    2.9.4 Cyclic Loading ............................................. 34
    2.9.5 Surface Friction ........................................... 35
  2.10 Chemical Stability ............................................ 36
  2.11 Antibacterial Sutures ......................................... 38
  2.12 Surgical Situations ........................................... 38
    2.12.1 Orthopedic ............................................... 39
    2.12.2 Dermal (Skin) ............................................. 43
    2.12.3 Cardiovascular ........................................... 45
    2.12.4 Gynecology ............................................... 49
    2.12.5 Pancreatic Fistula Surgery ............................... 50
    2.12.6 Dermal Closures ......................................... 51
    2.12.7 Scalp Closure Wound ...................................... 51
    2.12.8 Bone ...................................................... 51
    2.12.9 Ophthalmology ............................................ 52
  2.13 Structures of Tissues ......................................... 54
    2.13.1 Cardiovascular Tissues ................................... 55
    2.13.2 Respiratory and Digestive Tissues ....................... 62
    2.13.3 Urogenital Organ Tissues ................................ 71
  2.14 Biomechanics .................................................. 73
### 2.14.1 Symbols ...................................................... 73
### 2.14.2 Vector Mathematics ......................................... 75
### 2.14.3 Continuum Mechanics ....................................... 77
### 2.14.4 Constitutive Modeling ....................................... 80
### 2.14.5 Finite Element Modeling .................................... 93

#### 3 Barbed Suture Prototyping .................................. 100
3.1 Principle .......................................................... 100
3.1.1 Methods to Mount Cutting Blade .............................. 100
3.1.2 Batch Processes (Single and Multiple Barbs) ............... 100
3.2 Current Invention .................................................. 101
3.2.1 Machine ........................................................... 101
3.2.2 Continuous Process ............................................. 101
3.2.3 Path of Suture .................................................... 101
3.2.4 Take-up Assembly ............................................... 104
3.2.5 Let-off Assembly ............................................... 105
3.2.6 Barb Suture Cutting Process Control .......................... 105
3.2.7 Doffing ............................................................ 106
3.2.8 Specimen Individualization ..................................... 107
3.2.9 Horizontal Force Stabilizer (HFS) ............................. 108
3.2.10 Zero Blade Calibration .......................................... 110
3.2.11 Cutting Zone (CZ) .............................................. 115
3.2.12 Blade Assembly ................................................ 118
3.2.13 Cutting Base Assembly ........................................ 122
3.2.14 Image Analysis System ........................................ 124
3.2.15 Barb Quality ..................................................... 129

#### 4 Materials and Methods ........................................ 132
4.1 Suture Material .................................................... 132
4.2 Image Analysis ..................................................... 132
4.2.1 Barb geometry ................................................... 132
4.3 Design of Experiments ............................................. 133
4.4 Specimen Preparation .............................................. 134
4.4.1 Tensile test ...................................................... 134
4.4.2 Tissue Pullout Test ............................................. 134
4.5 Experiments .......................................................... 137
4.5.1 Tensile Testing .................................................. 137
4.5.2 Single Barb Pressure Point Loading .......................... 138
4.5.3 Suture/Tissue Pullout Test .................................... 141
4.6 Finite Element Analysis ........................................... 143
4.6.1 High Performance Computing Resources ..................... 143
4.6.2 Suture material properties ................................... 144
4.6.3 Tissue Material Properties .................................... 152
4.6.4 Solid Modeling and Meshing .................................. 154
4.6.5 New Design : ‘Geomcirc’ ....................................... 166
4.6.6 Boundary conditions ............................................ 168
4.7 Statistics ............................................................ 169
5 Results and Discussion ................................................. 170
5.1 Images of Prototyped Barbed Sutures .................... 170
5.2 Image Analysis of Prototyped Barbed Sutures ........... 171
   5.2.1 Diameter ........................................ 171
   5.2.2 Barb Geometry .................................. 172
5.3 Tensile Testing .............................................. 174
   5.3.1 Elongation at Peak Tensile Load .................. 174
   5.3.2 Peak Tensile Load ................................ 177
5.4 Suture/Tissue Pullout Testing ............................. 179
   5.4.1 Skin Tissue ...................................... 179
   5.4.2 Tendon Tissue ................................... 181
5.5 Finite Element Analysis .................................. 183
   5.5.1 Point Loading of a Single Barb .................. 183
   5.5.2 Effect of Varying the Cut Angle and Cut Depth .... 185
   5.5.3 New Design ’Geomcirc’ ............................ 191
   5.5.4 Tendon and Skin Tissue Pullout Test Simulations . 197
   5.5.5 Limitations of FEA ............................... 210
   5.5.6 Benefits of the FEA study ......................... 211
6 Conclusions ......................................................... 213
   6.1 Prototyping ............................................. 215
   6.2 Experiments and Simulations ............................ 215
7 Future Work ......................................................... 218
Appendices ......................................................... 233
   Appendix A .............................................. 234
   Appendix B .............................................. 236
   Appendix C .............................................. 267
   Appendix D .............................................. 268
   Appendix E .............................................. 269
   Appendix F .............................................. 270
   Appendix G .............................................. 271
   Appendix H .............................................. 272
   Appendix I .............................................. 273
   Appendix J .............................................. 274
   Appendix K .............................................. 275
   Appendix L .............................................. 276
   Appendix M .............................................. 277
   Appendix N .............................................. 278
   Appendix O .............................................. 279
   Appendix P .............................................. 280
LIST OF TABLES

Table 2.1 Suture sizes [nSA: Nonsynthetic absorbable; nAaS : Nonabsorbable and synthetic absorbable AnA: Absorbable and nonabsorbable materials] [25] .............. 7

Table 2.2 Suture sizes for different types of tissues ........................................... 7

Table 2.3 Suture biomaterials [86, 25] ................................................................. 12

Table 2.4 Suture thermal properties [25] ............................................................. 13

Table 2.5 Effect of diameter on tensile properties [112] .................................... 30

Table 2.6 Dynamic mechanical behavior of different polymers [25] ................. 33

Table 2.7 Suture strength retention [25] ............................................................. 37

Table 2.8 Blood pressure [12] .............................................................................. 46

Table 2.9 Default Parameters for Contact Analysis ............................................ 99

Table 4.1 Design of experiment for tissue specific barbed sutures .................. 133

Table 4.2 Barbed suture experiment: Tensile test ............................................ 133

Table 4.3 Barbed suture experiment: Skin tissue pullout test ......................... 133

Table 4.4 Barbed suture experiment: Tendon tissue pullout test .................... 134

Table 4.5 Prony coefficients for shear relaxation response ............................ 149

Table 4.6 Prony coefficients for bulk relaxation response ............................. 152
Table 4.7 Prony coefficients for tendon tissue relaxation..................153
Table 4.8 Prony coefficients for skin tissue relaxation ......................154
Table 5.1 Comparison of simulated and experimental values ..................183
LIST OF FIGURES

Figure 2.1 Polyglycolic acid ................................................................. 8
Figure 2.2 Polydioxanone ................................................................. 9
Figure 2.3 Maxon ................................................................. 9
Figure 2.4 Monocryl .......................................................... 10
Figure 2.5 Nylon 6 .......................................................... 10
Figure 2.6 Nylon 6,6 .......................................................... 10
Figure 2.7 Polytetrafluoroethylene .................................................. 10
Figure 2.8 Polyethylene terephthalate ............................................. 11
Figure 2.9 Classification chart for surgical sutures ......................... 13
Figure 2.10 A type of knotless suture with spherical projections .......... 15
Figure 2.11 A knotless suturing device ........................................... 15
Figure 2.12 Slender barbed projections fixed on a center filament for tissue approximation ................................................................. 16
Figure 2.13 Barbed suturing apparatus ........................................... 16
Figure 2.14 A photomicrograph of a polished surgical cat-gut suture showing grooves ................................................................. 17
Figure 2.15 Wavy filament surface a result of pulsatile polymer flow .... 17
Figure 2.16 Different types projections on knotless suture designs ........ 18
Figure 2.17 A bi-directional suture (1) and a uni-directional suture (2) .... 18
Figure 2.18 Methods for creating barbs on a monofilament suture ........ 19
Figure 2.19 Laser cutting method for creating barb on a suture monofilament ... 20
Figure 2.20 Paths of blade while creating a barb on a monofilament suture ... 21
Figure 2.21 Monofilament suture clamping device for creating barbs .......... 22
Figure 2.22 Rotating disc with blades for creating barbs ................. 22
Figure 2.23 Rotating die for creating barbs. .................................................. 23
Figure 2.24 Suturing with bi-directional barbed suture ................................. 24
Figure 2.25 Suturing techniques with a barbed suture. ................................. 25
Figure 2.26 Zones at the left end of a bi-directional barbed suture .......... 26
Figure 2.27 Barb geometry ........................................................................... 26
Figure 2.28 Light microscopic images of barbed sutures ........................... 27
Figure 2.29 Core sheath structure of PDSII [B=sheath] ............................... 29
Figure 2.30 Suture tissue pullout test ............................................................ 31
Figure 2.31 A soft barb unable to penetrate the tissue ................................. 33
Figure 2.32 Locking of barbed suture in anchor eyelet ............................... 36
Figure 2.33 Flexor tendon repair (A: 4 strand; B: 8 strand) with knotted sutures [2] 40
Figure 2.34 Suture anchor in tendon reconstruction. [99] ............................ 41
Figure 2.35 Suture anchor in tendon reconstruction. [105] ............................ 42
Figure 2.36 Suture anchor in tendon reconstruction. [105] ............................ 42
Figure 2.37 Suture with bead and anchor in bridge tendon repair. [115] ........ 43
Figure 2.38 Cross section of human skin (bar = 100 microns) [80] ................. 45
Figure 2.39 Pressure expansion curve for the human abdominal skin in 10th lunar month of pregnancy [52] ................................................................. 45
Figure 2.40 Protruding tail from suture knots made while suturing mitral valve tissue ......................................................................................... 47
Figure 2.41 Suturing artery (A,B,C) and vein (D,E,F) [45] ............................ 47
Figure 2.42 Fibrosis in vein and artery [45] .................................................... 48
Figure 2.43 Suture anchors and tissue pullout test [88] ............................... 52
Figure 2.44 Upper eyelid ptosis repair with knotted sutures [21] .................. 53
Figure 2.45 Different tissues in various organs of the human body [81] ....... 54
Figure 2.46 Striated cardiac muscle of the heart [102] ............................... 55
Figure 2.47 Stress strain curve for cardiac muscle in persons 20 to 29 years of age [52] .......................................................... 56
Figure 2.48 Cross section of a medium artery and medium vein (bar = 250 microns) [80] .................................................. 57
Figure 2.49 Cross section of an aorta (bar = 1 mm) [80] .............. 57
Figure 2.50 Cross section of a medium artery (bar = 100 microns) [80] .......... 58
Figure 2.51 Stress strain curve for arterial tissue in persons 20 to 29 years of age [52] 59
Figure 2.52 Cross section of a large vein (bar = 250 microns) [80] ............ 60
Figure 2.53 Cross section of a medium vein (bar = 100 microns) [80] ............. 61
Figure 2.54 Stress strain curve of human venous tissue in persons of age group 20 to 29 years. [52] ................................................ 61
Figure 2.55 Cross section of larynx wall tissue (bar = 250 microns) [80] ........... 62
Figure 2.56 Cross section of the upper third of an oesophagus (bar = 1 mm) [80] . 62
Figure 2.57 Stress strain curve of esophagus of persons 20 to 29 years of age [52] . 63
Figure 2.58 Cross section of the fundus region of the stomach (bar = 250 microns) [80] ................................................ 64
Figure 2.59 Cross section of the pyloric region of the stomach (bar = 250 microns) [80] ............................................ 65
Figure 2.60 Stress strain curve of the human stomach tissue in the transverse direction [52] ................................................ 66
Figure 2.61 Stress strain curve of the human stomach tissue in the longitudinal direction [52] ........................................ 66
Figure 2.62 Cross section of upper region of duodenum wall tissue (bar = 250 microns) [80] ............................................. 68
Figure 2.63 Cross section of lower region of duodenum wall tissue (bar = 250 microns) [80] ............................................. 68
Figure 2.64 Stress strain curves for small intestine in persons between 20 to 29 years of age [52] ............................................. 69
Figure 2.65 Cross section of jejunum/ileum wall tissue (bar = 250 microns) [80] ... 70
Figure 2.66 Stress strain curve for the large intestine of persons 20 to 29 years of age [52] ............................................. 70
Figure 3.10 A fractured barb ................................................................. 117
Figure 3.11 Adjustable guide ................................................................. 118
Figure 3.12 Steps in blade preparation .................................................... 119
Figure 3.13 A surgical skin graft blade super-glued to metal plate ................. 120
Figure 3.14 Damaged blade profile (carpet blade) ....................................... 121
Figure 3.15 The base fixture and base-to-MTS connector assembly .................. 122
Figure 3.16 Barbed Suture Imaging Clamp (BSIC) ...................................... 124
Figure 3.17 Barb geometry measurement in Matlab ..................................... 127
Figure 3.18 A good quality barb ............................................................. 129
Figure 3.19 Chipped suture due to unexpected blade contact ......................... 130
Figure 3.20 Barb bent due to failure to release ET-2 at take-up ...................... 131
Figure 3.21 A dead barb with no functional tip ......................................... 131

Figure 4.1 Specimen preparation for skin and tendon tissue pullout test .......... 135
Figure 4.2 Threading the barb into the tissue for preparing the pullout specimen . 136
Figure 4.3 Barb suture specimen mounting for tensile test using capstan clamping
effect ........................................................................................................ 138
Figure 4.4 Barb tip glued to rounded wire tip ............................................. 139
Figure 4.5 Barb tip glued to a pointed barbed wire tip ................................... 139
Figure 4.6 Pure loading of single barb ....................................................... 140
Figure 4.7 Specimen mounted ready for a skin tissue pullout test ................. 141
Figure 4.8 Specimen mounted ready for a tendon tissue pullout test ............ 142
Figure 4.9 Suture specimen geometry for measuring shear relaxation modulus ... 146
Figure 4.10 Suture mounting for cutting specimens ..................................... 147
Figure 4.11 Method of cutting suture specimen ......................................... 148
Figure 4.12 Calculating shear relaxation modulus for suture monofilament .... 148
Figure 4.13 Measuring bulk relaxation modulus of monofilament sutures ....... 150
Figure 4.14 Calculating shear relaxation modulus for suture monofilament ........ 151
Figure 4.15 Unbarbed suture bulk relaxation modulus in axial direction .......... 152
Figure 4.16 Human tendon tissue relaxation modulus [7] ......................... 153
Figure 4.17 Porcine skin tissue relaxation modulus [69] ........................... 154
Figure 4.18 Solid model of single barb for point loading of barb tip ............. 156
Figure 4.19 Lines and areas of a single barbed suture ............................. 156
Figure 4.20 Meshed barb: 150° cut angle & 0.12mm cut depth ................. 158
Figure 4.21 Meshed barb: 160° cut angle & 0.12mm cut depth ................. 158
Figure 4.22 Meshed barb: 170° cut angle & 0.12mm cut depth ................. 159
Figure 4.23 Straight pullout of single barb anchored in tissue ................. 160
Figure 4.24 Lines and areas of a anchored single barb in tissue ............... 161
Figure 4.25 Straight pullout of single barb anchored in tissue ................. 161
Figure 4.26 Straight pullout test of single barb anchored in tissue .......... 162
Figure 4.27 Magnified view: Anchored tissue ................................ 163
Figure 4.28 Straight pullout test of single barb anchored in tissue .......... 164
Figure 4.29 Target: Barbed suture [TARGE170 elements] ....................... 165
Figure 4.30 Contact: Tissue [CONTA174 elements] ............................ 166
Figure 4.31 A ‘Geomcirc’ barbed suture ........................................ 167
Figure 4.32 A meshed ‘Geomcirc’ barbed suture .................................. 167

Figure 5.1 150° at 0.07mm .................................................. 170
Figure 5.2 150° at 0.12mm .................................................. 170
Figure 5.3 150° at .18mm .................................................. 170
Figure 5.4 160° at 0.07mm .................................................. 171
Figure 5.5 160° at 0.12mm .................................................. 171
Figure 5.6 160° at .18mm .................................................. 171
Figure 5.7 170° at 0.07mm .................................................. 171
Figure 5.8  170° at 0.12mm ................................................................. 171
Figure 5.9  170° at .18mm ............................................................... 171
Figure 5.10 Mean±S.E. for suture diameter ................................. 172
Figure 5.11 Mean±S.E. for barb cut angle ..................................... 173
Figure 5.12 Mean±S.E. for barb cut depth ...................................... 174
Figure 5.13 Mean±S.E. for elongation % at peak tensile load ............. 175
Figure 5.14 Profile of a barbed and unbarbed suture tensile curve ......... 176
Figure 5.15 Mean±S.E. for peak tensile load ................................. 177
Figure 5.16 Barbed suture peak tensile load [Mean±S.E.] ................... 178
Figure 5.17 Peak tensile skin tissue pullout load (mean±S.E.) .......... 179
Figure 5.18 Chart ........................................................................... 179
Figure 5.19 Peak tensile tendon tissue pullout load (mean±S.E.) ....... 181
Figure 5.20 Chart ........................................................................... 181
Figure 5.21 Metal wire barb tip pull experimental curve .................... 184
Figure 5.22 150°at 0.07mm ............................................................ 185
Figure 5.23 150°at 0.12mm ............................................................ 185
Figure 5.24 150°at .18mm .............................................................. 185
Figure 5.25 160°at 0.07mm ............................................................ 185
Figure 5.26 160°at 0.12mm ............................................................ 185
Figure 5.27 160°at .18mm .............................................................. 185
Figure 5.28 170°at 0.07mm ............................................................ 185
Figure 5.29 170°at 0.12mm ............................................................ 185
Figure 5.30 170°at .18mm .............................................................. 185
Figure 5.31 Barb tip displacement at point pressure load ................... 186
Figure 5.32 Effect of cut angle on cut line stresses at 0.07mm cut depth 187
Figure 5.33 Effect of cut angle on cut line stresses at 0.12mm cut depth 187
Figure 5.34 Effect of cut angle on cut line stresses at 0.18mm cut depth ............. 188
Figure 5.35 Effect of cut depth on cut line stresses at 150° cut angle............... 189
Figure 5.36 Effect of cut depth on cut line stresses at 160° cut angle............... 189
Figure 5.37 Effect of cut depth on cut line stresses at 170° cut angle............... 190
Figure 5.38 Displacement (UZ) of new and original designs.......................... 191
Figure 5.39 Increased resiliency of new design........................................... 191
Figure 5.40 SYZ: New[c-150-07-10]; Original[150-07] at 0.07mm ................. 192
Figure 5.41 SYZ: New[c-150-07-10]; Original[150-07] at 0.12mm ................. 193
Figure 5.42 SYZ: New[c-150-07-10]; Original[150-07] at 0.18mm ................. 193
Figure 5.43 'Geomcirc': Vector plot(displacement) [ca:160°. cd;0.07mm] ......... 194
Figure 5.44 Original: Vector plot(displacement)[ca:160°. cd;0.07mm] ............. 195
Figure 5.45 'Geomcirc': Peeling stress (SYZ) (ca:160°. cd;0.07mm) ............. 196
Figure 5.46 Original: Peeling stress (SYZ) (ca:160°. cd;0.07mm) ................. 196
Figure 5.47 Tendon tissue pullout test simulation ...................................... 198
Figure 5.48 UZ: Tendon tissue & barb (ca:150°. cd;0.07mm) ....................... 199
Figure 5.49 Skin tissue pullout test simulation ........................................ 200
Figure 5.50 UZ: Skin tissue & barb (ca:150°. cd;0.07mm) ......................... 200
Figure 5.51 UY: Tendon tissue under barb (ca:150°. cd;0.07mm) ................ 201
Figure 5.52 UY: Skin tissue under barb (ca:150°. cd;0.07mm) .................... 202
Figure 5.53 Simulation comparison: Skin vs. Tendon tissue......................... 203
Figure 5.54 SYZ: skin [s-160-07] & tendon [t-160-07](cut depth 0.07mm) ....... 203
Figure 5.55 SYZ: skin [s-160-07] & tendon [t-160-07](cut depth 0.18mm) ....... 204
Figure 5.56 Displacement - symmetry-cut side (ca:150°. cd;0.07mm) ............ 205
Figure 5.57 Direction of displacement - LEFT side (ca:150°. cd;0.07mm) ....... 205
Figure 5.58 Wake of the barb (ca:150°. cd;0.07mm) ................................ 206
Figure 5.59 Barb fracture: Tensile & bending effect (ca:150°. cd;0.18mm) ..... 207
Figure 5.60 Tendon tissue behavior in a pullout test (ca:150°, cd:0.07mm) .......... 208
Figure 5.61 Tendon tissue behavior in a pullout test (ca:150°, cd:0.07mm) .......... 209
Figure 5.62 Tendon tissue behavior in a pullout test (ca:150°, cd:0.07mm) .......... 210

Figure 7.1 Curved suture ......................................................... 218
Figure 7.2 Meshed curved suture .............................................. 218
Figure 7.3 Magnified view of meshed barb in curved suture ......................... 219
Figure 7.4 A copper metal barb .................................................. 221
Figure 0.5 Variation in diameter for 150° .................................... 267
Figure 0.6 Variation in diameter for 160° .................................... 267
Figure 0.7 Variation in diameter for 170° .................................... 267
Figure 0.8 Variation in cut angle 150° ...................................... 268
Figure 0.9 Variation in cut angle 160° ...................................... 268
Figure 0.10 Variation in cut angle 170° ..................................... 268
Figure 0.11 Variation in cut depth 150° ..................................... 269
Figure 0.12 Variation in cut depth 160° ..................................... 269
Figure 0.13 Variation in cut depth 170° ..................................... 269
Figure 0.14 150° at 0.07mm ...................................................... 270
Figure 0.15 150° at 0.12mm ...................................................... 270
Figure 0.16 150° at .18mm ....................................................... 270
Figure 0.17 160° at 0.07mm ...................................................... 270
Figure 0.18 160° at 0.12mm ...................................................... 270
Figure 0.19 160° at .18mm ....................................................... 270
Figure 0.20 170° at 0.07mm ...................................................... 270
Figure 0.21 170° at 0.12mm ...................................................... 270
Figure 0.22 170° at .18mm ....................................................... 270
Figure 0.23 150° at 0.07mm ...................................................... 271
Figure 0.24 150° at 0.12 mm ......................................................... 271
Figure 0.25 150° at 0.18 mm ......................................................... 271
Figure 0.26 160° at 0.07 mm ......................................................... 271
Figure 0.27 160° at 0.12 mm ......................................................... 271
Figure 0.28 160° at 0.18 mm ......................................................... 271
Figure 0.29 170° at 0.07 mm ......................................................... 271
Figure 0.30 170° at 0.12 mm ......................................................... 271
Figure 0.31 170° at 0.18 mm ......................................................... 271
Figure 0.32 150° at 0.07 mm ......................................................... 272
Figure 0.33 150° at 0.12 mm ......................................................... 272
Figure 0.34 150° at 0.18 mm ......................................................... 272
Figure 0.35 160° at 0.07 mm ......................................................... 272
Figure 0.36 160° at 0.12 mm ......................................................... 272
Figure 0.37 160° at 0.18 mm ......................................................... 272
Figure 0.38 170° at 0.07 mm ......................................................... 272
Figure 0.39 170° at 0.12 mm ......................................................... 272
Figure 0.40 170° at 0.18 mm ......................................................... 272
Figure 0.41 150° at 0.07 mm ......................................................... 273
Figure 0.42 150° at 0.12 mm ......................................................... 273
Figure 0.43 150° at 0.18 mm ......................................................... 273
Figure 0.44 160° at 0.07 mm ......................................................... 273
Figure 0.45 160° at 0.12 mm ......................................................... 273
Figure 0.46 160° at 0.18 mm ......................................................... 273
Figure 0.47 170° at 0.07 mm ......................................................... 273
Figure 0.48 170° at 0.12 mm ......................................................... 273
Figure 0.49 170° at 0.18 mm ......................................................... 273
Figure 0.50 150° at 0.07mm .................................................. 274
Figure 0.51 150° at 0.12mm .................................................. 274
Figure 0.52 150° at .18mm .................................................. 274
Figure 0.53 160° at 0.07mm .................................................. 274
Figure 0.54 160° at 0.12mm .................................................. 274
Figure 0.55 160° at .18mm .................................................. 274
Figure 0.56 170° at 0.07mm .................................................. 274
Figure 0.57 170° at 0.12mm .................................................. 274
Figure 0.58 170° at .18mm .................................................. 274
Figure 0.59 150° at 0.07mm .................................................. 275
Figure 0.60 150° at 0.12mm .................................................. 275
Figure 0.61 150° at .18mm .................................................. 275
Figure 0.62 160° at 0.07mm .................................................. 275
Figure 0.63 160° at 0.12mm .................................................. 275
Figure 0.64 160° at .18mm .................................................. 275
Figure 0.65 170° at 0.07mm .................................................. 275
Figure 0.66 170° at 0.12mm .................................................. 275
Figure 0.67 170° at .18mm .................................................. 275
Figure 0.68 150° at 0.07mm .................................................. 276
Figure 0.69 150° at 0.12mm .................................................. 276
Figure 0.70 150° at .18mm .................................................. 276
Figure 0.71 160° at 0.07mm .................................................. 276
Figure 0.72 160° at 0.12mm .................................................. 276
Figure 0.73 160° at .18mm .................................................. 276
Figure 0.74 170° at 0.07mm .................................................. 276
Figure 0.75 170° at 0.12mm .................................................. 276
Figure 0.76 170° at .18mm ................................................. 276
Figure 0.77 150° at 0.07mm ............................................. 277
Figure 0.78 150° at 0.12mm ............................................. 277
Figure 0.79 150° at .18mm ............................................. 277
Figure 0.80 160° at 0.07mm ............................................. 277
Figure 0.81 160° at 0.12mm ............................................. 277
Figure 0.82 160° at .18mm ............................................. 277
Figure 0.83 170° at 0.07mm ............................................. 277
Figure 0.84 170° at 0.12mm ............................................. 277
Figure 0.85 170° at .18mm ............................................. 277
Figure 0.86 150° at 0.07mm ............................................. 278
Figure 0.87 150° at 0.12mm ............................................. 278
Figure 0.88 150° at .18mm ............................................. 278
Figure 0.89 160° at 0.07mm ............................................. 278
Figure 0.90 160° at 0.12mm ............................................. 278
Figure 0.91 160° at .18mm ............................................. 278
Figure 0.92 170° at 0.07mm ............................................. 278
Figure 0.93 170° at 0.12mm ............................................. 278
Figure 0.94 170° at .18mm ............................................. 278
Figure 0.95 150° at 0.07 .................................................. 279
Figure 0.96 150° at 0.12 .................................................. 279
Figure 0.97 150° at .18 .................................................. 279
Figure 0.98 160° at 0.07 .................................................. 279
Figure 0.99 160° at 0.12 .................................................. 279
Figure 0.100 160° at .18 .................................................. 279
Figure 0.101 170° at 0.07 .................................................. 279
Figure 0.102 70° at 0.12 ................................................................. 279
Figure 0.103 70° at .18 ................................................................. 279
Figure 0.104 50° at 0.07 ............................................................... 280
Figure 0.105 50° at 0.12 ............................................................... 280
Chapter 1

Introduction

1.1 Background

The successful performance of a surgical suture has until recently depended on the clinicians’ ability to tie an efficient and secure knot. In fact, suture performance has inevitably been closely associated with knot security. However, from time to time clinicians have experimented with various types of knotless sutures, which, if mechanically secure, can provide certain advantages over the traditional knotted suture.

One type of knotless suture is the "barbed" suture, in which protruding barbs are placed in one or two directions along the length of a monofilament suture [79]. In vitro studies have already reported incorporating image analysis to measure the barb geometry [82], comparing the tissue holding capacity of a barbed suture and a knotted suture [82, 83], and the effect of suture polymer microstructure on barb tissue holding capacity in a suture tissue pullout test [86]. In addition, in vivo animal studies have described the biostability of such sutures when exposed to body fluids [26]. In fact, barbed sutures have been found to be clinically successful in subdermal wound closure and in tendon repair in human patients. Currently they are used successfully by cosmetic surgeons such as Dr. Gregory Ruff, to undertake facelift and masklift procedures.

It would therefore be interesting to see if we could use barbed sutures for the repair and apposition of other organs and tissues having a wide range of different mechanical properties, and finding how this question might be answered is the ultimate goal of this study. For example, the geometric shape, frequency, alignment and sequence of barbs for a particular material may be optimized for use with skin tissue. However, this same barbed design may not be optimal for a suture to be used in tendon tissue.
or fatty tissue. It is therefore of great interest in this study to attempt to optimize the barb geometry and frequency for each type of suture material in each type of tissue. Finite element analysis is an important tool to do virtual prototyping and testing of the new designs and geometries of barbed sutures. Once the FEA model is optimized in the virtual environment, then manufacturing of that particular type of suture for a given tissue can be undertaken. This approach in the design and development of new tissue specific variants of barbed sutures will improve the efficiency of the research and development process.

1.2 Objectives

The primary objectives of this study are:

1. to design and establish a new prototyping method that will prepare barbed sutures with precisely controlled geometries and frequencies.

2. to quantify the effect of different independent variables in the geometry of a single barb, such as cut depth and cut angle, on the barb’s tissue holding capacity.

3. to create a 3D solid model for a single barb and run a finite element analysis simulation using Ansys software using point pressure loading at the tip of the barb and compare the results with the experimental result where the barb tip is pulled by metal wire. Optimize and validate the model so as to achieve a close approximation to and prediction of the experimental result.

4. to create and analyse 3D solid models so as to study the effect of varying cut angle and cut depth on the displacement under point pressure loading at the tip of the barb

5. to create and analyse 3D solid models of virtual suture/tissue pullout tests for skin and tendon tissue

6. to develop and test a virtual prototype of a new and improved design of barbed surgical suture

The steps to achieve the above objectives are listed below:

- experimentally determine the stress-strain and stress relaxation behavior of monofilament sutures under static conditions
• use curve fitting in Ansys to find the Prony series constants from the experimental data
• create barbs with different designs and geometries for use with various tissue types with varying properties. Note some experimental data for tissue properties have already been reported in the literature
• run experiments to find the tissue holding capacity of the specific design for a particular type of tissue or tissue simulant
• undertake a solid model analysis of various barb designs
• use finite element analysis software ANSYS to simulate the effect of loading on a single barb
• compare the simulation results with experimental results with a view to validating the FEA model
• analyse the results for barb deformation and areas of stress concentration with a view to optimizing and validating the design of the barb geometry suitable for particular tissue types.

1.3 Outline of Thesis

This thesis is written in a series of chapters. The following list indicates the contents of each chapter:

1. **Introduction:** Describes in general the importance and relevance of barbed suture technology in health care. Lists the primary objectives of the study.

2. **Review of Literature:** Describes various types of knotless sutures, anchors, staples and methods of making the same. The clinical literature is also reviewed and examples of surgeries where barbed sutures have potential advantages are listed.

3. **Barbed Suture Prototyping:** Describes in detail the method of prototyping barbed suture how the equipment was developed for the preparation of barbed sutures for the current project
4. **Materials and Methods:** Describes the type of materials used in this study and different methods used to undertake the laboratory experiments as well as the approach taken to perform finite element simulations.

5. **Results and Discussion:** Describes the results from the tensile and pullout tests undertaken in the laboratory experiments as well as presenting the findings from the various FEA.

6. **Conclusions:** Describes the conclusions from the current study by referring back to the list of primary objectives.

7. **Future Work:** Describes the future possibilities for further research on this project.

8. **Bibliography**

9. **Appendix:** Abbreviations

10. **Appendix:** ANSYS Parametric Design Language (ADPL) script

11. **Appendix:** Variation in diameter

12. **Appendix:** Variation in cut angle

13. **Appendix:** Variation in cut depth

1.4 **Abbreviations**

The list of abbreviations used in the thesis are listed in Appendix 'A'.
Chapter 2

Review of Literature

2.1 Brief History

In this era of technological innovations, the use of barbed surgical sutures have made their mark in the clinical arena. They are advantageous for patients undergoing cosmetic surgery because there is less or no scar formation after surgery [32, 50, 110, 68]. A barbed suture is a special kind of suture which can anastomose tissue without the need of tying a knot [31, 28, 34, 29, 33, 30, 86, 35, 27]. This is possible due to the profile and orientation of the barbs which are incorporated along the outer surface of a monofilament suture. The specific shape, geometry and placement of a series of barbs can be prepared by a variety of methods. One such method involves the use of a sharp razor to cut the rodlike monofilament so as to generate the required geometric design [79]. These geometrical designs may be inspired from nature, such as the arthropodic suture. For example, the powerful jaws of the army ants have inspired knotless suture staples for wound closure [103].

Knot security is still an important issue for knotted sutures [100, 24]. However, barbed sutures eliminate this type of risk associated with knot failure. Even so, the barb geometry has to be precise so that it can absorb the energy involved in holding different types of tissues together at the site of wound closure. Therefore, while designing a barb for a particular tissue, the primary objective is to design the barb so that it can sustain the force exerted by the surrounding tissue during the entire healing period. The forces the tissues may exert on the barbs of a suture may be static or dynamic. In dynamic situations the barbs will experience cyclic fatigue stresses and strains. Given that all known polymers that are used for making the barbed sutures exhibit viscoelastic
behaviour, their mechanical performance may be associated with hysteresis, and the barb may experience permanent deformation even when the loads and extensions are well below the elastic limit. One such property is stress relaxation, which can be useful. Consider the situation in which a barbed suture is sewn across a wound or incision and contains barbs distributed along its entire length. The suture can relax and each barb can conform independently to the optimal required forces in each region of the suture. Thus stress relaxation serves as a mechanism to eliminate unnecessary forces and stress concentrations that the suture might exert on the wound tissue. This can contribute to reduced trauma and tissue necrosis, foster quicker healing and reduce scar tissue formation.

**Suture sizes:**

Table 2.1 shows the United States Pharmacopoeia (USP) standard size number for permanent sutures together with the diameter range for the respective sizes. In general, the larger the number above zero, the larger the suture size. However if the number is followed by a zero, it means the opposite, i.e. the larger the number of zeros, corresponds to smaller sutures. So '3-0' means '000', which is finer than size '2−05'.

\[ 7 > \ldots > 3 > 2 > 1 > 0 > 1-0 > 2-0 > 3-0 > \ldots > 11-0 \]

(large suture diameter) (small suture diameter)
Figure below shows important information.

Table 2.1: Suture sizes [nSA: Nonsynthetic absorbable; nAaS : Nonabsorbable and synthetic absorbable AnA: Absorbable and nonabsorbable materials] [25]

<table>
<thead>
<tr>
<th>USP size codes</th>
<th>EP size codes</th>
<th>Suture diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>nSA</td>
<td>nAaS</td>
<td>AnA</td>
</tr>
<tr>
<td>11/0</td>
<td>0.1</td>
<td>0.01</td>
</tr>
<tr>
<td>10/0</td>
<td>0.2</td>
<td>0.02</td>
</tr>
<tr>
<td>9/0</td>
<td>0.3</td>
<td>0.03</td>
</tr>
<tr>
<td>8/0</td>
<td>0.4</td>
<td>0.04</td>
</tr>
<tr>
<td>7/0</td>
<td>0.5</td>
<td>0.05</td>
</tr>
<tr>
<td>6/0</td>
<td>0.6</td>
<td>0.06</td>
</tr>
<tr>
<td>5/0</td>
<td>0.7</td>
<td>0.07</td>
</tr>
<tr>
<td>4/0</td>
<td>0.8</td>
<td>0.08</td>
</tr>
<tr>
<td>3/0</td>
<td>0.9</td>
<td>0.09</td>
</tr>
<tr>
<td>2/0</td>
<td>1.0</td>
<td>0.10</td>
</tr>
<tr>
<td>1/0</td>
<td>1.1</td>
<td>0.11</td>
</tr>
<tr>
<td>0/0</td>
<td>1.2</td>
<td>0.12</td>
</tr>
<tr>
<td>1</td>
<td>1.3</td>
<td>0.13</td>
</tr>
<tr>
<td>2</td>
<td>1.4</td>
<td>0.14</td>
</tr>
<tr>
<td>3</td>
<td>1.5</td>
<td>0.15</td>
</tr>
</tbody>
</table>

The various suture sizes used for different types of surgery with particular tissue types are shown in Table 2.2.

Table 2.2: Suture sizes for different types of tissues

<table>
<thead>
<tr>
<th>Suture size range</th>
<th>10-0 to 8-0</th>
<th>7-0 to 5-0</th>
<th>4-0 to 3-0</th>
<th>2-0 to 0</th>
<th>1 to 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>microvascular</td>
<td>ophthalmic</td>
<td>skin</td>
<td>abdominal</td>
<td>rib retention</td>
<td></td>
</tr>
<tr>
<td>corneal</td>
<td>neural</td>
<td>subcutaneous</td>
<td>stomach</td>
<td>cutaneous stents</td>
<td></td>
</tr>
<tr>
<td>vascular</td>
<td>bladder</td>
<td>hernia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ureteral</td>
<td>bowel</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

So far barbed sutures have only been made from monofilaments. These monofilaments are normal sutures that are classified either as resorbable or as nonresorbable [13]. Different types of polymeric materials have been used for injection molding barbed surgical sutures. Some of these polymers are polypropylene, polyimide, polyamide (Nylon 6 and Nylon 66), polyester and polycarbonate, which comprise the nonresorbable sutures. Also, bioreosorbable polymers, such as polylactic acid, polyglycolic acid, polyglactin, polyepislon-caprolactone, polydioxanone, polyoorthoester, polyethylene oxide, and their copolymers, can also be used [43]. The needles for these sutures may be straight or curved depending upon the end use. They may be manufactured
from stainless steel (e.g. 302, 304 and 316 series), cobalt-iron alloys (e.g. Elgiloy and Carpenter MP35), nickel and nickel alloys (e.g. alloy 42) or nickel-titanium alloys [43].

2.2 Suture Biomaterials

Here is a list of the common types of polymeric materials used to make synthetic absorbable and nonabsorbable surgical suture.

**Acronyms:**

- Polyglycolic acid (PGA)
- Polydioxanone (PDS)
- Maxon
- Monocryl
- Nylon 6
- Nylon 6,6
- Polytetrafluoroethylene (PTFE)
- Polyethylene terephthalate (PET)

The chemical structures of the most common suture polymers are given below:

![Chemical Structure of Polyglycolic Acid](image)

**Figure 2.1: Polyglycolic acid**
Figure below shows important information.

Figure 2.2: Polydioxanone

Figure 2.3: Maxon
Figure below shows important information.

Figure 2.4: Monocryl

Figure 2.5: Nylon 6

Figure 2.6: Nylon 6,6

Figure 2.7: Polytetrafluoroethylene
Figure below shows important information.

![Polyethylene terephthalate](image)

Figure 2.8: Polyethylene terephthalate
The suture biomaterials shown in Table 2.3 have been reported by our laboratory earlier to have successfully formed barbed sutures [82, 86].

<table>
<thead>
<tr>
<th>Suture Trade Name</th>
<th>Manufacturer</th>
<th>Polymer Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absorbable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biosyn</td>
<td>Covidien</td>
<td>PGA-PTMC-PDO (60% : 26% : 14%)</td>
</tr>
<tr>
<td>Maxon</td>
<td>Covidien</td>
<td>PGA-PTMC (67.5% : 22.5%)</td>
</tr>
<tr>
<td>Monocryl</td>
<td>Ethicon</td>
<td>PGA-PCL (75%:25%)</td>
</tr>
<tr>
<td>PDS II</td>
<td>Ethicon</td>
<td>PDS (100%)</td>
</tr>
<tr>
<td>Vicryl</td>
<td>Ethicon</td>
<td>PGL copolymer (90%:10%)</td>
</tr>
<tr>
<td>Dexon</td>
<td>Covidien</td>
<td>PG (100%)</td>
</tr>
<tr>
<td>Non-absorbable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethilon</td>
<td>Ethicon</td>
<td>Nylon 6 (100%)</td>
</tr>
<tr>
<td>Nurolon</td>
<td>Ethicon</td>
<td>Nylon 66 (braided)(100%)</td>
</tr>
<tr>
<td>Novafil</td>
<td>Covidien</td>
<td>PTMT (100%)</td>
</tr>
<tr>
<td>Prolene</td>
<td>Ethicon</td>
<td>i-P (100%)</td>
</tr>
<tr>
<td>Mersilene</td>
<td>Ethicon</td>
<td>Polyester (braided)(100%)</td>
</tr>
<tr>
<td>Panacryl</td>
<td>Ethicon</td>
<td>PLG copolymer (95%:5%)</td>
</tr>
</tbody>
</table>

PDO = poly-1,4-dioxane-2-one; PGA = polyglycolic acid; PTMC = polytrimethylene-carbonate; PCL = polycaprolactone; PGL = poly(glycolid-lactide); PG = polyglycolide; PDS = p-dioxanone; PTMT = polytetramethylene terephthalate; i-P = isotactic polypropylene; PLG = poly(lactide-glycolide)
Table 2.4 shows the melting temperature and the glass transition temperature for different suture materials.

Table 2.4: Suture thermal properties [25]

<table>
<thead>
<tr>
<th>Suture Type</th>
<th>$T_m$ °C</th>
<th>$T_g$ °C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vicryl</td>
<td>198.1</td>
<td>36-45</td>
</tr>
<tr>
<td>PDS II</td>
<td>104.7</td>
<td>-10</td>
</tr>
<tr>
<td>Maxon</td>
<td>206.7</td>
<td>20</td>
</tr>
<tr>
<td>Monocryl</td>
<td>-</td>
<td>18-43</td>
</tr>
<tr>
<td>Polypropylene</td>
<td>165</td>
<td>-15</td>
</tr>
<tr>
<td>PTFE</td>
<td>327</td>
<td>-113; 127-130</td>
</tr>
</tbody>
</table>

2.3 Classification of Sutures

Sutures can be classified into different groups depending on their origin (natural or synthetic), their structure (monofilament or braided), their biostability (resorbable or non-resorbable) and whether or not they contain barbs, Figure 2.9.

Figure 2.9: Classification chart for surgical sutures.
2.4 Comparison of Knotted and Knotless Sutures

Until recently most surgical sutures were held in place by the tying of a knot. However, because of the disadvantages of having to tie knots, the idea of a knotless suture has gained increasing interest over recent years.

Disadvantages of knotted sutures:

- Delay of wound healing
- Constriction of blood flow
- Distortion of tissue which can lead to necrosis and scar formation
- Loss of knot security due to increased local stress concentrations

Advantages of barbed knotless sutures:

- Faster placement - eliminates the necessity to tie a knot
- More uniform distribution of holding forces within the tissue
- Elimination of complications associated with knots, e.g. infection and suture "spitting"
- Less scarring and improved cosmesis

2.5 Types of Knotless Sutures

Various types of knotless suturing methods have evolved over the years. Lemole in 1971 patented a suture which had a needle, a notched suture, and a latched collar. After suturing, the suture is pulled to the correct tension for closure and then locked by the latch and collar [77].

Akiyama in 1978 patented a surgical suture with a plurality of spherical projections on the surface. The suture had a needle on one end and a threading member on the other end. This type of suture can close an opening, such as a blood vessel, without tying a knot. Figure 2.10 shows the mold for producing these spherical projections made of a synthetic resin such as polyvinyl alcohol [104].
Figure below shows important information.

Figure 2.10: A type of knotless suture with spherical projections.

Wilk et al patented a suturing device, Figure 2.11, with a looped end which is shown in the figure below. There are four different types of projections on the suture. By passing the needle through the loop and tightening, the suture can be used for two purposes; for closing an open vessel and for tissue approximation, without the need for a knot [62].

Figure 2.11: A knotless suturing device.

Brotz at al in 1996, Figure 2.12, patented a suturing device which has lateral members with spikes in two directions. These lateral members have a pointed tip, and can penetrate tissue for wound closure. Once inserted the lateral members hold the tissue in position [94].
Figure below shows important information.

Figure 2.12: Slender barbed projections fixed on a center filament for tissue approximation.

Yoon in 1993 patented a range of suturing devices useful in endoscopic surgery. Figure 2.13 shows various forms of the suturing apparatus. The surface morphology can be varied from barbs to serrated surfaces. These devices are made of bioresorbable polymers. They have a sharp tip, with a slender barbed length to penetrate through the tissue. Instead of a knot, these devices need to be bent and secured in an adjustable plug or loop so as to hold the tissue in position [54].

Figure 2.13: Barbed suturing apparatus.

One of the first attempts to acknowledge the importance of surface morphology was made by Cox in 1944. He patented an apparatus for grinding and polishing ligatures. His objective was to make a surgical cat-gut suture with a circular cross-section and a smooth surface, Figure 2.14 [3].
Figure below shows important information.

![Image of surgical cat-gut suture showing grooves](image1.png)

Figure 2.14: A photomicrograph of a polished surgical cat-gut suture showing grooves.

It was in 1958 that Matlin et al patented a method for manufacturing wool-like artificial fibers. The fibers he made had a surface structure as shown below. It was produced by imparting an intermittent flow to the molten polymer at the spinneret. These pulses traveled beyond the spinneret into the coagulating bath, Figure 2.15 [9].

![Image of wavy filament surface](image2.png)

Figure 2.15: Wavy filament surface a result of pulsatile polymer flow.

Alcamo in 1964 patented a number of different designs for barbed sutures Figure 2.16. The designs are described as [63]:

- barbs/spicules at acute angles (large barbs)
- barbs/spicules at acute angles (small barbs)
- projections terminating in curved edges
- projections at right angles
- projections having curved edges and alternating directions
- knurled surface
- spiral
- sharp curved edges
• spherically triangular curved facets
• annular notched rings
• sinuous suture body with barbs

Figure 2.16: Different types projections on knotless suture designs.

Buncke in 1999 patented a bi-directional and a uni-directional surgical suture, Figure 2.17. The uni-directional suture had one needle at one end. The bi-directional suture had two needles, one at each end of the monofilament suture (Figure 2.17). While suturing with the uni-directional needle, a combination of two sutures had to be used in opposite directions [56].

Figure 2.17: A bi-directional suture (1) and a uni-directional suture (2).

2.6 Methods of Creating a Barb on a Monofilament Suture

Buncke in 1999 patented three alternative methods of creating a barb on the surface of a monofilament with a diameter ranging from 100 to 500 microns. The first method, shown in Figure 2.18, consists of a bar with cutting blades that moves inwards and outwards against the stationery monofilament to produce barbs. The second method consists of a rotating cutting wheel which has blades on the surface. The monofilament is held under tension and the blades from the opposing pair of wheels cut into the monofilament and push it forward to form two rows of parallel barbs [56].
In another embodiment of his apparatus the barbs are created by the use of a laser. As shown in Figure 2.19 a sharp focusing industrial laser is directed at the cross hatched areas. The laser removes these areas to form barbs. The barbs can be formed in a spiral around the monofilament by inserting twist into the monofilament prior to creating the barbs. When returned to a straightened and relaxed state the barbs then form a spiral around the monofilament suture [56].
Figure 2.19: Laser cutting method for creating barb on a suture monofilament.

Williams et al in 2003 filed an application for patenting methods to form barbs on a monofilament surface. As seen in Figure 2.20, A, B, C, D, show that the principle of cutting is with the sharp edge of a knife. One method of creating a barb is by Method A, wherein the knife has only one degree of freedom. Hence the knife moves along the x-axis to cut the filament and create a barb. In case of Method B, the knife has 2 degrees of freedom. So the knife moves forward in the y direction as it simultaneously moves along the x-axis. The third Method C, consists of a blade which has 3 degrees of freedom. Here the knife moves forward (y axis) on its way down (z axis), and is then pulled out in the x-axis direction after cutting the barb. The Method D, has a blade also with 3 degrees of freedom. But this time the knife has a zig-zag motion imparted to it as shown in Figure 2.20  [39, 6, 84]
Figure below shows important information.

![Diagram showing paths of blade while creating a barb on a monofilament suture.]

Figure 2.20: Paths of blade while creating a barb on a monofilament suture.

Each of the above methods of cutting barbs with blades having different degrees of freedom creates different barb designs. It is this movement of the blade inside the monofilament suture that decides the final geometry of the barb.

As shown in Figure 2.21 the barb cutting apparatus includes a vise assembly with notches. They hold the monofilament firmly along its whole length. The cross-sectional view is shown in A, B and C. The firm grip of the vise ensures the filament is stationary. A blade then comes to cut into the filament to create the barb. Another view of the vise is shown in I and II. The third inset shows the four stages of the suture while barbs are being created. The inset (1) shows a monofilament before cutting in a relaxed state, where the dotted line is the fiber axis. Stage 2 shows the same suture after insertion of twist. In stage (3) the barbs have just been formed. They all lie along the top of the suture. The inset (4) shows the final barbed suture in a relaxed state. The barbs can then be seen formed in a spiral around the monofilament once the twist has been removed.
Figure 2.21 shows monofilament suture clamping device.

In another embodiment for creating barbs on the suture, the suture filament is guided between the feed roller and the delivery roller, Figure 2.22. A cutting apparatus cuts barbs on the tensioned filament between these two rollers [79].

Die embossing, cutting or chemical etching of a flat suture material or injection moulding to create a barbed surgical suture has also been reported [43]. As shown in
Figure 2.23 the flat suture material is being fed between the two roller embossing dies. The dies reform the flat strip of suture material to create barbs. The barbs so formed can be in one direction or two opposing directions.

Figure 2.23: Rotating die for creating barbs.

2.7 Suturing Techniques

Buncke used a uni-directional suture to stitch two pieces of tissue together. This type of suture has only one needle. So, one suture has to be stitched in one direction and another suture is used to stitch in the opposing direction so that the opposing barbs of the two separate sutures hold the tissue in position [56].

Kaplan et al in 2003 filed an application for patenting various suturing techniques with a bi-directional barbed suture [8]. His techniques require the use of only one bi-directional suture to anastomose tissue. Since this type of suture has two needles, and barbs are facing in opposite directions starting from the center of the suture (marked by arrows in Figure 2.24)
Figure 2.24 shows suturing with barbed suture.

The first step in suturing is to put one of the needles through both tissue layers at the center of the wound and to pull the suture through to the center locking point. This is because at this point the first pair of opposing barbs face each other and the suture cannot be pulled further through the tissue against the opposing barbs. To complete the wound closure both ends of the suture can be stitched in various ways such that the entire suture remains concealed beneath the tissue. Figure 2.25 depicts four such suturing techniques [8].
Figure 2.25 shows suturing technique.

Figure 2.25: Suturing techniques with a barbed suture.
2.8 Image Analysis of Barbed Sutures

Barbed surgical sutures can be unidirectional or bidirectional. The left end of a bidirectional suture is shown in Figure 2.26

![Figure 2.26: Zones at the left end of a bi-directional barbed suture](image)

The different zones provided a method of sampling the barbs along the length of the entire suture [86]. The geometry of each barb can be measured and in terms of characterized by different dimensions (Figure 2.27),

![Figure 2.27: Barb geometry](image)

\[\theta = \text{cut angle (angle that blade made with monofilament axis)}\]

\[2 = \text{cut depth, } D_c\]
• 3 = diameter
• 4 = barb angle (angle that the projecting barb made with monofilament axis)
• 5 = barb base length
• 6 = distance between barbs
• 7 = spiral angle
• 8 = barb length
• 9 = cut length, $L_c$ (calculated)

The images of the barbs were taken at 1X, 2X and 6X magnification under a microscope, Figure 2.28.

The measurements were then made directly from these images after calibrating the scale against the number of pixels. The cut length was calculated from Eq. 2.1 [82, 86].

$$Cut - length, L_c = \frac{D_c}{sin(180 - \theta)}$$  \hspace{1cm} (2.1)
2.9 Mechanical Properties

2.9.1 Tensile

The tensile breaking strength and elongation together with the modulus of elasticity, and suture size are important properties that determine a sutures performance [24] An earlier study has concluded that polydioxanone (PDS) sutures have a higher tensile breaking load (max. ~6500kg/sq.cm) than polypropylene (Prolene) sutures (max.~5000 kg/sq.cm) for all sizes between 1 and 3-0. The values for knot strength were lower than for the unknotted monofilaments in all cases. Also, the knot strength was again higher for PDS (max. ~5000 kg/sq.cm) compared to polypropylene Prolene (max. ~3000kg/sq.cm). However, when implanted in a rabbit, the resorbable PDS suture lost all of its strength during the first 56 days in vivo [64]. Both of these types of sutures have been used successfully to make barbed sutures, as reported earlier [82, 86].

The tensile properties of monofilament suture materials of different diameters are depicted in Table 2.5. The initial gauge length was 3 cm. The crosshead speed was not reported. The ePTFE porosity was 50 percent by volume. As expected, the breaking load increased with increasing diameter. However there was an observed increase in breaking tensile strength (stress) as the diameter for the straight monofilaments decreased [112]. While the reasons for this phenomenon were not specified, there is possibly a structural explanation. Stress is force divided by cross-sectional area. So for the same polymer, assuming that it has the same molecular orientation and a homogeneous structure throughout its cross-section, then the force that a monofilament can sustain up to the breaking point should decrease as the monofilament becomes thinner. However, in the case of monofilament sutures, it is known that the crystalline structure and molecular orientation, are not uniform across the width of the cross-section. The rapid quenching process experienced by the outside of the monofilaments during the melt spinning operation leads to a two phase sheath/core structure within the cross-section, Figure 2.29.
Figure 2.29 shows core sheath.

Figure 2.29: Core sheath structure of PDSII [B=sheath]

The sheath has a fixed thickness and contains a more fully developed crystalline structure and molecular orientation, which are associated with higher mechanical resistance compared to the core material. Hence, as the diameter of the monofilament decreases, so the proportion of sheath structure within the cross-section increases, and the overall breaking tensile strength and ability of the monofilament to support stress improves [25].
Table 2.5: Effect of diameter on tensile properties \[112\]

<table>
<thead>
<tr>
<th>Type</th>
<th>Diameter</th>
<th>FL Straight</th>
<th>FL Knotted</th>
<th>E</th>
<th>FE</th>
<th>TS</th>
</tr>
</thead>
<tbody>
<tr>
<td>ETHILON (Nylon)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>0.450</td>
<td>6.60</td>
<td>4.06</td>
<td>6.00</td>
<td>24.02</td>
<td>4152.1</td>
</tr>
<tr>
<td>0</td>
<td>0.380</td>
<td>5.03</td>
<td>2.94</td>
<td>4.64</td>
<td>13.51</td>
<td>4436.1</td>
</tr>
<tr>
<td>2-0</td>
<td>0.315</td>
<td>3.79</td>
<td>2.08</td>
<td>4.12</td>
<td>8.75</td>
<td>4860.1</td>
</tr>
<tr>
<td>3-0</td>
<td>0.247</td>
<td>2.48</td>
<td>1.40</td>
<td>3.30</td>
<td>4.62</td>
<td>5188.9</td>
</tr>
<tr>
<td>4-0</td>
<td>0.188</td>
<td>1.64</td>
<td>0.80</td>
<td>2.92</td>
<td>2.65</td>
<td>5875.3</td>
</tr>
<tr>
<td>5-0</td>
<td>0.145</td>
<td>0.89</td>
<td>0.53</td>
<td>3.11</td>
<td>1.52</td>
<td>5374.7</td>
</tr>
<tr>
<td>6-0</td>
<td>0.088</td>
<td>0.39</td>
<td>0.28</td>
<td>2.33</td>
<td>0.58</td>
<td>6309.9</td>
</tr>
<tr>
<td>GORE-TEX (Expanded polytetrafluoroethylene)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CV2</td>
<td>0.388</td>
<td>4.21</td>
<td>3.70</td>
<td>2.09</td>
<td>5.00</td>
<td>1550.3</td>
</tr>
<tr>
<td>CV3</td>
<td>0.513</td>
<td>3.18</td>
<td>2.86</td>
<td>1.74</td>
<td>3.34</td>
<td>1535.1</td>
</tr>
<tr>
<td>CV4</td>
<td>0.382</td>
<td>1.78</td>
<td>1.75</td>
<td>1.42</td>
<td>1.55</td>
<td>1558.8</td>
</tr>
<tr>
<td>CV5</td>
<td>0.297</td>
<td>1.16</td>
<td>1.04</td>
<td>1.70</td>
<td>1.23</td>
<td>1675.5</td>
</tr>
<tr>
<td>CV6</td>
<td>0.235</td>
<td>0.79</td>
<td>0.68</td>
<td>0.80</td>
<td>0.39</td>
<td>1812.7</td>
</tr>
<tr>
<td>CV7</td>
<td>0.198</td>
<td>0.49</td>
<td>0.47</td>
<td>0.70</td>
<td>0.23</td>
<td>1597.9</td>
</tr>
<tr>
<td>MAXON (Polyglyconate)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>0.550</td>
<td>12.97</td>
<td>7.82</td>
<td>4.85</td>
<td>32.06</td>
<td>5457.1</td>
</tr>
<tr>
<td>0</td>
<td>0.466</td>
<td>10.03</td>
<td>6.96</td>
<td>5.02</td>
<td>27.27</td>
<td>6256.5</td>
</tr>
<tr>
<td>2-0</td>
<td>0.386</td>
<td>7.09</td>
<td>4.41</td>
<td>4.39</td>
<td>15.92</td>
<td>6056.5</td>
</tr>
<tr>
<td>3-0</td>
<td>0.296</td>
<td>4.38</td>
<td>3.24</td>
<td>3.78</td>
<td>8.63</td>
<td>6366.4</td>
</tr>
<tr>
<td>4-0</td>
<td>0.232</td>
<td>2.74</td>
<td>2.19</td>
<td>3.77</td>
<td>5.39</td>
<td>6492.4</td>
</tr>
<tr>
<td>5-0</td>
<td>0.174</td>
<td>1.49</td>
<td>1.09</td>
<td>2.85</td>
<td>2.19</td>
<td>6256.8</td>
</tr>
<tr>
<td>6-0</td>
<td>0.112</td>
<td>0.70</td>
<td>0.50</td>
<td>2.42</td>
<td>0.91</td>
<td>7101.7</td>
</tr>
<tr>
<td>NOVAFIL (Polybutester)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>0.487</td>
<td>8.80</td>
<td>4.93</td>
<td>2.39</td>
<td>9.78</td>
<td>4730.6</td>
</tr>
<tr>
<td>0</td>
<td>0.382</td>
<td>6.18</td>
<td>3.41</td>
<td>2.82</td>
<td>8.19</td>
<td>5401.9</td>
</tr>
<tr>
<td>2-0</td>
<td>0.342</td>
<td>4.35</td>
<td>2.57</td>
<td>2.94</td>
<td>6.29</td>
<td>4749.4</td>
</tr>
<tr>
<td>3-0</td>
<td>0.245</td>
<td>2.54</td>
<td>1.33</td>
<td>3.08</td>
<td>3.70</td>
<td>5380.0</td>
</tr>
<tr>
<td>4-0</td>
<td>0.180</td>
<td>1.33</td>
<td>0.92</td>
<td>3.02</td>
<td>2.03</td>
<td>5210.9</td>
</tr>
<tr>
<td>5-0</td>
<td>0.140</td>
<td>0.97</td>
<td>0.54</td>
<td>3.04</td>
<td>1.41</td>
<td>6271.3</td>
</tr>
<tr>
<td>6-0</td>
<td>0.105</td>
<td>0.53</td>
<td>0.38</td>
<td>2.98</td>
<td>0.80</td>
<td>6155.1</td>
</tr>
<tr>
<td>PROLENE (Polypropylene)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>0.457</td>
<td>7.01</td>
<td>5.56</td>
<td>2.90</td>
<td>12.53</td>
<td>4278.6</td>
</tr>
<tr>
<td>0</td>
<td>0.357</td>
<td>4.54</td>
<td>3.69</td>
<td>2.75</td>
<td>8.02</td>
<td>4502.1</td>
</tr>
<tr>
<td>2-0</td>
<td>0.323</td>
<td>3.37</td>
<td>2.75</td>
<td>2.69</td>
<td>5.81</td>
<td>4104.1</td>
</tr>
<tr>
<td>3-0</td>
<td>0.235</td>
<td>1.98</td>
<td>1.77</td>
<td>2.87</td>
<td>3.66</td>
<td>4557.9</td>
</tr>
<tr>
<td>4-0</td>
<td>0.188</td>
<td>1.29</td>
<td>1.08</td>
<td>3.09</td>
<td>2.56</td>
<td>4627.0</td>
</tr>
<tr>
<td>5-0</td>
<td>0.137</td>
<td>0.74</td>
<td>0.66</td>
<td>3.15</td>
<td>1.54</td>
<td>5076.2</td>
</tr>
<tr>
<td>6-0</td>
<td>0.093</td>
<td>0.42</td>
<td>0.32</td>
<td>2.96</td>
<td>0.80</td>
<td>6088.4</td>
</tr>
</tbody>
</table>

[FL = failure load; E = elongation; FE = failure energy; TS = tensile strength]
2.9.2 Suture/Tissue Pullout Test

A suture/tissue pullout test method was developed by our laboratory to quantify the tissue holding capacity of barbed surgical sutures [87]. In this test the suture was in curved state which would be similar to a stitch in-vivo in anastomosing tissue.

![Suture pull out direction](image)

The barbed suture specimen was sutured into a tissue simulant in the direction opposite to the suture pullout direction Figure 2.30. The semicircular configuration was chosen to imitate the typical *in-vivo* form the suture would experience given its attachment to a semicircular curved needle. It is in this configuration that the barbs will stand out from the monofilament and penetrate the tissue simulant more deeply. The idea was to achieve a maximum pullout force. The recorded pullout force for size '0' barbed sutures was in the range of 1.4 to 2.1 kg, compared to 0.02 to 0.04 kg for unbarbed sutures [87].

It will therefore be of interest to perform a finite element simulation of this suture/tissue pullout test using the same geometry and material properties. From this it will then be possible to test in a virtual environment the tissue holding capacity of any geometry and configuration of a barbed surgical suture. If this simulation is successful, then in the future the costs and time associated with experimental trials in the development of new and improved barbed suture designs for other applications may be considerably reduced.
2.9.3 Stress Relaxation

The stress relaxation of three suture materials, namely, polypropylene, polydioxanone and polyglycolic acid, was studied, and the findings revealed that polypropylene exhibited the greatest relaxation of 40 percent of the initial value [10]. This suggests that barbs made out of polypropylene would undergo rearrangement at two different points in time. One is immediately when they are created on the monofilament surface, and secondly when they are loaded by surrounding tissue. Therefore, when interacting with tissue, a polypropylene barb will change the angle at which it stands out (the barb angle) depending on the applied forces it experiences and with time.

Further when a barbed suture is used in places such as the arteries, it will be under constant fatigue loading. Therefore it is important to understand the effect of this cyclic fatiguing on the stress relaxation properties. Prolene, Maxon, Vicryl and silk sutures were characterized to study the dynamic mechanical behaviour of the polymers. The experiment consisted of ramping the temperature from -100 deg.C. to a maximum of 275 deg.C at 2 deg.C/min at frequencies 1,2,5, 10 and 20 Hz with an amplitude of ± 30 µm. The specimen length was 8mm. The objective was to find out if any of these polymers exhibited stress relaxation behavior at room temperature (25°C). To do this first the above experiment was run to get the plot for E'(dynamic tensile storage modulus). Only Prolene and Maxon showed a sharp drop in E' at (25°C). The other sutures were relatively stable at this temperature. Then a frequency sweep experiment was run at this temperature, and it could be clearly seen from the plot of E' vs. frequency, that E' was changing with frequency (i.e. time), for Prolene and Maxon. This represents stress relaxation. The β-transition (T_g; glass transition) for Prolene was at ∼2°C and for Maxon it was at ∼25°C. Hence stress relaxation effects were more pronounced for Maxon than Prolene [5]. The dynamic mechanical properties of most commonly used suture materials are shown in Table 2.6.

So for a barbed suture to be stable in vivo, it requires the choice of a polymer that has its T_g well above 37°C, i.e. above human physiological body temperature. Otherwise, the barbs holding the tissue may experience a loss in tensile storage modulus, which means that the energy required to rupture the barbs decreases, thus permitting, failure at lower loads. In addition, the reduced stiffness of the barbs above T_g, may cause them to bend prematurely and slip out of the surrounding tissue, as shown in
Table 2.6: Dynamic mechanical behavior of different polymers [25]

<table>
<thead>
<tr>
<th>Suture</th>
<th>E'</th>
<th>E''</th>
<th>Tanδ</th>
<th>Tanδ</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Pa)</td>
<td>(MPa)</td>
<td>(°C)</td>
<td>(°C)</td>
</tr>
<tr>
<td>Dexon</td>
<td>3.9 x 10^9</td>
<td>3828</td>
<td>-55</td>
<td>72</td>
</tr>
<tr>
<td>Maxon</td>
<td>2.8 x 10^9</td>
<td>3846</td>
<td>-78</td>
<td>30</td>
</tr>
<tr>
<td>Prolene</td>
<td>4.4 x 10^9</td>
<td>1125</td>
<td>2</td>
<td>106</td>
</tr>
<tr>
<td>PDS</td>
<td>2.2 x 10^9</td>
<td>1225</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Vicryl</td>
<td>2.0 x 10^10</td>
<td>2069</td>
<td>-65</td>
<td>68</td>
</tr>
<tr>
<td>Silk</td>
<td>4.0 x 10^10</td>
<td>3219</td>
<td>-</td>
<td>226</td>
</tr>
</tbody>
</table>

[E' = storage modulus; E'' = loss modulus; Tanδ = β transition; Tanδ = α transition]

Figure 2.31: A soft barb unable to penetrate the tissue

This will represent a case of barb failure without barb rupture. Sometimes a second relaxation region can be seen by an inflexion in either the E' or the E'' curve at temperatures above room temperature. For example with PVDF it occurs at 60°C [48]). This represents a change in viscoelastic behavior due to reorganization of the crystalline regions [116, 85], which occurs at a higher temperature after the first Tg [48]. The Tg of silk (Mersilk) and polyglactin 910 (Vicryl) sutures has been observed to decrease ~2°C after coating with silver-doped bioactive glass [55]. However, since the Tg remains well above room temperature, a plot of varying frequency from 0.001 Hz to 100 Hz of these materials will continue to show little or no change in the storage or loss modulus.

The glass transition temperature for chitosan is reported to be 102°C (375 K) [96]. So resorbable sutures made from chitosan will also be stable at physiological body temperature.

In a stress relaxation experiment, the rate at which the load is applied to the specimen has a significant effect on the results. A study on stress relaxation of tissue porcine heart valves indicated that the faster the extension rate, the longer the time to recover. Also the state of the tissue and degree of crosslinking are important. For example, a gluteraldehyde fixed tissue has a relaxation curve with a greater slope
compared to that for fresh tissue [53].

Another factor that might affect suture performance in vivo is the handling of the sutures by the surgeon with forceps. A creep and stress relaxation study on damaged polypropylene sutures has been reported in which a range of graded injuries were applied to sutures by compressing with DeBakey forceps. Results revealed that damage significantly increased the risk of breakage with chronic loads. The criteria for chronic loading, which refers to the application of a load that is less than the breaking force, over an extended period of time, say $\sim 175 \text{ gf} \,(1.72 \text{ N})$ which is very small compared to the breaking load, very critical when designing sutures for cervical spine surgery. The Safety Ratio is qualified as the ratio of breaking force of the suture to the force applied to the suture. It was reported that 5-0 sutures had a higher safety ratio of $\sim 3.37$ compared to $\sim 1.73$ for 6-0 sutures [16]. This indicates that if we were to make barbed sutures from 6-0 sutures, they would be more vulnerable to fatigue or creep failure due to their lower safety ratio. It is proposed that this threat to the use of barbed sutures can be reduced by reducing the crack propagation at the cut point, by using different barb geometries and barb formation techniques. For example, the use of hot fusion. Where the blade temperature approximates the softening temperature of the suture polymer is one option. Special padding can be developed for surgical forceps so as to handle barbed sutures and avoid damage to the delicate barbs by pinching.

### 2.9.4 Cyclic Loading

Crack initiation testing is used extensively for testing the fatigue in terms of the number of cycles it takes for brittle material, such as steel, to fracture completely. The data are interpreted in the form of a cyclic stress amplitude vs. cycles to failure (S-N) curve as described by August Wohler [67]. The same concept has been applied to study the crack initiation stress of gluteraldehyde fixed heart valve tissues [53]. First the crack initiation stress for a monofilament of a particular material is determined on the virgin suture before the barbs are inserted. Once the number of cycles it takes to initiate a crack in the virgin monofilament is known, we can then compare this result with the number of cycles it will take to initiate a crack at the cut point in the same barbed suture. This will provide evidence of the life expectancy of such a barb in vivo. This is crucially important, given that the loads exerted by different tissues are different, and therefore the number of cycles it takes to initiate a crack in a barbed suture will likely differ from tissue to tissue. Obviously, the in vivo performance will also depend
on the amount of physical activity associated with the tissue function, such as the pericardium which surrounds the heart, the skin which is stretched at the elbow joint, the tendons which flex in the knee, the peristaltic action of the stomach and the pulsatile flow of blood in the arteries. The forces and frequencies of these cyclic functions have been reported previously. For example, the mechanical forces in the human stomach and intestine are 1.9 N and 1.2 N respectively, as measured by the 'Destructive force Dependent Release System (DDRS)' [76].

2.9.5 Surface Friction

While suturing through the eyelet of a fixation device, such as an osteogenic anchor eyelet, the suture abrades against the metal and hardened polymer surface of the eyelet. In such cases, a lower frictional force between the suture and the eyelet surfaces would reduce the potential damage to the suture, and result in a higher breaking load [38, 37].

A study of absorbable PLA, PLLA and PGA suture anchor eyelets with steel wires in saline at pH 7.4 at temperatures of 20 and 37°C concluded that both the testing speed and temperature influence the results of static tensile testing by a factor of up to 50 % [36]. Firstly, the effect of the testing speed may have been because at slower speeds there was more time for the water to swell the polymer and reduce its strength by resorption compared to higher rates where there was less time. Secondly, the closer the testing temperature was to the Tg of the polymer, the higher would have been the strain or displacement caused by the frictional forces. This was because at Tg the molecular chains undergo conformational reorganization so as to achieve a more relaxed minimum energy state. In this study, PLA had a glass transition temperature around 57°C [40], while for PGA($\alpha$) it was 46.5°C and for PLLA it was 56.6°C [107]. This can be confirmed from a study which reported the effect of test temperature (20°C vs 37°C) on the mechanical performance of absorbable suture anchors in saline. It was reported that the drop in suture anchor pullout force for PGA was the highest at 31 %, compared to a lower pullout force for PLA and PLLA at ~13 % [36]. In a study of biodegradable anchors, it was found that abrasion against the sutures was one of the reasons for the cutting of the anchor eyelet. This abrasion was found to be less severe in wet environments due to the lubrication effect of the surrounding fluid and due to heat dissipation [117]. So if we were to design barbed sutures for use with tissue anchors, the surface contact between the suture and the anchor eyelet should have minimum
friction, which is possible by having no barbs in that region of the suture. The suture can go into the eyelet only once, when anastomosing a distal flexor digitorum profundus tendon to the distal phalanx due to the small size of the suture eyelet [71]. There is another reason why a barbed suture can pass only once, and that is if the inner diameter of the eyelet is the same as the outer diameter of the monofilament. This is because the opposing barbs on each side of the barb free zone will lock the suture anchor inside it once it has passed through, as shown in Figure 2.32. Therefore the barb free region should extend from the point where the suture leaves the tendon, pass through the eyelet of the anchor, up to the point of re-entry of the suture back into the tendon.

2.10 Chemical Stability

It is important to incorporate the aspect of chemical stability when modelling absorbable sutures, since absorbable materials change their mechanical properties with time when exposed to moisture which is abundant in the human body. These changes such as breaking load and elongation should be considered in a transient model. Table 2.7 shows the breaking strength retention (%) and breaking elongation (%) for few commercial sutures.
Table 2.7 shows important information.

<table>
<thead>
<tr>
<th>Suture</th>
<th>BSR (%)</th>
<th>BE (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>pH 3.0</td>
<td>pH 7.4</td>
</tr>
<tr>
<td>Absorbable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plain Catgut</td>
<td>7</td>
<td>37</td>
</tr>
<tr>
<td></td>
<td>28</td>
<td>0</td>
</tr>
<tr>
<td>Dexon</td>
<td>7</td>
<td>96</td>
</tr>
<tr>
<td></td>
<td>28</td>
<td>0</td>
</tr>
<tr>
<td>Vicryl</td>
<td>7</td>
<td>93</td>
</tr>
<tr>
<td></td>
<td>28</td>
<td>0</td>
</tr>
<tr>
<td>Non-absorbable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mersilene</td>
<td>7</td>
<td>99</td>
</tr>
<tr>
<td></td>
<td>28</td>
<td>98</td>
</tr>
<tr>
<td>Nurolon</td>
<td>7</td>
<td>72</td>
</tr>
<tr>
<td></td>
<td>28</td>
<td>66</td>
</tr>
<tr>
<td>Ethilon</td>
<td>7</td>
<td>104</td>
</tr>
<tr>
<td></td>
<td>28</td>
<td>96</td>
</tr>
<tr>
<td>Prolene</td>
<td>7</td>
<td>97</td>
</tr>
<tr>
<td></td>
<td>28</td>
<td>103</td>
</tr>
</tbody>
</table>

[BSR = breaking strength retention; BE = breaking elongation]

In a study on the degradation of collagen sutures it was found that in vitro enzymatic degradation occurred gradually as an erosion mechanism from the surface to the core. Collagen or "catgut" sutures are made from the submucosal layer of sheep intestines or from the serosal layer of bovine intestines. There were two types of catgut sutures used in the study, namely chromic treated (chromic salts for cross-linking to increase strength and retard the resorption time) and the plain (untreated) suture. The enzymes used were collagenase at pH 7.4 and pepsin at pH 1.6 [109].

In another study the self reinforced poly L-lactide (SR-PLLA) sutures had prolonged strength retention when immersed in phosphate-buffered distilled water (pH 7.4) at 37°C for 26 weeks as compared to PDS and Maxon. So this suture may be used for tissues in need of support for a longer time as in bone [89].

Other synthetic resorbable sutures such as PLDLA (poly-L/D-lactide) have been found to retain their strength for a longer time compared to Maxon in a 6 weeks study [59]. Vicryl and PDS sutures (‘0’ or ‘2-0’) have shorter term and longer term stability respectively in synovial fluid and phosphate buffered saline at 37°C. Panacryl (2-0) however may be used for longer-term applications of wound closure, tendon repair and arthroplasty because it takes 12 weeks to reach 69 % of its original strength when
exposed to PBS (phosphate buffer saline) [95].

2.11 Antibacterial Sutures

One of the clinical concerns over the use of barbed sutures is whether the crack under each barb may serve as a nidus for harboring bacteria and supporting bacterial growth. While there is no evidence to support this possibility, it is worth considering the option of including antibacterial agents within the suture’s structure.

The Vicryl-Plus, polyglactin 910 coated with triclosan, antibacterial sutures have recently been reported to have no significantly different inflammatory reaction compared to regular Vicryl sutures. The study was limited however by a small sample size [73]. Nevertheless this concept can be applied to barbed sutures as well. The crack created in the monofilament surface by creating a barb may be less susceptible to bacterial attack if the suture is coated with an anti-bacterial finish. Antibacterial sutures also may be made from absorbable phosphate-based glass fibers. Copper ions in the form of copper oxide (CuO) can be embeded in PGF, which has been shown to have a 3 hour attachment and biocidal effect against *Staphylococcus epidermidis* bacteria [11]. Also resorbable polycaprolactone coatings containing clindamycin and other antibacterial agents have been shown to be effective against staphylococcus aureus bacteria when applied to polyester suture materials [113].

2.12 Surgical Situations

The various surgical applications where barbed suture may be effective will be reviewed. The human body consists of numerous types of tissues, the most relevant of which will be described in this section. The stiffness of these tissues encompasses an entire spectrum from soft tissues, that are easily bent, to bones that are very stiff. Therefore the appropriate stiffness of the barb in a barbed suture will be different for different tissues. This may be achieved by varying the barb geometry and the configuration of the barbs along the monofilament suture, as well as selecting a different polymer material.
2.12.1 Orthopedic

O’Broin and co-workers have reported the use of PDS and Prolene monofilament sutures to repair the flexor digitorum longus tendon in rabbits. While the breaking tensile strength of the tendon was ~225N, both types of sutures were equally strong during the first two post-operative weeks of healing. After that, even though the PDS started to resorb, with a half life of 9 weeks, the overall strength of the repaired tendon did not differ significantly regardless of whether it was sutured with PDS or Prolene. In view of this, it is concluded that PDS is a better choice, since eventually, after complete healing, the PDS suture will be totally resorbed. In both rabbits and dogs the early weak repair phase lasts for 10 and 14 days respectively. The values for humans have not been reported. If we assume that it also takes 4 to 8 weeks to complete this early repair phase in humans, and given that the human digital flexor tendon exerts a force of ~9N in active flexion, then the PDS sutures which has a strength of at least 9N for about 14 days, will be able to support the dynamic tendon load [101]. In the case of a barbed PDS suture therefore, as discussed earlier, the rate of enzymatic degradation will most likely depend on the cut depth of the barb. Therefore, it may be necessary to use a PDS suture with a larger diameter so that when the barbs have been cut it can still sustain a load of 9N for the first 2 postoperative weeks following tendon repair. In a similar study to find the best type of stitch to anastomose ovine tendons, a series of samples with a single running stitch, cross-stitch, interlocking cross-stitch and interlocking horizontal mattress stitch were tested. It was found that the interlocking horizontal mattress stitch gave the best mechanical performance. It required a load of ~26 N (2.65 kgf at 20mm/min) in order to generate a 2mm gap with 6-0 Prolene sutures [46]. And interestingly in the same year another study in our own laboratory, found that barbed sutures could support a load of ~27 N (i.e.2.83 kgf at 50mm/min) when stitched through a skin simulant using a 4-0 polydioxanone suture [83]. The most distinct advantage of using a barbed suture is that the suture lies inside the tissue, so for tendon repair there is no friction between the suture knot and the bone or soft tissue adjacent to the tendon. This will reduce patient trauma and improve healing and functionality.

Another study has reported that the characteristic of inferior gap resistance or separation of joined tendon segments is due to sliding of the suture within the tissue rather than due to the inferior creep or fatigue strength of the suture polymer Figure 2.33 [2].
Figure 2.33 shows flexor tendon repair.

In arthroscopic shoulder surgery, the main function of the suture anchor is to fix the bone to a soft tissue tendon or ligament. Tying a knot in this type of surgery is difficult to master. A suture anchor is generally a screw or post which is inserted into the bone with a eye for suture attachment at one end (Figure 2.34).
Figure 2.34 shows important information. A new technique of twist-lock or lashing around the suture anchor has been proposed. By wrapping braided, size 4, Ethibond: polybutylate coated polyester sutures a number of times around the post the frictional holding force was increased to 60 N for tendon fixation. In the pullout test for this twist-lock approach failure occurred by breaking the suture in the eyelet at 137 N or at the knot. The conventional method failed at the knot at 122 N [99]. One concern with the lashing method is the cutting of the screw into the suture when it is being screwed into the bone. This will reduce the tensile strength of the suture and the suture breakage may occur prematurely. However, since all the breakages occurred at the eyelet, the mechanical damage to the suture by screwing may be small. It is proposed that a barbed suture may be used in place of the conventional knotted suture, since a barbed suture can lock into the soft tissue of the tendon to fix it to the anchor eyelet. As reported earlier, single barbed Maxon sutures (size 0 and 0.95mm distance between barbs) can withstand forces up to 39.2 N [86]. Hence if we use two such sutures, then they will exceed the minimum required force for anchor attachment of 60 N. The sutures can be added in multiples of two. Four such sutures will give a breaking force of 156 N, which provides a safety factor in excess of the conventional method strength of 122 N. Further this method does not require the surgeon to tie sliding knots as usually needed in arthroscopic surgery. Also, it does not interfere with the screw threads of the
post inside the bone, which eliminates the risk of suture damage.

When repairing the zone I flexor digitorum profundus researchers have used a 3-0 braided caprolactone suture with 3 different approaches (Figure 2.35). The tendon to bone tunnel with a peripheral knotted suture showed a high resistance (83 N) to 2 mm gap formation compared to the tunnel-only (44 N) and surface-only (30 N) repair techniques (Figure 2.36). These values are well above the $\sim 9$ N passive post-operative force required during rehabilitation and the maximum applied physiological load of 20 N experienced during active conditions [105]. The force required to create a 2 mm gap for different types of conventional tendon repair techniques with 4-0 polyester, polypropylene and 6-0 nylon sutures have been reported to be in the range from 23.6 N.
to 58.9 N [115]. We have reported that barbed sutures with a specific geometry offer a
resistance of \(~27\) N before forming a 2 mm gap [83]. This could be improved further by
optimizing the geometry of the barbs and their configuration along the monofilament
surface so as to achieve resistance forces comparable to the existing techniques. The
main advantages of using a barbed suture would be to lessen patient trauma due to
the elimination of external knots, to reduce the friction between the suture and the
surrounding sheath. This can be accomplished by inserting the suture completely inside
the tendon and bone tunnel.

A Teno-fix device composed of a stainless steel suture was designed to repair
torn and ruptured tendons. In this technique the suture stays concealed inside both
tendon fragments and is secured at both end by an anchoring coil and bead (Figure
2.37) [115]. This method has the disadvantage that the stress concentration is only at

![Diagram of Tendon Repair with Suture, Anchor, and Bead](image)

**Figure 2.37**: Suture with bead and anchor in bridge tendon repair. [115]

the two extreme ends of the suture tissue junction, and there is no positive frictional
support along the suture length. If a barbed suture were to be used in this scenario, if
would support the tendon at multiple points for better transmission of forces from one
broken tendon fragment to the other.

### 2.12.2 Dermal (Skin)

Skin is the largest organ of the human body. It has many functions, one of
which is to protect the inner organs. It is a randomly oriented structure of collagen;
therefore it is anisotropic [57]. The random arrangement of the collagen fibers is like a
nonwoven web. When such a structure is stretched the initial large extension is due to
the rearrangement of these randomly arranged fibers. It is after this initial extension that the fibers start bearing the load, and that is when the skin becomes stiffer and less extensible.
Figure 2.38 shows important information. Figure 2.38 shows the cross-section of the skin. It consists of two layers, the inner dermis and the outer dermis.

Figure 2.39 shows the pressure expansion curve for the human abdominal skin in 10th lunar month of pregnancy [52].

Figure 2.39 shows the pressure expansion curve for the human abdominal. The curve also depicts the elastic nature of the skin tissue.

2.12.3 Cardiovascular

The working stress experienced by a suture in a situation where it is used to suture a prosthetic valve to biological tissue is less than 1MPa (1 N/mm² or 0.1019
kgf/mm$^2$) [74]. Also we can see from Table 2.8 that the stresses exerted on an arterial anastomosis are comparatively low, say 0.02 N, i.e. 2.03 gf (where 1 N = 101.97 gf) for a monofilament of cross sectional area 1 mm$^2$ [12]. A similar study on testing the tensile properties of sutures found that braided sutures had a higher elastic modulus compared to monofilament sutures regardless of their chemical composition [42]. However braided sutures have an inherent disadvantage of causing trauma to surrounding tissue due to the frictional forces associated with tissue drag. Furthermore bacteria and viruses can thrive in the interstices of a multifilament yarn in a braided structure making it more vulnerable to infection. Hence a monofilament suture is always preferred when the risks of infection or tissue trauma are elevated. A tissue drag test consisting of pulling a 20 cm length of suture through the posterior dorsal skin of a rat at 30 cm/min has been reported. The tissue was mounted in a square frame, and the results indicated that the monofilament sutures had comparatively less tissue drag than the catgut sutures [98]. This observation would apply equally to barbed sutures, since the barbs remain completely inside the cut area and the suture is pulled in the opposite direction. The use of knotted sutures for mitral valve reconstructive surgery has its own disadvantages. A size 5-0 polypropylene suture has been reported to leave stiff sharp tails or ears protruding from their knots that could damage the opposing anterior leaflet after quadrangular resection (Figure 2.40) [22].

<table>
<thead>
<tr>
<th>BP Type</th>
<th>Systolic</th>
<th>Diastolic</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mmHg</td>
<td>N/mm$^2$</td>
</tr>
<tr>
<td>Ml.H</td>
<td>$\geq 140 &amp; &lt; 160$</td>
<td>$\geq 0.0187 &amp; &lt; 0.0213$</td>
</tr>
<tr>
<td>Md. H</td>
<td>$\geq 160 &amp; &lt; 180$</td>
<td>$\geq 0.0213 &amp; &lt; 0.0239$</td>
</tr>
<tr>
<td>Sv.H</td>
<td>$\geq 180$</td>
<td>$\geq 0.0213$</td>
</tr>
</tbody>
</table>

[BP = blood pressure; Ml.H = mild hypertension; Md.H = moderate hypertension; Sv.H = severe hypertension]
Figure 2.40 shows important information.

It may be possible for a barbed suture to eliminate this complication if the suture can be inserted within the thickness of the mitral valve tissue.

Another study has focussed on comparing the transverse and longitudinal growth at the anastomotic site of arteries and veins following the use of either clips or conventional sutures (Figure 2.41).

Figure 2.41: Suturing artery (A,B,C) and vein (D,E,F) [45]

It has been reported that the transverse growth was greater in sutured arteries than in clipped arteries. Though this was not statistically significant, it was apparent from the extent of periarterial fibrosis (i.e. an over-exuberant collagen tissue reaction).
Figure 2.42 shows important information.

This fibrosis was greater in veins as compared to arteries in both cases. On the other hand, the longitudinal growth at the anastomoses was greater for clipped arteries and veins than for those which were conventionally sutured (Figure 2.42). The veins recovered completely from a 1mm eversion or folding at the anastomotic site in 6 months. However the arteries did not regain their original position (i.e. 1mm eversion) after 6 months in either case. It was also observed that at the site of the anastomosis, the clipped vessels showed less scarring and less retraction of the vessel wall due to less fibrosis. The sutured vessels showed more retraction due to more fibrotic reaction around the suture. This reaction may have resulted in the replacement of muscle fibers in the media of the vessel wall by fibrous tissue, caused by the penetration of the suture across the entire width of the wall as compared to the clips which only penetrated the media and did not compromise the intima. This reinforces the importance of avoiding damage to the venous or arterial intima and minimizing damage to media and the adventitia when anastomising veins or arteries wall to wall [45]. The intima is the innermost layer composed of endothelial cells attached to the basement membrane. While the media is the middle layer containing smooth muscle cells, connective matrix: collagen I and III, vitronectin, laminin, and elastin fibrils. The adventitia is the outermost layer containing fibroblasts, nerve cells, collagen, and elastin fibrils and its function is to supply blood to the cells of the vessel wall. It also contains fibroblasts, which are precursors to the inflammatory reaction. The media provides elasticity and dimensional stability to the vessel wall. Therefore, if it is possible to anastomose the walls of two vessels together in such a way that the suture lies only in the media, then there will be no excess of fibroblast activation and no disruption of the adventitial layer. Hence the generation of
excess collagen, which is associated with fibrosis, will not be activated, thus eliminating a chronic inflammatory reaction. The thickness of the intimal media layer has been reported to be 0.2 to 0.4 mm for the carotid artery [111]. So ideally the suture should have a diameter less than 0.4 mm. A barbed suture designed for this type of anastomosis would require shallower cut angles with shorter cut lengths. This will make sure that the barbs do not penetrate beyond the media on either side after interlocking with medial tissue. According to Laplace’s law, the tension in the arterial wall can be written as [1]:

\[
\text{wall tension} = \text{internal pressure} \times \text{radius}
\]

So the tissue and suture composite structure will experience this wall tension near the anastomotic site. In addition, the suture itself will be subjected to tensile loading along the longitudinal axis of the vessel.

### 2.12.4 Gynecology

Barbed size 0 polydioxanone (PDS) sutures have also been used in closing cesarean sections. A study, conducted on 154 women, concluded that barbed sutures resulted in equivalent cosmesis to that of unbarbed sutures when measured by the Hollander cosmesis score [78].

The tensile stress/strain plot for vaginal tissue in post-menopausal patients between age 40 and 80 showed a peculiar behavior. As the elongation at break increased from 6 to 10 mm, the breaking force fell from 60 N to 5 N [72]. In such cases where the strength of the tissue itself is very low, a barbed suture may prove more useful. Normal sutures may cause tearing of the tissue at the entrance and exit points. However, in the case of a barbed suture, the multiple attachment points are likely to hold the tissue web in place for better healing and cosmesis.

Using knotted sutures for deep tissue wound closure is not always successful. Examples during obstetrical and gynecological cases include vaginal cuff closure at hysterectomy, the repair of vaginal mucosa during colporraphy, hysterotomy via cesarean section and the closure of abdominal wall fascia. These postoperative situations do not always permit the use of conventional flat surgeons knots. So a sliding knot is often used in combination with a flat surgeons knot. Even this last alternative has potential risks associated with knot security [58]. On the other hand, the use of a barbed suture could provide both ease of suturing and better wound healing without the risks associated with knot security. The forces experienced by the suture in the anterior abdominal wall aponeurosis and lower abdominal structures have been found to be of the order of 110 N.
Conventional flat surgeons knots in a loop-to-strand configuration have been observed to fail at loads of 30 N and 24 N for suture sizes 0 and 2-0 respectively. So, there is an urgent justification to develop barbed sutures for deep tissue repair that can withstand this level of applied force. To achieve this it will be necessary to optimize the suture size, the barb geometry and barb distribution along the suture length. Polypropylene sutures are known to be stable at a range of pH between 1.0 and 10.5 with no loss in strength over a period of 14 weeks. Nylon on the other hand loses 50 percent of its original strength at pH 1.0 in 14 weeks [65]. Hence Prolene would be the material of choice for making permanent barbed sutures for deep tissue repair.

It is also important that the suture material is stable to radiation. This can occur when, following gynecologic cancer, a woman patient is prescribed abdominal radiation for palliative or curative therapy. The ionizing effect of the radiation may adversely effect the suture strength, and may lead to wound dehiscence [114]. The use of a knotted monofilament suture is at high risk in such cases, since, if the suture breaks at one point, the entire length of the suture stitch is rendered ineffective in keeping the wound closed. Alternatively, several small suture stitches may be used. This however increases the time of operation and can lead to complications due to the presence of multiple knots. A barbed suture, however can effectively eliminate both these risks. Firstly, since it anchors at multiple points, should the suture break it will still hold the wound tissue in closed apposition at the next barb. Secondly, as explained earlier, since the suture stays inside the tissue there is less scar formation.

2.12.5 Pancreatic Fistula Surgery

Suture dehiscence rates following pancreatic fistula surgery lie in the range of 10 to 20%. Catgut sutures derived from sheep submucosal are susceptible to proteolytic digestion which can occur when exposed to fluids such as pancreatic and bile juices. On the other hand polydioxanone sutures are more resistant to degradation by pancreatic and bile juices, and so are a better choice for treating pancreatic fistulae [108]. Similarly, barbed polydioxanone sutures could be used to anastomose pancreatic tissue. In fact it would be interesting to determine how the pattern of strength loss of a barbed suture compares to that of a monofilament suture. It may be that a larger diameter monofilament with shallower barbs would provide a preferable design in terms of its rate of resorption.
2.12.6 Dermal Closures

If the suture used to anastomose dermal tissue is only superficially buried below the skin surface, then suture fraying, breakage, infection and reactive fibrosis can lead to exposure of the suture knots and cause trauma [70]. Hence for subepidermal closures, which are often required in cosmetic surgical procedures, barbed sutures may be preferred. The optimal design for this type of suture could vary and different barb geometries are possible by altering the cut depth, the cut angle, the barb length and the distribution of the barbs along and around the monofilament’s surface. It has been reported that the elasticity and stretchability of skin decreases after the age of 30, and that the Young’s modulus has been reported to double with age [49]. It is therefore logical to assume that the energy absorbed by the barbs in a barbed suture should be different for varying age groups, and that the geometric design of the barb should be modified to reflect such changes due to age.

2.12.7 Scalp Closure Wound

Closure of the scalp is associated with a higher rate of dehiscence (8 percent) because these wounds are closed with sutures under significantly high tension [93]. A barbed suture in such cases therefore should be a monofilament with a larger diameter, so as to provide adequate tensile strength to hold the tissue in apposition. If a plaster cast is employed in such cases, then the suture knots inside this cast may cause severe itching. Knotless barbed sutures can reduce the overall itching by eliminating the need to tie knots.

2.12.8 Bone

A suture-anchor tissue pullout test was conducted on a shoulder joint. The anchor was made to penetrate into the glenoid bone. A suture through the eye of the anchor eyelet was used to attach the labrum and capsular tissues to the glenoid. The average failure strength was reported to be in the range of 471 to 650 N. The large deviations within each of the three groups of anchors (Figure 2.43) was associated with variations in bone density [88]. A barbed suture anchor may be also be developed for hard tissues.
Figure 2.43 shows important information.

![Image of suture anchors and tissue pullout test](image)

Figure 2.43: Suture anchors and tissue pullout test [88]

2.12.9 Ophthalmology

In the field of ophthalmology, frontalis sling surgery is done to reshape the eye. In a study by Bajaj et al., an ePTFE suture (4-0) were found to provide superior upper eyelid ptosis repair 1-2mm compared to a braided polyester suture, which appeared to have more frequent acute postsurgical complications, such as infection. On the other hand, it was also reported that ePTFE was associated with the long term problem of granuloma formation and reoccurrence of the ptosis [97]. If the formation of granuloma is caused by tissue drag and bacterial infection, then the use of a barbed suture may provide a superior outcome. Since the barbed suture is made from a monofilament rather than a multifilament braid, there are no interstices between filaments where bacteria can hide to cause infection. Also, since the barbed suture anchors inside a tissue at multiple points, there is less relative movement between the suture and the surrounding tissue. Most of the energy of any lateral or axial movement would be absorbed by the rocking motion of the elastic barbs, which would reduce or eliminate any migration or tissue drag on the suture. Hence there would be minimal granulation tissue formation, given that there would be no slippage at the suture-tissue interface.

Other studies have shown that ePTFE sutures are associated with fewer reoperations than nylon sutures using a single loop and double pentagon suturing design (Figure 2.44) [21].
Figure 2.44 shows important information.

![Figure 2.44: Upper eyelid ptosis repair with knotted sutures [21]](image)

Fine sutures (such as size 10-0 nylon) are used in ophthalmologic surgery [51]. However, there are certain disadvantages and complications associated with the use of these sutures, including the need for general anesthesia at the time of their removal [20]. The complications include the growth of bacteria inside the knots, and abrasion between the protruding knot and the tissue surrounding the eye. The use of a barbed suture could be a possible alternative to traditional sutures, since the barbed suture would stay inside the eye so there would be no abrasion with surrounding tissue. Further, the need for removal of the suture could be eliminated by using a resorbable polymer.
2.13 Structures of Tissues

The mechanical properties of all the tissues in this section are available from the book by Yamada [52]. These properties are in the form of stress strain curves under static (monotonic) loading. In this section we discuss the structure of the tissues that exhibit these properties.

Figure 2.45: Different tissues in various organs of the human body [81]

Figure 2.45 shows the different organs in the human body. All the tissues have different structural properties owing to their different structural composition. The wall of the artery for example is a three-layered composite structure. In the analysis we assume that the external forces due to the movement of the persons body parts while
standing, sitting, bending, walking etc. are negligible.

2.13.1 Cardiovascular Tissues

Heart

The heart is the blood pump of the body. It is always in a dynamic state, all throughout the life of the person. Hence it is essential that the muscle of the heart wall does not fatigue or lose its elasticity, which might be fatal. The cardiac muscle is a striated muscle, i.e. the myofilaments are oriented in a preferential direction. This orientation helps the heart to function efficiently [102].

Figure 2.46: Striated cardiac muscle of the heart [102]

Figure 2.47 shows the stress strain curve for the cardiac muscle of human heart. In a mild hypertensive patient the blood pressure is around 1.9 gf/mm² (0.0187 N/mm²) (Table 2.8). Now referring back to the curve, we can see that the curve is almost a straight line below stress levels of about 1.0 gf/mm². If we consider the case of a severe hypertensive patient, with blood pressure at 2.17 gf/mm² (0.0213 N/mm²) the stress strain curve is nonlinear and shows deformation beyond the yield point (i.e. the end point of the perfectly elastic region). Hence the heart in the case of the severe hypertensive patient becomes enlarged. However the heart valves do not enlarge to the increased orifice size of the inlet and outlet. Hence there is backflow of blood into the heart, which is undesirable. Therefore attempts have been made to surgically reduce the orifice size (Figure 2.40).
Figure 2.47 shows important information.

While using a barbed suture in such a case, it is important that the barbs sutured into the cardiac muscle should stay in the perfectly elastic region when loaded by the tissue dynamically. So even if the breaking load of a barb is higher, a barbed suture may not be suitable for the cardiac tissue if it exhibits permanent deformation at sinusoidal stresses of 2 gf/mm².

Arteries

Arteries are responsible for carrying the oxygenated blood from the heart to different parts of the body. In arteries the blood is under higher pressure. Therefore
the walls of arteries are thicker. Figures 2.48, 2.49 and 2.50 show the histological cross-
sections for comparison between different size arteries and veins [57].

Figure 2.48: Cross section of a medium artery and medium vein (bar = 250 microns) [80]

The blood vessel wall is made up of three layers:

- **intima**: which is a longitudinally oriented structure
- **media**: which is a circumferentially oriented structure
- **adventitia**: which is the outermost layer of the vessel wall and is connected to the
tissue surrounding the blood vessel by connective tissue.

Figure 2.49: Cross section of an aorta (bar = 1 mm) [80]

The aorta is the largest artery and is closest to the heart. This artery ex-
periences the highest blood pressure and hence high pulsatile loading. It is therefore
necessary that this artery is perfectly elastic to maintain the shape and hence the blood
pressure between heart beats. Accordingly the walls of these arteries are thick as compared to veins, see Figure 2.48. The scale shown in the figures gives us a measure of the thickness of the arterial wall. The media contains a large amount of elastin. Also, there is a large amount of collagen in the adventitia to maintain the shape of the arterial lumen.

![Figure 2.50: Cross section of a medium artery (bar = 100 microns) [80]](image)

The medium size arteries (Figure 2.50) have the function of distributing the blood through smaller branches to the body extremities. The vessel walls here have a large amount of smooth muscle cells which are arranged helically around the circumference of the vessel. All these layers are connected either to the sympathetic or parasympathetic nervous system to maintain a constant volume and pressure of blood through the vessels. For example, a high blood pressure will trigger sensors that will carry the impulse to the brain, which then will be redirected to the blood vessels to make them dilate. Thus the mechanical properties of blood vessels are not represented by a single value. They keep changing and adjusting themselves to the requirements at any moment of time.
Figure 2.51 shows important information.

![Stress strain curve for arterial tissue](image)

Figure 2.51: Stress strain curve for arterial tissue in persons 20 to 29 years of age [52]

Similar to the cardiac muscle, for a barbed suture to be used in arterial tissue, it should satisfy the condition that the barbs do not undergo permanent deformation under the loads at which the artery is perfectly elastic. From Figure 2.51 we can see that at extensions below 10 percent, the stresses are almost linear. The stresses experienced by the arteries depend upon their distance from the heart. While developing barbed sutures for arteries it is also important to consider the direction in which the surgeon will suture, i.e. transverse or longitudinal. The barbs will need to be designed to effectively support the architecture of the tissues in these two different directions.

**Veins**

The veins carry deoxygenated blood from different parts of the body back to the heart which then sends it to the lungs for oxygenation. Like arteries there are large veins, small veins and venules. The large veins, Figure 2.52, are relatively thin walled as compared to arteries. At the same time they experience considerably lower blood pressure. Therefore there is less smooth muscle in the wall, more collagen and some elastin [57].
Figure 2.52 shows important information.

Figure 2.52: Cross section of a large vein (bar = 250 microns) [80]
Figure 2.53 shows a medium vein in which the media is primarily made up of smooth muscle cells [57]. The stress-strain curves are shown in Figure 2.54.

While developing barbed sutures for anastomosing vein tissues, smaller diameter sutures will have to be used owing to the thin wall. Also the loads these barbs will be subjected to will be lower than those experienced in the arterial wall. And it is for the same reason that if a vein graft is implanted to replace or bypass a diseased artery, it is vulnerable to aneurysm formation.
2.13.2 Respiratory and Digestive Tissues

Larynx

The Figure 2.55 shows the cross section of the larynx which is called the voice box. It is primarily made of cartilage bound by ligaments and muscle.

![Cross section of larynx wall tissue](image)

Figure 2.55: Cross section of larynx wall tissue (bar = 250 microns) [80]

Oesophagus

The Figure 2.56 shows the cross section of an oesophagus wall. It is also made up of cartilage and muscle.

![Cross section of the upper third of an oesophagus](image)

Figure 2.56: Cross section of the upper third of an oesophagus (bar = 1 mm) [80]

The structure of the esophagus is different in the upper, middle and lower parts which contribute to different levels of elongation. Furthermore it is more elastic in the transverse direction that in the longitudinal direction, Figure 2.57.
Figure below shows important information.

![Stress strain curve of esophagus of persons 20 to 29 years of age](image)

Figure 2.57: Stress strain curve of esophagus of persons 20 to 29 years of age [52]

However, below strain levels of 40 percent, except for the lower portion of the esophagus in the longitudinal direction, the stress strain profile is almost the same. Accordingly if a barbed suture were to be used to anastomose tissue of the esophagus, the specific geometry of the barb should facilitate anchoring in cartilagenous tissue which is stiffer than arteries, veins or cardiac muscle. Here the barbs will not experience as vigorous a dynamic environment as in the cardiovascular system. However the loads to hold the tissue together in a given shape will be higher.

**Stomach**

Figure 2.58 shows the cross-section of the wall of the fundus of the stomach. It is also a layered structure consisting of numerous secretory glands. The wall mostly comprises of smooth muscle cells.
Figure below shows important information.

Figure 2.58: Cross section of the fundus region of the stomach (bar = 250 microns) [80]
Figure 2.59 shows the pyloric, the farthest part of the stomach, which is close to the small intestine. It is mainly made up of smooth muscle cells.

Figure 2.59: Cross section of the pyloric region of the stomach (bar = 250 microns) [80]
Figure below shows important information.

Figure 2.60: Stress strain curve of the human stomach tissue in the transverse direction [52]

Figure 2.61: Stress strain curve of the human stomach tissue in the longitudinal direction [52]

The stomach is very active when it has food inside it. Figure 2.60 shows that it is extremely elastic in the transverse direction as compared to its elasticity in the longitudinal direction (Figure 2.61). Now depending upon the part of the stomach that
needs to be sutured and the direction in which the surgeon closes the tissue of the stomach wall, the barbs of a barbed suture will have to be designed appropriately. As against the arteries, here stress levels are of little concern. However the strain levels become important. It is essential for a barb in this case to be able to recover completely after the strain levels have reached 60 percent, because stress stiffening starts and it may be beyond the yield point.
Small intestine

The duodenum or small intestine, Figures 2.62 and 2.63, is composed of a thin layer of smooth muscle cells called the muscularis mucosa.

Figure 2.62: Cross section of upper region of duodenum wall tissue (bar = 250 microns) [80]

Figure 2.63: Cross section of lower region of duodenum wall tissue (bar = 250 microns) [80]
Figure below shows important information.

![Stress strain curves for small intestine in persons between 20 to 29 years of age](image)

Figure 2.64: Stress strain curves for small intestine in persons between 20 to 29 years of age [52]

The small intestine is more elastic in the transverse direction as compared to its longitudinal direction. This allows the intestines to create a pulse that moves the digested material forward through its lumen. The elasticity of the walls is considerably less than that of the stomach wall. Here again the stresses become more important than the strains. The barbs should be able to recover completely at stresses of 10 gf/mm$^2$ which corresponds to the linear part of the curve (Figure 2.64).
Large intestine

Figure 2.65 shows a histological cross section of the large intestine or the jejunum. It has villi on the inner surface which increase the surface area for greater absorption.

Figure 2.65: Cross section of jejunum/ileum wall tissue (bar = 250 microns) [80]

Figure 2.66: Stress strain curve for the large intestine of persons 20 to 29 years of age [52]

Figure 2.66 shows that the slope of the stress strain curve for the large intestine is less steep than that of the small intestine in both the directions. In the transverse direction the loads generated by 40 percent elongation are extremely low. And hence the barbs for this region would have characteristics somewhere between those of the stomach and the small intestine.
2.13.3 Urogenital Organ Tissues

Figure 2.67 shows the histological cross section of the wall of the ureter. The ureter is a thick-walled tube that carries the urine from the kidneys to the urinary bladder for excretion. The wall is of three layers. The inner layer has a lining of the mucousa, and the middler layer is mostly smooth muscle cells, and the outer layer is fibrous connective tissue.

Ureter

Figure 2.67: Cross section of ureter (bar = 1 mm) [80]
Figure below shows important information.

Figure 2.68: Stress strain curve of ureter tissue in persons between 20 to 29 years of age [52]

The barbs to be designed for a ureter suture have to be strictly dependent upon the direction of suturing. Figure 2.68 shows that the slope of the two curves is drastically different, even at the extension levels of below 40 percent.
2.14 Biomechanics

2.14.1 Symbols

Following is the list of symbols used only in this chapter for purposes of explaining alternative models.

**Vector mathematics:**

\[\cdot\] = single dot product  
\[:\] = double dot product  
\[\times\] = cross product  
\[\text{trace}\] = trace of a matrix i.e. sum of diagonal terms  
\[\text{div}\] = divergence of a vector  
\[\nabla\] = gradient

**Continuum mechanics:**

\[\sigma\] = stress  
\[u_i, v_i\] = any vector  
\[\rho\] = mass density  
\[\dot{x}\] = reference configuration of a particle  
\[x\] = deformed configuration of a particle  
\[b_i\] = vector component of body force  
\[S\] = total surface area  
\[V\] = total volume  
\[F_{ij}\] = deformation gradient tensor  
\[J\] = Jacobian tensor  
\[C_{ij}\] = Right Cauchy-Green deformation tensor  
\[B_{ij}\] = Left Cauchy-Green deformation tensor

\[t_{ij..}\] = traction vector  
\[n_{ij..}\] = normal vector  
\[e_i\] = unit vectors  
\[\varepsilon_{ij..}\] = tensor formed by unit vectors \(e_i\)  
\[E_{ij}\] = Green-Lagrange strain tensor  
\[I\] = Identity tensor
σ_{ij} = Cauchy stress tensor
T_{ij} = First Piola-Kirchoff stress tensor
S_{ij} = Second Piola-Kirchoff stress tensor

**Constitutive modeling:**

Hyperelasticity:
I_1 = first invariant
I_2 = second invariant
I_3 = third invariant
W = strain energy function

Viscoelasticity:
σ = shear stress
ε = shear strain
\dot{\varepsilon}, 3 - 4 = shear rate
f = frequency
\omega = radian frequency
η = viscosity of newtonian fluid in dashpot
E' = storage modulus
E'' = loss modulus
δ = phase angle
E = modulus of perfectly elastic spring
τ = relaxation time

**Finite element analysis:**
K = Stiffness matrix
B = Strain displacement matrix
\dot{t}K = is the linear strain incremental stiffness matrix without initial displacement effect
\dot{t}_0 K_L, \dot{t} K_L = linear strain incremental stiffness matrices
\dot{t}_0 K_N L, \dot{t} K_N L = nonlinear strain incremental stiffness matrices
\dot{t} + \Delta t \mathbf{R} = vector of externally applied nodal point loads at time t + \Delta t
\dot{t} F, \dot{t}_0 F, \dot{t} F = vectors of nodal point forces equivalent to the element stresses at time t
\dot{t}_0 B_L, \dot{t} B_L = linear strain-displacement transformation matrices
\dot{t}_0 B_N L, \dot{t} B_N L = nonlinear strain-displacement transformation matrices
\( C = \) stress-strain material property matrix

\( 0C, tC = \) incremental stress-strain material property matrices

\( t\tau, t\hat{\tau} = \) matrix and vector of Cauchy stresses

\( t_0S, t\hat{S} = \) matrix and vector of second Piola-Kirchhoff stresses

### 2.14.2 Vector Mathematics

![Unit vectors in 3D space.](image)

Figure 2.69: Unit vectors in 3D space.

The unit vectors can be represented in three dimensional space as \( e^1, e^2 \) and \( e^3 \) as shown in Figure 2.69.

Thus a vector can be represented as:

\[
\mathbf{u} = \sum_{i=0}^{n} u_i \mathbf{e}_i = u_1 e_1 + u_2 e_2 + u_3 e_3
\]

(2.2)

The Kronecker delta is given by the dot product of two unit vectors as:

\[
\mathbf{e}_i \cdot \mathbf{e}_j = \delta_{ij} = \\
\begin{pmatrix}
\delta_{11} & \delta_{12} & \delta_{13} \\
\delta_{21} & \delta_{22} & \delta_{23} \\
\delta_{31} & \delta_{32} & \delta_{33}
\end{pmatrix}
\]

The vector cross products are calculated as:
Therefore the cross product is:

\[
u \times v = (u_2v_3 - u_3v_2)i + (u_3v_1 - u_1v_3)j + (u_1v_2 - u_2v_1)k\]  

(2.3)

Thus the nine possible cross products with orthogonal unit vectors are:

\[
\begin{pmatrix}
e_1 \times e_1 = 0 & e_2 \times e_1 = -e_3 & e_3 \times e_1 = e_2 \\
e_1 \times e_2 = e_3 & e_2 \times e_2 = 0 & e_3 \times e_2 = -e_1 \\
e_1 \times e_1 = -e_2 & e_2 \times e_3 = e_1 & e_3 \times e_3 = 0
\end{pmatrix}
\]

Therefore we have,

\[
\varepsilon_{ijk} = \begin{cases} 
1 & \text{for clockwise } (i,j,k) : 123, 231, 312 \\
-1 & \text{for anti-clockwise } (i,j,k) : 132, 321, 213 \\
0 & \text{for repeated index of either } i \text{ or } j \text{ or } k : 112, 221, 331
\end{cases}
\]

The area can be calculated as the magnitude of cross products of two vectors, as:

\[
\text{Area}_{uv} = |u \times v| \quad \text{Area}_{uv} = \sqrt{(u_2v_3 - u_3v_2)^2 + (u_3v_1 - u_1v_3)^2 + (u_1v_2 - u_2v_1)^2} \quad (2.4)
\]

The volume is the cross product of two vectors multiplied by (dot product) a third vector:

\[
\text{Volume} = (u \times v) \cdot w 
\]

(2.5)

A Gradient (del) is taken from a scalar field to give a vector field. This new vector field (tensor) always points in the direction of the greatest rate of increase of the scalar field. And the magnitude of this new vector field is the greatest rate of change.

\[
\text{grad} u_i = \nabla \times u_i = \frac{\partial u_i}{\partial x_j} e_i \times e_j 
\]

(2.6)

The divergence measures the tendency of a vector field in terms of where it is
originating form where it is trying to converge.

\[ \text{div} \cdot A = \nabla \cdot A_{ij} = \frac{\partial A_{ij}}{\partial x_j} e_i \]  \hspace{1cm} (2.7)

### 2.14.3 Continuum Mechanics

A tensor has different orders depending upon its size. For example:

\[ A_{ij} \] - is a second order tensor. This tensor can be written as:

\[
\begin{bmatrix}
A_{11} & A_{12} & A_{13} \\
A_{21} & A_{22} & A_{23} \\
A_{31} & A_{32} & A_{33}
\end{bmatrix}
\]

Similarly the third order tensor is represented as \( A_{ijk} \) and the fourth order tensor is represented as \( A_{ijkl} \).

The invariants of a stress tensor are the first, second and third invariant.

**First Invariant:**

\[ I_1(A) = A_{ii} = \text{trace}A = A_{11} + A_{22} + A_{33} \]  \hspace{1cm} (2.8)

**Second Invariant:**

\[ I_2(A) = \frac{1}{2}(A_{ii}A_{jj} - A_{ji}A_{ij}) \]  \hspace{1cm} (2.9)

**Third Invariant:**

\[ I_3(A) = \varepsilon_{ijk}A_{1i}A_{2j}A_{3k} = \text{det}A \]  \hspace{1cm} (2.10)

A body force acting on a body could be gravity or electromagnetic forces acting over the volume of the body. These can be written as:

\[ \int_V \rho_b i dV \]  \hspace{1cm} (2.11)

The surface traction can be given by the equation:
\[
\int_S t_i dS \tag{2.12}
\]

The Cauchy stress tensor is given by:

\[
\begin{bmatrix}
\sigma_{11} & \sigma_{12} & \sigma_{13} \\
\sigma_{21} & \sigma_{22} & \sigma_{23} \\
\sigma_{31} & \sigma_{32} & \sigma_{33}
\end{bmatrix}
\]

The traction vector can be related to the Cauchy stress tensor as:

\[
t_i = \sigma_{ij} n_j \tag{2.13}
\]

The equilibrium equation for an infinitesimal cube (one continuum) can now be written in terms of the Cauchy stresses and the body forces as:

\[
\frac{\partial \sigma_{ij}}{\partial x_i} + b_j = 0 \tag{2.14}
\]

The small deformation strain tensor is given as:

\[
\varepsilon_{ij} = \frac{1}{2} \left( \frac{\partial u_i}{\partial x_j} + \frac{\partial u_j}{\partial x_i} \right) \tag{2.15}
\]

If we consider the displacement vector:

\[
x_i = \dot{x}_i + u_i \tag{2.16}
\]

where, \( \dot{x}_i \) represents the vector in the undeformed configuration of the body, and \( x_i \) represents the vector in the deformed configuration of the body.

The vector \( u_i \) is the displacement vector. These vectors are related to each other by the chain rule as:

\[
dx_i = \frac{\partial x_i}{\partial \dot{x}_j} d\dot{x}_j \tag{2.17}
\]
The deformation gradient for the above case is given by the relation:

\[ F_{ij} = \frac{\partial x_i}{\partial \hat{x}_j} \quad (2.18) \]

The finite strain tensor in the form of the deformation gradient tensor is given as:

\[ E_{ij} = \frac{1}{2}(F_{ki}F_{kj} - \delta_{ij}) \quad (2.19) \]

The deformation gradient shown above also forms the Right Cauchy deformation tensor:

\[ C_{ij} = F_{ki}F_{kj} = F^T F \quad (2.20) \]

Also the Left Cauchy deformation tensor is given as:

\[ C_{ij} = F_{ik}F_{jk} = FF^T \quad (2.21) \]

The Jacobian tensor gives the relation between the undeformed and the deformed states of the material, as:

\[ J = \frac{dV}{d\hat{V}} \quad (2.22) \]

This Jacobian tensor can be used to compute the stresses in the undeformed state, called the Piola-Kirchoff (PK) stress. The 1st PK traction tensor is related to the Cauchy stress tensor in the deformed state as:

\[ F_{kj}T_{ij}J^{-1} = \sigma_{ik} \quad (2.23) \]

The 2nd PK stress tensor is given as:

\[ S_{ij} = (F_{ir})^{-1}\sigma_{rk}J(F_{jk})^{-1} \quad (2.24) \]

Now we can write the stress equilibrium equations in term of the PK stress and Cauchy stresses as follows:

In terms of 1st PK:

\[ \frac{\partial T_{ij}}{\partial \hat{x}_j} + \dot{\rho}\dot{b}_i - \rho \frac{d^2 \hat{x}_i}{dt^2} = 0 \quad (2.25) \]

In terms of 2nd PK:

\[ \frac{\partial(F_{ij}S_{kj})}{\partial \hat{x}_j} + \dot{\rho}\dot{b}_i - \rho \frac{d^2 \hat{x}_i}{dt^2} = 0 \quad (2.26) \]
In terms of the Cauchy stress tensor:

$$\frac{\partial \sigma_{ij}}{\partial x_j} + \rho b_i - \rho \frac{d^2 x_i}{dt^2} = 0$$

(2.27)

The 2nd PK stress and the finite strain tensor in the case of large deformations can be related to the strain energy function as:

$$S_{ij} = \frac{\partial W(a_i, E_{ij})}{\partial E_{ij}}$$

(2.28)

Similarly we can relate the deformed configuration to the strain energy function in case of small deformations using Cauchy stress tensor as:

$$\sigma_{ij} = \frac{\partial W(a_i, \varepsilon_{ij})}{\partial \varepsilon_{ij}}$$

(2.29)

We can also write the strain energy functions using the principle stretches. Thus using the 1st PK stress we can write:

$$T_i = \frac{\partial W}{\partial \lambda_i}$$

(2.30)

For the 2nd PK stress we can write:

$$S_i = \frac{1}{\lambda_i} \frac{\partial W}{\partial \lambda_i}$$

(2.31)

And for the Cauchy stress we can write:

$$\sigma_i = J^{-1} \lambda_i \frac{\partial W}{\partial \lambda_i}$$

(2.32)

If we assume that the material is isotropic and incompressible, then we can re-write the Jacobian in the form of principal stretches, as:

$$J = \lambda_1^2 \lambda_2^2 \lambda_3^2$$

(2.33)

### 2.14.4 Constitutive Modeling

Constitutive equations for different types of tissues can be developed from the force extension curve [18, 17, 19, 92]. The method for forming the constitutive equation of a rabbit mesentery (a double layer of peritoneum) was reported earlier. The first step is to select either a straight line or a quadratic or higher order expression to fit the
elastic curve such as $dT/d\lambda$ vs $T$.

\[
\frac{dT}{d\lambda} = aT(1 - bT) \quad (2.34)
\]

where,

\[
\lambda = \frac{l}{l_0} \quad (2.35)
\]

$l = $ is the length of the specimen under strain

$l_0 = $ is the unstrained length

$T = $ is the elastic tension

dT/d\lambda = slope of the tension deflection curve

Here we make an assumption that all biological tissues are incompressible.

\[
\lambda_1 \lambda_2 \lambda_3 = 1, \lambda_2 = \lambda_3 \quad (2.36)
\]

when the strain tensor is:

\[
\begin{pmatrix}
\gamma_1 & \gamma_1 & \gamma_1 \\
\gamma_2 & \gamma_2 & \gamma_2 \\
\gamma_3 & \gamma_3 & \gamma_3 \\
\end{pmatrix}
\]

which is equal to the matrix,

\[
\begin{pmatrix}
\frac{1}{2} \lambda_1^2 - 1 & 0 & 0 \\
0 & \frac{1}{2} \lambda_1^2 - 1 & 0 \\
0 & 0 & \frac{1}{2} \lambda_1^2 - 1 \\
\end{pmatrix}
\]

Integrating Eq. 2.34 gives:

\[
T = \frac{e^{a\lambda}}{c + be^{a\lambda}} \quad (2.37)
\]

Eq. 2.37 can be used to fit any experimental data of biological tissue to obtain the constants. Thus the best fit will give the constants for that particular tissue. These
constants can be back substituted in this equation to form a constitutive equation for that tissue.

However in Eq. 2.37, \( T = 0 \) when \( \lambda = \infty \). But we need \( T = 0 \) when \( \lambda = 1 \) i.e. no tension when no extension. Therefore we can modify Eq. 2.34 to,

\[
\frac{dT}{d\lambda} = a(T + \beta) \quad (2.38)
\]

Integrating Eq. 2.38 we obtain,

\[
T = (T^* + \beta)e^{a(\lambda - \lambda^*) - \beta} \quad (2.39)
\]

where,

\( T = T^* \) when \( \lambda = \lambda^* \) and \( T = 0 \) when \( \lambda = 1 \)

Substituting the values for \( T \) in Eq. 2.39 we get,

\[
\beta = \frac{T^*e^{-a(\lambda^*-1)}}{1 - e^{-a(\lambda^*-1)}} \quad (2.40)
\]

Thus we have Eq. 2.39, with which we can do optimization curve fitting to the force extension curve under tension so as to obtain all the constants. One study reported the equation for resting muscle fibers in Eq. 2.41.

\[
T = 34.3e^{-10.3(\lambda - 1.6)} \quad (2.41)
\]

The stress-strain curves for such analysis can be obtained either by uniaxial testing or by biaxial testing. It is important to note that the shape of the specimen in a biaxial testing does influence the resulting curve [44, 18, 17, 19, 92].

**HYPERELASTICITY**

The Ogden strain energy function is derived from principal stretches, and is given as:

\[
W = W(\lambda_1, \lambda_2, \lambda_3) = \sum_{p=1}^{N} \frac{\mu_p}{\alpha_p} (\lambda_1^{\alpha_p} + \lambda_2^{\alpha_p} + \lambda_3^{\alpha_p} - 3) \quad (2.42)
\]

The Mooney-Rivlin hyper-elastic model is derived from the Ogden strain energy function by substituting \( N=2, \alpha_1 = 2 \) and \( \alpha_2 = -2 \). Thus after solving the equations we have:

\[
W = \frac{\mu_1}{2} (I_1 - 3) - \frac{\mu_2}{2} (I_2 - 3) \quad (2.43)
\]
The Lagrangian stress can also be derived from Eq. 2.43 as Eq. 2.44 [18, 17, 19, 92].

\[ T = 2\left(\lambda - \frac{1}{\lambda^2}\right)\left(\frac{\partial W}{\partial I_1} + \frac{1}{\lambda} \frac{\partial W}{\partial I_2}\right) \]  \(2.44\)

**VISCOELASTICITY**

Viscoelasticity is a combination of viscous and elastic properties exhibited together. Polymers and tissues are considered both to be viscoelastic. They are also called shape memory materials, when once deformed the effect is permanent. In theory, however, we assume that the stresses will relax after an infinite time. Fourier integrals can be used to solve the partial differential equations, where the boundary conditions range for the time period from \(-\infty\) to \(+\infty\). It is important to consider the time interval from \(-\infty\), because it contains a complete history of the viscoelastic material. If we are able to incorporate these effects by way of Fourier integrals, then the results from 0 to \(\infty\) (using Heaviside function), would be more realistic for tissue suture interactions.

**Creep** :

Creep is defined as the change in length over a period of time on application of a constant load [41]. This behavior can be modelled using one or more springs and dashpots. This will be helpful in predicting the life and durability of the suture *in-vivo*. 
Figure 2.70 shows important information.

Figure 2.70: Creep behavior in viscoelasticity

Figure 2.70 shows a creep experiment being performed. We can see that when a constant load of 10 lbs is applied to the specimen, over a period of 30 minutes there is a change in length. This can be recorded as a creep spectrum.

**Relaxation**:
Relaxation is defined as the relaxation of an applied stress to a constant value (if not zero), when stretched by a certain displacement and held at that distance over a period of time[41].
Figure below shows important information.

**Stress Relaxation**

![Stress Relaxation Diagram](image)

Figure 2.71: Relaxation behavior in viscoelasticity

It can be seen from Figure 2.71 that after stretching by length L a load of 5 lbs is generated in the specimen. And then if after 30 minutes the load is reduced to zero, this means that the specimen has relaxed. This can also be recorded as a stress relaxation spectrum.

**Storage and loss moduli:**

![Young's Modulus Curve](image)

Figure 2.72: Curve for Youngs modulus
Figure below shows important information.

Figure 2.73: Curves for storage and loss moduli

Figure 2.72 shows a stress-strain curve. Young’s modulus is defined as the tangent of the angle at the initial linear part of the curve. Figure 2.73 shows the curves for storage ($E'$) and loss ($E''$) moduli plotted against frequency. As can be seen from the figure, $E''$ dominates at lower frequencies and later $E'$ crosses over to become higher at higher frequencies. When $E'' > E'$, it means that there are more viscous components in the material, such as a gel. When $E' > E''$, it means that the elastic component dominates, which is usually the case with a fiber or a suture.

Figure 2.74: Crystalline and amorphous regions

Figure 2.74 shows that the storage modulus represents the crystalline regions and the loss modulus represents the amorphous component.

**Fourier Mathematics:**
The Fourier integral function $f(x)$ that is defined as an integral between $(-\infty, +\infty)$, is given as [75]:

\[
f(x) \text{ given as } [75]
\]
\[
\int_0^\infty [A(\omega)\cos(\omega x) + B(\omega)\sin(\omega x)]d\omega \tag{2.45}
\]

where,

\[
A(x) = \frac{1}{\pi} \int_0^\infty f(t)\cos(\omega t)dt \tag{2.46}
\]

\[
B(x) = \frac{1}{\pi} \int_0^\infty f(t)\sin(\omega t)dt \tag{2.47}
\]

\(t = \) duration of a pulse or wave \(\omega = \pi n\), \(n\) is the frequency response.

The Laplace transforms can then be used to convert the differential equations to algebraic equations.

**Assumptions**:

- Dashpot contains Newtonian fluid (linear viscoelastic)
- Upon application of an instantaneous force, the dashpot does not extend
- Spring is perfectly elastic

Maxwell model:

![Maxwell Model](image)

Figure 2.75: Maxwell model of spring and dashpot

In this model, the spring and dashpot are in series Figure 2.75, so their extension
(strain) is additive [41].

\[ \varepsilon = \varepsilon_1 + \varepsilon_2 \] (2.48)

\[ \sigma = \sigma_1 = \sigma_2 \] (2.49)

The constitutive equation for the Maxwell model is,

\[ \frac{d\varepsilon}{dt} = \frac{1}{E'} \frac{d\sigma}{dt} + \frac{\sigma}{\eta} \] (2.50)

This model cannot be used to model creep because if a load is applied to the spring and dashpot in series, the elastic spring will extend instantly taking up all the load and the dashpot will not extend. This can be shown by the relation below:

\[ \varepsilon(t) = \frac{\sigma}{\eta} = \text{constant} \] (2.51)

The relaxation behavior, however can be modeled by the Maxwell model. If the spring and dashpot are strained instantaneously and kept in the strained position. Then the dashpot displaces slowly releasing the stresses. The relaxation stress is given by:

\[ \sigma(t) = E.\varepsilon_0.e^{-\frac{\omega t}{\eta}} \] (2.52)

The relaxation modulus is given by:

\[ E(t) = E.e^{-\frac{t}{\tau}} \] (2.53)

Using Fourier and Laplace transforms we can derive the the dynamic modulus for the Maxwell model. The elastic/storage modulus i.e. stored energy during deformation, which is in phase with strain, is given as:

\[ E'(\omega) = E.\left[\frac{\omega.\tau}{1 + \omega^2.\tau^2}\right] \] (2.54)

Also, the loss modulus which represents the energy lost during deformation is given by:

\[ E''(\omega) = E.\left[\frac{\omega^2.\tau}{1 + \omega^2.\tau^2}\right] \] (2.55)
The compliance which is the inverse of the modulus is given as:

$$J' = \frac{1}{E'} J'' = \frac{1}{E''}$$  \hspace{1cm} (2.56)

Finally the tangent modulus for the Maxwell model is given as:

$$\tan(\delta) = \frac{1}{\omega \tau}$$  \hspace{1cm} (2.57)

**Voigt model**:

![Voigt Model](image)

Figure 2.76: Voigt model of spring and dashpot

The Voigt model has the spring and the dashpot arranged parallel to each other Figure 2.76. Thus any applied stress $\sigma$ is distributed equally in the two arms (spring and the dashpot) of the system. Thus we have,

$$\sigma = \sigma_1 + \sigma_2$$  \hspace{1cm} (2.58)

The constitutive equation for this model,[41], is:

$$\sigma(t) = E \varepsilon(t) + \eta \frac{d \varepsilon(t)}{dt}$$  \hspace{1cm} (2.59)
In comparison with Maxwell model, this Voigt model can represent creep behavior. However, it cannot represent the stress relaxation behavior. This can be seen from the equations below:

\[ \varepsilon(t) = \frac{\sigma_0}{E} \left(1 - e^{-\frac{t}{\eta}}\right) \]  

(2.60)

The relaxation equation is a constant, as can be seen below:

\[ \sigma(t) = \varepsilon_0 [E + \eta \delta(t)] = \text{constant} \]  

(2.61)

The storage modulus and loss modulus for the voigt model are given by:

\[ E'(\omega) = E E''(\omega) = \eta \omega \]  

(2.62)

**Kelvin / Standard linear model:**

![Kelvin/Standard Linear Model](image)

Figure 2.77: Kelvin / Standard linear model of springs and dashpot

This model is a combination of the Maxwell model in parallel with a elastic spring (Figure 2.77) [41].

The constitutive equation for this model is:

\[ \sigma(s) = [E_e + \frac{E_m s}{s + \frac{1}{\tau_m}}] \varepsilon_m(s) \]  

(2.63)

Creep can also be modeled using the Kelvin model as:
\[ \varepsilon(s) = \frac{\sigma(s)}{E_s + \frac{E_m s}{s + \frac{\tau_m}{s}}} \] (2.64)

The relaxation behavior can also be modeled by this system as:

\[ \sigma(t) = [E_e + E_m e^{-\frac{t}{\tau_m}}] \varepsilon_0 \] (2.65)

The Kelvin model can also model the storage modulus and the loss modulus (dynamic properties) better than either Maxwell or Voigt model alone. It is given as:

\[ E'(\omega) = E_m \frac{\omega \tau}{1 + \omega^2 \tau^2} \] (2.66)

\[ E''(\omega) = E_e + E_m \frac{\omega^2 \tau^2}{1 + \omega^2 \tau^2} \] (2.67)

**Prony Series**:  
The Prony Series consists of a spring in parallel with a number of Maxwell elements, Figure 2.78 [60].

**Prony Series material model**

![Prony Series diagram](image)

Figure 2.78: Prony Series of springs and dashpots

The shear (G) and bulk (K) moduli are as given below:

\[ G = G_{\text{inf}} + \sum_{i=1}^{n_G} G_i e^{-\frac{t}{\tau_i}} \] (2.68)
\[ K = K_{\text{inf}} + \sum_{i=1}^{n_K} K_i e^{-\frac{t}{\tau_i}} \]  

(2.69)

where, \( G_{\text{inf}} \) and \( G_i \) are shear elastic moduli and \( K_{\text{inf}} \) and \( K_i \) are bulk elastic moduli.

\( \tau_i^G \) and \( \tau_i^K \) are relaxation times for each Prony component.

**Quasi-linear model:**

Next, we state the Quasi-linear model of viscoelasticity (QLV). This model can give the complete stress history of the material at any time interval, \( t \), as:

\[ \sigma(t) = \int_{-\infty}^{t} G(t-\infty) \frac{\partial \sigma^e(t)}{\partial \varepsilon} \partial \varepsilon \frac{\partial \sigma}{\partial \tau} \]  

(2.70)

where,

\( G = \) is the reduced relaxation function,

\( \frac{\partial \sigma^e(t)}{\partial \varepsilon} = \) instantaneous elastic response,

\( \frac{\partial \varepsilon}{\partial \tau} = \) strain history.

Soft tissues such as ligaments and tendons can be modelled with QLV. However, the QLV model does not show a good fit for data at different strain levels [90]. When comparing the data of stress relaxation at different strain levels, it is necessary to normalize the data. For QLV modelling of soft tissue, such as sheep flexor tendon, the following relationship for normalizing the data [61] is required:

\[ \frac{\sigma(t) - \sigma_F}{\sigma_P - \sigma_F} = \frac{Q(t)_i}{Q(t_P)} = Q(t)_n \]  

(2.71)

where,

\( t_P = \) peak time

\( Q = \) relaxation factor

\( Q_n = \) normalized relaxation factor

\( i = \) increment

\( t_F = \) time at which relaxation is stopped

\( \sigma = \) stress

This normalizing function gives a better fit to the stress relaxation data.
2.14.5 Finite Element Modeling

Finite element modeling is a useful method for performing stress analysis of a given solid model. In the stress analysis of barbed suture and the suture tissue pullout test, it is necessary to locate the areas of stress concentration. This is important as it will help in optimizing the barb geometry to shift or reduce or eliminate areas of stress concentration along the length of the suture. This will enable us to design a barb with the geometry that will enable it to withstand higher loading by the surrounding tissue, and eventually increasing the suture tissue pullout force.

Finite element analysis is an essential tool for manufacturing barbed sutures. Different types of barb geometries and configurations can be modeled with different types of surrounding tissues. Thus we will be able to optimize the barb geometry for any particular type of adjacent tissue, whether it be connective tissue, skin, cartilage, fatty tissue or bone. The clinical significance of the results from such a study will be to reduce patient trauma and scarring, and improve the tissue healing response with superior comesis.

Figure 2.79 shows the steps required to solve externally applied stresses to or displacement of a structure by the finite element method.

In nonlinear finite element analysis the steps shown in Figure 2.79 can be used with modified equations for displacement, shape factor and the governing equilibrium equation.

Non-linear analyses can be classified into three types [66]:

- material nonlinearity only
- large displacement, large rotation but small strains
- large displacement, large rotation and large strains.

In our analysis of the interaction of barbed sutures with tissues we will observe large displacements, large rotations and large strains in the majority of soft tissues (small strains are less than 4 percent). Two types of formulations can be used in the case of large strains [14]:

- Total Lagrangian (TL)
Figure 2.79: Displacement based linear finite element method algorithm

- Updated Lagrangian (UL)

In a TL configuration the solution scheme is such that all the static and kinematic variables are referred to in the initial configuration at time 'zero'. In a UL configuration the solution procedures are the same as in TL. The only difference is that the solution of all static and kinematic variables are referred to the last calculated configuration.

In both types of formulations, we make the following assumptions:

1. damping effects are negligible
2. volume of the body does not change with deformation
3. the constitutive equations follow the strain-rate-dependent material law
The principal of virtual displacements in the TL formulation is given by Eq. 2.72.

\[
\int_{0}^{t+\Delta t} S_{ij} \delta_{ij} d^0 V = t + \Delta t \mathcal{R}
\] (2.72)

This equation of virtual work can be linearized to the form in Eq. 2.73 by Taylor series expansion.

\[
\int_{0}^{t} C_{ijrs} \frac{\partial^{2} \epsilon_{ij}}{\partial a_{k} \partial a_{l}} d^0 V + \int_{0}^{t} S_{ij} \frac{\partial^{2} \eta_{ij}}{\partial a_{k} \partial a_{l}} d^0 V d a_k \delta a_l = t + \Delta t \mathcal{R} - \left( \int_{0}^{t} S_{ij} \frac{\partial^{2} \epsilon_{ij}}{\partial a_{l}} d^0 V \right)
\] (2.73)

The method for deriving the equations for nonlinear analysis is the same as for linear analysis, although there are a few additional steps. In nonlinear analysis we consider the isoparametric continuum elements with displacement degrees of freedom. The finite element matrices for the TL formulation are given in integral and matrix forms in Eqns. 2.74 - 2.79.

Integral forms:

\[
\int_{0}^{t} C_{ijrs} \delta_{0} \epsilon_{rs} d^0 V
\] (2.74)

\[
\int_{0}^{t} S_{ij} \eta_{ij} d^0 V
\] (2.75)

\[
\int_{0}^{t} S_{ij} \epsilon_{ij} d^0 V
\] (2.76)

Matrix forms:

\[
t \, K_{L} \hat{u} = \left( \int_{0}^{t} B_{L}^{T} C_{0} B_{L} d_0 V \right) \hat{u}
\] (2.77)

\[
t \, K_{N} \hat{u} = \left( \int_{0}^{t} B_{N}^{T} L_{0} S_{0} B_{N} L_{0} d_0 V \right) \hat{u}
\] (2.78)

\[
t \, F = \int_{0}^{t} S_{0} \hat{d} d_0 V
\] (2.79)

Eqns. 2.80 - 2.85 show the integral equations with corresponding matrix forms for UL formulations.
Integral forms:
\[
\int_{iV} t C_{ijrst} e_{rs} \delta t e_{ij} dt V \quad (2.80)
\]
\[
\int_{iV} t \tau_{ij} \delta \eta_{ij} dt V \quad (2.81)
\]
\[
\int_{iV} t \tau_{ij} \delta \varepsilon_{ij} dt V \quad (2.82)
\]

Matrix forms:
\[
\int_{iV} t \tau_{ij} \delta \varepsilon_{ij} dt V \quad (2.83)
\]
\[
\int_{iV} t \tau_{ij} \delta \varepsilon_{ij} dt V \quad (2.84)
\]
\[
\int_{iV} t \tau_{ij} \delta \varepsilon_{ij} dt V \quad (2.85)
\]

These integral equations can also be written in matrix form. In the case of static analysis we can write the equations as:

TL formulation:
\[
(t_0 K_L + t_0 K_{NL}) U = t + \Delta t R - t_0 F \quad (2.86)
\]

UL formulation:
\[
(t_1 K_L + t_1 K_{NL}) U = t + \Delta t R - t_1 F \quad (2.87)
\]

The classical Newton-Raphson iterative method can be used to solve Eqns.2.86 and 2.87 for stresses at nodal points with increments of time from 't' to 't + \Delta t'. These iterations will continue till Eq. 2.88 is satisfied.

\[
t + \Delta t R - t + \Delta t F = 0 \quad (2.88)
\]

However, it may not always be possible to achieve. So we may wish to include the value of 'zero' in Eq. 2.88 so we can approximate the expression to an error value of say '0.0001'.
Figure 2.80 shows the 10 node element in Ansys to model viscoelasticity [15].

- Element Name: SOLID187
- Nodes: I, J, K, L, M, N, O, P, Q, R
- Degrees of Freedom: UX, UY, UZ
- Real Constants: None
- Material Properties:
  - EX, EY, EZ, ALPX, ALPY, ALPZ (or CTEX, CTEY, CTEZ or THSX, THSY, THSZ),
  - PRXY, PRYZ, PRXZ (or NUXY, NUYZ, NUXZ),
  - DENS, GXY, GYZ, GXZ, DAMP

The Prony series model depicted earlier is based on the spring and dashpot model of the viscoelastic behavior. The data for stress and bulk relaxation is input to the ANSYS software for curve fitting to obtain the required Prony constants.

**TARGE170 and CONTA174**

A surface-to-surface contact analysis uses the TARGE170 and CONTA174 elements as shown in Figures 2.81 and 2.82.
Figure below shows important information.

Figure 2.81: TARGE170 - target element [15]

Figure 2.82: CONTA174 - contact element[15]

These elements can be used in situations where there is large sliding and when there is a flexible-to-flexible contact. The default contact algorithm ‘Augmented Lagrange method’ was selected. In this method penalty updates are done iteratively to find the Lagrange multipliers. Therefore this method leads to better conditioning and is less sensitive to contact stiffness coefficient. Further the contact was detected by using the ‘Gauss integration point’ method. These integration points are located at nodal or Gauss points, and the penetration of a contact ele-
ment into the target surface is limited to its integration points. However the target surface is allowed to pass through the contact surface. In this current project the default contact stiffness factor (FKN) was used. The resulting contact stiffness was calculated from this value of FKN. A default penetration tolerance (FTOLN) and a default pinball region (PINB) were used, because they were found to generate a convergent solution, while manual settings did not, 2.9.

Table 2.9: Default Parameters for Contact Analysis

<table>
<thead>
<tr>
<th>Contact algorithm</th>
<th>Augmented Lagrange method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact detection at</td>
<td>Gauss integration point</td>
</tr>
<tr>
<td>Contact stiffness factor</td>
<td>1.0</td>
</tr>
<tr>
<td>Penetration tolerance factor FTOLN</td>
<td>0.1</td>
</tr>
<tr>
<td>Pinball region factor PINB</td>
<td>2.0</td>
</tr>
</tbody>
</table>
Chapter 3

Barbed Suture Prototyping

A new method for preparing prototype barbed sutures with known barb geometries and configurations was developed, using a controlled cutting action provided by a tensile testing machine.

3.1 Principle

The barbs were cut on a stationary monofilament by the vertical downward movement of a blade attached to the crosshead with a constant rate of traverse of 0.01 inches per minute.

3.1.1 Methods to Mount Cutting Blade

Among the very first methods that were used to attach the blade to the crosshead were:

1. direct clamping in the pneumatic flat metal jaws
2. direct clamping in the zig-zag shaped metal jaws

3.1.2 Batch Processes (Single and Multiple Barbs)

Single barb

The required length of the monofilament suture was predetermined. Then the suture was cut into pieces corresponding to that length. Each piece was barbed
individually. The disadvantage of this process was that it was very time consuming and hence slow. In addition, there was variability introduced in aligning and clamping each specimen to be barbed.

**Multiple barbs**

Lengths of monofilament sutures (80 in number) were aligned parallel to each other. This was a very promising idea at first because it could increase the preparation speed of barbed sutures by almost 80 times. However, it soon ran into problems as the force required to cut the sheet of 80 monofilaments was too high, and it exceeded the capacity of the tensile testing machine.

### 3.2 Current Invention

#### 3.2.1 Machine

An MTS ReNew (1122) constant rate of traverse tensile testing machine was used for the preparation of prototype barbed sutures.

#### 3.2.2 Continuous Process

This process was a continuous process, and not a batch process. Thus it eliminated all the disadvantages of a batch process such as machine downtime, suture wastage, variable distance between barbs and non-uniform alignment. Being continuous, it had ease of operation and reduced the barb to barb geometric variation within a lot.

This method could also have been used to apply twist to the suture. However, in this project zero twist or no twist was applied to the suture so as to simplify finite element modeling considerations.

#### 3.2.3 Path of Suture

As shown in Figure 3.1 the unbarbed monofilament suture was unwound from its spool and threaded through various different components, under the movable crosshead of the tensile machine.
The suture spool was mounted at a height of about 60 cm above the machine floor. The suture released from the spool was threaded through a guide to keep it in a straight vertical position. Then it passed underneath two stop clamps. Both these clamps helped to maintain a sustained tension on the monofilament at the time of let-off from the spool. The suture then passed through an eyelet guide attached to a dead weight of 60 gms. This dead weight had an important function to keep the suture under adequate tension and avoid buckling. Then after passing over scotch tape, the suture entered the cutting zone. The point of entry into the cutting zone (CZ) was by passing around an adjustable guide (AG-1) and immediately over glass slide base. This glass slide base had a central dark region (CDR) (Figure 3.2).
Figure below shows important information.

![Diagram of Central Dark Region (CDR)](image)

**Figure 3.2: Central dark region (CDR)**

When the suture entered the CDR it passed below an elastic tensioner - 1 (ET-1). The suture was free to move vertically in the CDR. It was important that the suture passed over the critical cutting point (CCP) which was at the center of the CDR. After this as the suture left the CDR it passed underneath a second elastic tensioner (ET-2). The function of ET-1 and ET-2 was to keep the suture touching the glass slide in the CDR, avoiding lateral movement and maintaining adequate tension. As the suture left ET-2, it passed around AG-2 and proceeded towards an edge-ninety turn (EN) which was a sharp $90^\circ$ turn for the monofilament down towards G-3. It was critical to maintain very low tension in the thread line at EN so as to avoid suture fracture. At AG-3 the suture passed through a guide with a polished steel surface and moved towards the take-up assembly. After the suture left AG-3 it left the cutting zone (CZ) through an eyelet guide (AG-4) and entered the take-up assembly onto a rotating take-up cylinder (TUC), where it was wound. The eyelet had to be collinear with the winding point on the TUC, where it was wound. Otherwise suture slippage would occur as it was wound on the TUC. The TUC had a guide eyelet that allowed the suture to pass through and anchor itself onto the central shaft of the TUC.
3.2.4 Take-up Assembly

The take-up assembly is shown in Figure 3.3. It consisted of rectangular aluminium metal frame with a hole on the smaller side, which contained a bearing. A central shaft passed through this bearing, which allowed the shaft to rotate. An aluminium metal disc or take-up cylinder (TUC) having a diameter of 3 inches was mounted on this shaft as shown in Figure 3.3. A plate was locked on to this shaft by a lock-nut. This lock-nut allowed rotational motion of the shaft to be passed onto the TUC. The other end of this shaft has a circular turnable knob (TK) mounted on the outer side. This knob could be turned manually in a clockwise direction to wind the suture on to the TUC and thus in effect serve as a take-up assembly.

Another important component of this take-up assembly was the reverse lock (RL). The reverse lock was a small screw of 2mm diameter that sat in the clearance between the wall of the rectangle and the TUC. It was always in contact with the wall and the TUC. Now, when the TUC turned in clockwise direction this screw rotated in an anticlockwise direction and thus allowed take-up. However if the TUC turned in the counterclockwise direction, the screw needed to turn in the clockwise direction. This clockwise motion was prevented by the wall of the rectangle, which was stationary. Thus the RL served as a brake to avoid any
slippage or reversal of the suture while cutting. At the same time it helped in maintaining adequate tension in the monofilament suture line.

The distance between barbs (DBB) could be controlled by the circular scale mounted on the TUC. A marker just above the RL would point to the length of suture wound onto the TUC and the circular scale would indicate the DBB distance as the TK was turned clockwise.

3.2.5 Let-off Assembly

The let-off assembly consisted of a drum shaped spool mounted above the cutting zone. The spool was mounted on a stud with the outer diameter approximately equal to the inner diameter of the hollow shaft of the spool. The surface of this metal stud was knurled. This combination provided sufficient friction between the outer surface of the stud and the inner surface of the spool shaft. This helped to maintain proper tension in the thread line and avoid the creation of slack spots slacking by overrunning the suture due to spool rotational slippage.

The suture released from the spool was passed through two flat stop clamps. Since the let off was manual, the release of the stop clamp controlled the amount of suture drawn from the spool. The pulling force was provided by the dead weight located just after the second stop. Thus these two stops and the dead weight worked in tandem to achieve the let off function.

3.2.6 Barb Suture Cutting Process Control

Because the suture feeding mechanism was manually operated, it was important to follow the list of instructions indicated below, so as to advance the suture through the cutting zone in a controlled and reproducible manner. After the suture has been threaded completely, as described in the previous sections, but before cutting the first barb, the TK was turned clockwise to remove any slack in the thread line. After the first barb had been cut, the following sequence of steps was followed in order to cut the second barb,

**Step-1:** Release ET-2

**Step-2:** Release ET-1

**Step-3:** Hold the dead weight
Step-4a: Turn TK clockwise by the distance equal to distance between barbs (DBB)

Step-4b: While turning TK gradually lift the dead weight just so as to release the threadline tension just so that it is easy to take-up. If suture fracture occurs in EN zone, the tension should be zero till the barb clears.

Step-5: Stop TK and leave the dead weight

Step-6: Put ET-2 back on

Step-7: Put ET-1 back on

Step-8: Check for the length of the suture in the dead weight zone (DWZ). If necessary, release ST-1 and ST-2 simultaneously to feed required length of suture into DWZ.

Step-9: Check for the RL. If the screw is slipping/falling out of TUC and wall clearance, move it back into position.

Step-10: Check for slippage of the suture off of TUC. If required move the suture inwards.

Step-11: Turn TK slightly to check tension in the thread line. Adjust AG if required.

Step-12: Check clearance of any obstructions for dead weight

Step-13: Check for alignment of suture to the CCP in CDR.

Step-14: Check that let off stops are locked.

Step-15: Check the threadline for possible abrasive contact surfaces

After completing these steps the suture was ready to cut the next barb.

3.2.7 Doffing

Doffing means removing the barbed suture from the takeup roller. The barbed suture wound on the TUC was carefully doffed manually by slowly turning the turnable knob while holding the frame vertically by hand. The barbed suture thus produced was in the form of a single long continuous suture with all the barbed specimens attached to each other, coiled up together in a 'suture ring'.
3.2.8 Specimen Individualization

Once the suture ring had been produced and doffed, it was then sectioned into individual specimens. This was done on a barbed suture specimen preparation table. The surface of the table was covered with a white sheet of paper. This allowed for easy visualization of the barbs, and at the same time permitted markings with a pencil to identify the location of each barb that was not visible to the naked eye.

One end of the suture was taped to one side of the table, called 'point-one'. The other end, called 'point-two', was taped at the other side of the table. Next a Nikon microscope eyepiece of 10x magnification was used to manually scroll down across the entire length of the suture that was mounted on the table for specimen individualization. This was done using a diffused backlight from a table lamp. In doing so identification of the barbs was started from the first taped end and continued towards the other end. A pencil was used to mark the position of the barb as soon as it was seen through the eyepiece. After the entire length of the suture was marked, a blade was used to cut the suture into specimens. This was done in a fixed order. First a finger was placed just after the point where the blade sectioned the monofilament. This prevented recoiling of the suture after sectioning, and it reduced the need to tape each and every specimen separately; hence reducing processing time.

Once the first round was complete, all the individual specimens were collected in a ‘suture dish’. The suture dish was a specimen holder that had a white base, so that all the specimens were clearly visible. The edges of it were raised so that the specimens did not easily fall out when a specimen was lifted from the stack for image analysis.

The next round began by untaping point-two and taping it over again point-one, and as earlier, holding and taping the suture at point-two. If there was still some length of suture left, it was allowed to hang down from the table. This process was repeated till the entire suture-ring was individualized and cut into separate specimens.

Care was taken not to run ones fingers along the suture to feel the barbs located them, because that might have caused damage to the barbs. So, in order to make sure the monofilament suture lay straight while tapping at point-two, one hand
held the suture in between two barbs, as located by the eyepiece, and the other hand was used to apply a light force to pull the suture straight.

These were the Challenges in locating the barbs on the prototype cut sutures:

– Although the barbs were cut only on one side of the monofilament. In a relaxed state the monofilament turned on itself into a curved state. So after mounting the suture for cutting, all barbs were not on the same side. This was because the inherent small twist or turn in the suture. Therefore sometimes the barbs were on the other side of the suture and so were not be visible. In this case the monofilament was carefully turned over.

– Sometimes the barbs were in the shadow region of the suture and so were not visible. In this case the focus of back light was readjusted.

– Particularly for those prototypes sutures with very small cut depths and/or very small angles, the barbs may have been difficult to locate. In this case the constant distance between the barbs (DBB) was used as a guide to find the next barb.

3.2.9 Horizontal Force Stabilizer (HFS)

When cutting at an angle, the blade experienced a horizontal force (HF) at the cutting edge. The force increased from the moment the blade made contact with the monofilament suture until it reached the pre-set cut point. This force gave rise to a ‘blade sliding’ effect in which the blade moved laterally by a micrometer distance, instead of moving downwards. Because of this lateral motion, the barbs were cut to a cut depth lower than the preset cut depth.
Figure below shows important information.

A ‘horizontal force stabilizer’ (HFS) was installed to avoid this lateral movement of the blade by providing a negative force equal and opposite to HF (Figure 3.4). It thus played an important role in maintaining the downward movement of the blade in a straight line. This in turn controlled the accuracy of the cut depth. In the current project the HFS provided a constant negative force of up to 40 lbf.
The unit consisted of a metal frame as shown in Figure 3.5. The cylindrical steel shaft (TSS) lay parallel to provided a line contact to the metal plate to which the blade was attached. Dead weights of up to 40 lb (four 10lb cast iron discs) were placed into the carrier alongside the metal frame (two discs on each side). These dead weights held the metal frame down and prevented it from any lateral micro sliding movement. This in turn allowed the TSS to serve as a rigid line of contact. This prevented any lateral micro movement of the blade as the blade attached to the crosshead travelled along a straight downwards path into the viscoelastic monofilament suture material.

3.2.10 Zero Blade Calibration

In order to accurately cut a barb on the monofilament suture to a required predetermined cut depth the blade first needed to be zeroed on the base plate.

Blade contact sensing and critical contact point (CCP) determination

To facilitate this process a diffuse light source was created from a table lamp covered with paper and placed behind the tensile testing machine with a focus on
the CDR. The idea was to see how the light was visible between the metal plate and the blade as the crosshead was lowered to the zero point and the blade made contact with the base.

The metal plate, with the blade attached, was already mounted in the upper jaw. The crosshead was lowered slowly using the manual scroll wheel located on the external wired control unit. Simultaneously the scale on the computer screen using ‘Test Works’ software was monitored.

The zero point reached when bright light viewed between the blade cutting edge and the base glass slide in the CDR was reduced to zero. When this occurred it meant that the blade had touched the base. At this point the HFS unit was put in place using a backlight from the table lamp, such that the plate made a firm horizontal contact. This line of contact was extremely crucial in zero calibrations.

For example, there was an inherent variation of about ± 0.1 mm in the cutting edge profile of a new skin graft surgical blade (Sterile Skin Graft Blade, Swann-Morton Ltd., Sheffield 6, England) Figure 3.6. Therefore, when the blade made contact with the glass slide base, it was not complete contact along the entire cutting edge. This means that there were certain regions where there was no contact and light came through (Figure 3.7).
Figure below shows important information.

![Diagram](image)

**Figure 3.7: Critical cut point (CCP) at zero contact**

At this time the movement of the crosshead was stopped and the software program was set to ‘zero’. All the points where the blade made complete contact in the CDR were marked. A point within this complete contact region was then selected to become the critical contact point (CCP).

**Zero calibration trials**

After the suture had been threaded through the setup, the guides AG-1 (and AG-2 if required) were adjusted to that the suture coincides with the selected CCP point. The first barb was cut as described below in the cutting section. A DBB of 1mm was used, and 10 barbs were cut. During calibration there was no need to release ET-1, since there was no barb passing through it. This was because the smaller DBB of 1mm only moved the suture by a take-up displacement of 10mm, which was smaller than the size of the CDR.

After the 10 barbs had been cut, the crosshead was then moved up out of the way. These barbs were then image analyzed. Calibration was correct only when there was zero variation in the cut depth of all ten barbs. If that was not the case, then the entire zero calibration procedure was repeated after checking for errors due to micromotion. The tolerance for cut depth was 0.00% (least count was 0.01mm) and for cut angle it was ±0.001%.

Following list of instructions is an error check list for possible areas to correct for micromotion. This list may not be complete and there may be additional points
that have not yet been identified.

1. Blade and metal plate epoxy contact: look for unglued regions, redo if found.
2. Metal plate in the upper jaw loose: use a very high force to turn the screw
3. The top connector into which the top jaw is mounted: use more packing, hence more force to lock it in position
4. The top machine connector: not screwed completely
5. The blade metal plate is not using the entire surface area of the jaws for clamping.
6. The base fixture lock nut is loose
7. The base fixture rear bottom support is absent or not placed properly
8. The suture is not aligned at CCP
9. AG-1 and AG-2 are not inline with the suture line and the CCP
10. AG-1 is loose
11. The HFS is incorrectly placed: line of contact is not complete
12. The HFS is wobbly: add packing at the base of the frame, readjust dead weights
13. ET-1 and ET-2 have worn out or are too loose
14. Suture monofilament itself is damaged: remove the affected lengths
15. Dead weight on suture feed is obstructed on its way upwards causing very high tension in suture line
16. Dead weight on suture feed is lifted from bottom causing a very rapid drop in suture line tension
17. Dead weight on suture line is itself insufficient
18. Placing hand or elbow on the metal frame: resulting in faulty blade contact sensing, faulty TSS to metal plate line contact sensing
19. The lock nut in the RL has fallen out causing drop in suture line tension.
20. The suture has slipped off the TUC
21. The upper crosshead and hence the blade was not moved to a sufficient height upwards after cutting the barb, for minimal barb clearance: causes the barb to get trapped into the blade which in-turn increases take-up tension rapidly and may lead to suture line breakage if not identified immediately
22. Zero in the software was not done at blade contact
23. Early or late sensing of blade contact with the glass base
24. The glass slide not in full contact with the base
25. The cutting edge of the blade is damaged after using it in a previous cutting operation
26. The cutting edge of the new blade is uneven: check profile under microscope before using it
27. The metal plate holding the blade itself is bent: even a slight bend is undesirable
28. The packing material used in securing the connectors is too soft and gets compressed
29. The length of the threaded portion screwed into the upper crosshead is insufficient
30. The bolts on the metal frame of HFS are loose
31. The lower manual stop of the MTS is set too high
32. The bolts on the bottom base support of the MTS are not fastened properly
33. The ETs are placed too far away: CES is not corrected
34. The heat from the backlight is causing the ETs to soften: switch off the backlight when not required to allow it to cool down and replace the ETs with new ones.
35. Faulty blade to glass base contact sensing as line of back light is cut off due to debris at the top of the cutting edge and the debris on the glass base: clean it carefully
36. Sliding of the suture line off the CCP after manual takeup: manually readjust the suture line
37. Barb fracture resulting from a high tension at EN.
38. Suture abrading over rough metal surfaces: remove them or cover them with scotch tape
39. Clamp pressure in the stop clamps at let off is too high: causing flattening of the suture monofilament
40. Backlight improperly placed: results in early or late detection of the blade contact.

41. Suture polymer itself has a very high modulus and the blade is not sharp enough to cut it accurately: try using a finer and more rigid blade, reduce the distance between the metal plate edge and the blade cutting edge while applying super-glue.

42. Flattening of the suture is observed in image analysis in the regions just below the barb, although the barb geometry is correct: the setup is correct and a sharper blade should be used.

43. Variation observed in image analysis after cutting certain number of barbs: life of blade may have passed sometime while cutting that lot. This can happen even after accurate zero calibration.

44. Image analysis reveals that the cut depth on one side of the barb is different than the other side of the barb: its due to unparallel line of contact of (a) the blade cutting edge with the glass cutting base (b) TSS with the metal plate. Correct (a) by twisting/turning the top jaw alongwith the connector to make a parallel contact. Correct (b) by readjusting the metal frame of HFS to make sure the line of contact extends across the entire width of the metal plate.

3.2.11 Cutting Zone (CZ)

The cutting zone consisted of the

**Part 1:** elastic tensioner, ET-1 and ET-2

**Part 2:** adjustable guide, AG-1 and AG-2

**Elastic Tensioner (ET)**

When the suture passed over the glass base at a slant angle because of the cutting base fixture, it should ideally have laid flat on that surface. However due to the rigidity of the monofilament it did not. It floated above the glass slide even under high suture line tension, causing a concaving effect of suture (CES) (Figure 3.8.
Figure below shows important information.

**Figure 3.8: Concaving phenomenon in suture**

This resulted in faulty barb geometry because the cut was initiated too early as the filament was lifted up in the air above the glass base due to concaving. And as it traveled down with the blade already in contact with the monofilament, it caused variation in suture line tension, and changed position of the suture line over the CCP, before the monofilament made contact with the glass base to initiate the cut.

The elastic tensioner helped in keeping the suture lying flat on the glass base at the CCP (Figure 3.9)

**Figure 3.9: Elastic Tensioner (ET)**
During take-up it was important to release ET-1 and ET-2 to reduce the tension in the suture line. Especially while dealing with lower cut angles such as 150 degrees an additional negative force may have been required to be applied to the dead weight. This brought the tension in the suture line to zero. So during take up as the barb passes over the EN region the suture was more or less concave. This avoided any acute bending of the suture and hence there was no fracture of the barb. If the tension in ET-1 and ET-2 was not released the barb suture fractured immediately after leaving EN as shown in Figure 3.10

![Figure 3.10: A fractured barb](image)

**Adjustable Guide (AG)**

The adjustable guide (AG-1) provided alignment of the incoming suture line with the CCP in combination with AG-2 (Figure 3.11). In this project an Allen key was clamped at the base of the cutting base fixture using a aluminum plate and a screw. This method of clamping was very stable and provided a consistent feeding point to guide the suture.
Figure below shows important information.

![Adjustable guide diagram](image)

Figure 3.11: Adjustable guide

The semi-adjustable guide (AG-2) was a pin that could be inserted in the hole on the base fixture. This hole was located just after EN. This needed to be used if AG-1 was set for a CCP that lay halfway beyond the width of the slant of the base fixture. In all other cases the screw that directly went into the base fixture just before EN could be used in place of AG-2.

### 3.2.12 Blade Assembly

The blade assembly consisted of the following parts

- **Part 1**: A top clamp
- **Part 2**: A rigid flat metal plate
- **Part 3**: A blade (Sterile Skin Graft Blade, Swann-Morton Ltd., Sheffield 6, England) and super-glue (Krazy Glue)
Preparing the blade

Firstly it was most important to check the cutting edge profile of the blade under a microscope using image analysis. This was performed on used and even new blades before they were used any further.

The entire surface of the flat metal plate was cleared to make it smooth. The inner edge of the blade was aligned to the edge of the metal plate as shown in Figure 3.13. The inner edge of the blade was allowed to stand beyond the edge of the metal plate by 0.5 to 1.0 mm. This was sufficient clearance to avoid getting any super-glue/epoxy on the sharp cutting edge. Then Scotch tape was applied to the metal plate to hold the blade and the metal plate together in the aligned position. Then a narrow width of Scotch tape was applied to the cutting edge of the blade to make sure that no super-glue got attached to that edge and to avoid blunting the blade. After checking for alignment, super-glue was applied evenly to the metal surface just below the blade in the glue-region (GR) as shown in Figure 3.12. Glue was not applied near the metal plate edge, because once the blade was
lowered the glue would flow into this region. The blade was then lowered slowly and gradually from the taped end to the free end, and a dead weight added. It was allowed 2 to 3 hours for the super-glue to dry. The tape was then removed from the cutting edge and the blade was ready for cutting (Figure 3.13).

**Mounting the blade**

Before the metal plate and blade were mounted into the clamps, the clamps needed to be set up. The upper connecting rod/stud/sleeve of the clamp was placed into a cylindrical metal connector, packing paper was added and the required connecting pin was secured in position. The other end of this connector was closed and was screw-fastened directly into the top of the cross head.

The end of the metal plate (opposite to the blade) was then mounted between the manual clamps with a zig-zag inner surface (Figure 3.4).

**Life of a Cutting Blade**
Figure below shows important information. It was difficult to identify the moment when a blade was no longer functional (Figure 3.14). Also, it was not advisable to change the zero calibration, which meant also changing the blade within a single lot. So the use of a high quality blade that had a durable cutting edge was important, and in this project a Surgical Skin Graft Blade was used which had a life span in the range between 60 to 100 barbs. The functional life of a cutting blade depends on:

1. the quality of the blade
2. the number of barbs cut
3. the rigidity of the suture polymer and
4. the number of attempts at zero calibration when it was necessary to identify zero contact of the blade with the glass slide

The higher the number of attempts the greater the chances were that the life of the blade was reduced. Also, dexterity to stop the crosshead at the point of contact was a factor. If the hit the base at high speed, there would be blade damage that would require the blade to be replaced. Continuing to cut or calibrate with that damaged blade would result only in incorrect barb geometry. Thus sharpness of
the blade was very important to cut the monofilament suture polymer material [106].

3.2.13 Cutting Base Assembly

The cutting base assembly consisted of a main part which is the base fixture (Figure 3.15).

![Base fixture (150°)](image)

Figure 3.15: The base fixture and base-to-MTS connector assembly

**Part 1:** The base fixture with seven screws

**Part 2:** The base to MTS connector with lock pin

**Part 3:** Two elastic rubber bands (ET-1 and ET-2)

**Part 4:** Additional pin for AG-2

**Part 5:** Glass slide, black permanent marker, Scotch tape

**Part 6:** Packing material (paper), metal washers and nut

Designing and Preparing the base

The base was made of aluminum metal which was softer than the stainless steel blade. Hence during initial zero calibration trials when the blade happened to
touch the base surface, it would cut into the softer aluminum. This created ridges and erosion to the order of 0.02 mm. This damaged aluminum surface resulted in erroneous zero blade calibration and led to wrong cut depths.

In order to avoid this problem, the base fixture was redesigned and a glass slide was placed and secured on the cutting surface. The required length of the glass slide was cut so that it was at least 10 mm less than the slant length of base fixture. This was essential because the glass slide was not to stick out beyond the slant length and create an acute angle bend in the suture line. This was not desirable and would have caused suture fracture after cutting a barb. So in the redesigned base fixture the blade came into contact with a highly even surface. Plus this surface was easily replaceable, if damaged. Scotch tape was used to secure this glass slide to the base, making sure that all the sharp edges of the glass slide were covered.

Because a backlight was used to sense the contact of the blade cutting edge with the cutting base surface (now the glass slide), and because a transparent surface caused refraction of the light through the glass, therefore light was still visible even after the blade had made contact with the glass base. In order to solve this problem, it was necessary to make the top surface of the glass slide opaque. This was done by using a black permanent marker. This opaque region was called the central dark region (CDR) as discussed earlier. Now it was much easier to identify the blade-glass contact for zero calibration.

**Mounting the base**

A base fixture of aluminum metal plate was created for each of the three cut angles (150°, 160° and 170°). It provided the base for the suture monofilament to make cutting of barbs possible. It was necessary to add packaging material and paper to the base socket of the tensile testing machine before inserting the base connector and locking it with a pin. This was required in order to ensure there was absolutely no micromotion in the base. Then the base fixture was mounted once the position was appropriate and the lock nut was tightened securely. It was important check for micromotion and readjust if necessary.

While cutting steep angles, such as 160 or 170 degrees, an additional rear support was needed to avoid micromotion. This micromotion occurred due to an offset
center of gravity of the base fixture. As the vertical blade started cutting it also pushed the base backwards, and the lock nut on the base fixture was unable to provide sufficient force to avoid micromotion. This was resolved by adding the support of a bolt and washers. They were placed underneath the rear side of this fixture. So if it tried to move, the additional support would push back with an equal amount of negative force.

3.2.14 Image Analysis System

Specimen Mounting Method

In order to facilitate image analysis of the prototype barbed sutures, Barbed Suture Imaging Clamp (BSIC) was designed to hold the barbed suture specimens (Figure 3.16).

![Figure 3.16: Barbed Suture Imaging Clamp (BSIC)](image)

The advantages of using this clamp were:

1. Minimum suture length was as short as 3 cm
2. The curved suture monofilament (due to being wound on a spool) could be easily focused
3. Turnable knob allowed ease of locating the barb while establishing focus
4. Ease of mounting and removing the specimen

5. Adjustable bush for extremely curved suture to support a barb at close proximity, so that the barb maintained a steady position while turning the knob. Alternatively, it would go in and out of focus due to the curvature.

6. No damage to barb due to ease of mounting and no abrasive contacts

Some practice was needed to be able to mount the specimen and hold it and position it manually while focusing.

**Lighting**

Two top light sources and one bottom light were used to illuminate the barb. The two top light sources were required to remove the shadows created by either light. Also, they helped in removing the edge aberration effects while focusing.

Top lights:

- Variable light intensity controlled: Cole-Parmer Illuminator
- Fixed intensity: conventional table lamp

**Microscope**

The Nikon stereomicroscope with an objective of 10x and an eyepiece of 10x was used. The total magnification for the entire image analysis system was thus 100x.

**Microscope Scale Calibration**

The microscope was calibrated using a microscale. Each division on the eyepiece was equal to 0.01 mm (10 microns).

**Digital Camera**

A 3.1 megapixel Logitech Webcam was used to take pictures. This camera was directly attached to the microscope eyepiece.
**Computer and Software**

The software for performing manual measurements of the barb geometry was Image J. The scale was calibrated and set to 812 pixels per mm. The software had direct options to measure both the cut angle and the cut length.

**Image Analysis Method and Measurement**

The barb was focused sideways, such that the cut point was visible. Then depending on the visibility of the cut, measurements were made manually by placing points using a mouse cursor.

The dimensions measured were:

- Monofilament diameter (ribbon width)
- Cut angle
- Cut depth

**Automated Barb Geometry Measurements**

An automatic barb geometry measurement script was written in Matlab (Appendix S). However this was useful only if the cutting edge was clearly visible and the barb stood out of the monofilament. Since this was not the case with all the barbs, measurements were performed manually as described in the next section. The program however works well, Figure3.17. This section briefly describes how the automated process worked.
Figure below shows important information.

Figure 3.17: Barb geometry measurement in Matlab

The image of a barb was first saved in RGB color in jpeg format. The program converted this image to a monochrome scale. This image had only two colors: black, which has a value 0, and white, which had a value 1. The calibrated number of pixels per mm were input into the program. The dimensions of the image were typed in the program. When run the program located the cutpoint, the point of entry of the blade and a point away from the barb on a line parallel to the monofilament axis. Using these three points the program calculated the cut angle, the cut depth and the cut length. These image analysis data were used to calculate the mean, standard deviation and standard error values for each dimension. They were also saved in an MS Excel spreadsheet in the same directory.

Rule for measuring cut angle

The first point was always the cut point. The second point was the end of the straight line that coincided with the cut starting from the cut point. The third point was the edge of the monofilament (on the same side as the cut-point, i.e. opposite side to the barb) that was parallel to the monofilament axis. This measurement was very sensitive.
Rule for measuring cut depth

The first point was the cut depth and the second point was the edge of the monofilament parallel to monofilament axis.

Image Measuring Challenges

1. Poor visibility of cut: The visibility of the cut depended largely on the quality of the cut. Sometimes the cut is crude or not in a straight line. In this case there is light reflecting from most of the cut length. In this case try to locate the non-reflecting surface and reduce the intensity of light. Position and focus this edge and take the image.

2. Manual errors in measuring cut angles: The imaging software is very sensitive when it comes to measuring angles. Even a slight movement will cause change in angles by up to 5 to 10°. Therefore if you measure the same angle again, sometimes it may show it as a different angle. So consistency in measuring is of utmost important.

3. Wake of blade entry: This may mislead the person measuring into thinking that the initial cut when the blade enters the monofilament is actually the set cut angle. In this case, ignore this initial slant portion of the cut edge.

4. Highly distorted suture: Sometimes the suture is so curved that it is not possible to find a straight line on the side opposite to barb. In this case try to find a line parallel to the monofilament axis on either side of the suture.

5. Sometimes the barb does not open up completely if it has been cut on the inside of the inherent curvature of the suture (due to being wound on the spool). In this case the cut point can be detected at the end of a fine line. Increase the intensity of light to see this line.

6. Sometimes if there is debris along one side of the barb cut, try using the other side.

7. If you notice that the cut angle and the cut depth are correct, but the barb is very small. It is because its a damaged barb. Take a top view of the barb and you will see that half of the barb has been eaten away.

8. Sometimes the cut edge that needs to be measured is not straight. This is because of unidentified micromotion during the cut, and the blade could not
continue into the monofilament along a straight path. In this case measure the exit angle of the blade at the cut point. This will be the straight line of the cut edge at the cut point. In this case if you try to measure along the edge, it will not be possible to fit the entire edge along one straight line. Due to the curvature, multiple straight lines would be needed to be fitted. However use the one that gives a closest approximation to the cut angle that was pre-set for cutting on the MTS.

9. Sometimes if the cut depth for a barb is too high or low: it is possibly because the suture line shifted off the CCP.

10. Sometimes if the cut depth is too low even after accurate zero calibration: it is because of an inherent change in the diameter of the monofilament. In other words, under the pressure of the blade, the circular cross-section changes to an elliptical shape.

3.2.15 Barb Quality

Good quality barbs are crucial for the best suture anchoring performance, Figure3.18.

Figure 3.18: A good quality barb

Good quality barbs are those that in addition to having an accurate geometry
have the following characteristics:

1. sharp cut edges
2. minimal or no erosion of the barb surface
3. sharp curved tip of the barb: for cutting into the tissue and for anchoring
4. no fracture of the barb at the base of the cut line
5. no flattening of the suture monofilament below the barb
6. the barb should not be bent
7. the tip of the barb should not be broken off
8. no debris stuck in the cut open region of the barb: especially in the case of small barbs
9. the suture monofilament used for cutting should not be severely curled

There are many reasons why the barb or the suture may become damaged in the process of cutting if the process parameters are not monitored precisely. Figure 3.19 shows a damaged suture monofilament caused by any slight unexpected contact with the blade cutting edge during takeup.

![Figure 3.19: Chipped suture due to unexpected blade contact](image)

If the ET-2 was not released during take-up after a barb was cut, the bending of the barb might have occurred. This was because the barb was trapped in the
elastic tape (Figure 3.10). And as the take-up force increased, it had to bend in order to pass under ET-2 (Figure 3.20).

Figure 3.20: Barb bent due to failure to release ET-2 at take-up

In another case when the blade was not sharp and not clean, the barb was dragged inwards at the end of the cut. The tip of the barb was hence permanently bent inwards (Figure 3.21). Barbs of this quality are undesirable because the "dead barb" has no "functional tip" for tissue penetration.

Figure 3.21: A dead barb with no functional tip
Chapter 4

Materials and Methods

In this section the test methods and the materials used for the experiments are described. The specimens made available for the experimental testing were prototyped in the Biomedical Textiles Laboratory.

4.1 Suture Material

The suture material used was blue color polypropylene monofilament of size ’0’ (zero). The available suture material for the project was 150 meters wound on a spool which was provided by courtesy of Covidien (US Surgical), Tyco Healthcare. The theoretical specimen length for each test was set to 50 mm, to accommodate sutures for a variety of trials to be taken from the 150 meter length. The actual specimen length varied between 50 to 70 mm.

4.2 Image Analysis

4.2.1 Barb geometry

The cut angle and cut depth were measured using a Nikon microscope at 100x magnification (10x eyepiece and 10x objective). As discussed earlier in the Chapter 3, two top light sources were used.

The Figure 2.27 shows the cut angle and cut depth.
4.3 Design of Experiments

The objective was to determine if there is any effect of the cut angle and cut depth on the anchoring properties of a barbed suture in different types of tissues. Therefore three levels of cut angles and three levels of cut depth and two tissue types were selected for the suture/tissue pullout test experiments.

Table 4.1: Design of experiment for tissue specific barbed sutures

<table>
<thead>
<tr>
<th>Cut depth</th>
<th>Cut angle</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150°</td>
</tr>
<tr>
<td>0.07 mm</td>
<td>*</td>
</tr>
<tr>
<td>0.12 mm</td>
<td>*</td>
</tr>
<tr>
<td>0.18 mm</td>
<td>*</td>
</tr>
</tbody>
</table>

As shown in Table 4.1, there are a total of nine blocks. So, for each of the block a number of 60 to 120 single barbed suture specimens each of 50 to 70 mm in length were cut. A total number of 700 barbs (of barbed suture specimens) were image analyzed and kept ready for testing. However, preliminary experimental trials used up a number of these specimens. Consequently the following tables indicate the specimen distribution in the experiments for the tensile test (Table 4.2), skin tissue pullout test (Table 4.3), and tendon tissue pullout test (Table 4.4).

Table 4.2: Barbed suture experiment: Tensile test

<table>
<thead>
<tr>
<th>Cut depth</th>
<th>Cut angle</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150°</td>
</tr>
<tr>
<td>0.07 mm</td>
<td>15</td>
</tr>
<tr>
<td>0.12 mm</td>
<td>15</td>
</tr>
<tr>
<td>0.18 mm</td>
<td>15</td>
</tr>
</tbody>
</table>

Table 4.3: Barbed suture experiment: Skin tissue pullout test

<table>
<thead>
<tr>
<th>Cut depth</th>
<th>Cut angle</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150°</td>
</tr>
<tr>
<td>0.07 mm</td>
<td>6</td>
</tr>
<tr>
<td>0.12 mm</td>
<td>6</td>
</tr>
<tr>
<td>0.18 mm</td>
<td>6</td>
</tr>
</tbody>
</table>
Table 4.4: Barbed suture experiment: Tendon tissue pullout test

<table>
<thead>
<tr>
<th>Cut depth</th>
<th>Cut angle</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.07 mm</td>
<td>6 6 6</td>
</tr>
<tr>
<td>0.12 mm</td>
<td>6 6 6</td>
</tr>
<tr>
<td>0.18 mm</td>
<td>6 6 6</td>
</tr>
</tbody>
</table>

4.4 Specimen Preparation

4.4.1 Tensile test

No preparation was required for testing unbarbed sutures, as they were used directly from the spool for clamping. In case of the barbed sutures, the specimens were already prepared as they were made ready for image analysis.

4.4.2 Tissue Pullout Test

The fresh (not frozen) tissue was procured from a local store. The skin tissue was porcine skin tissue and the tendon tissue was bovine tendon tissue. All tests were performed within 12 hours of procurement of the tissue. The cut specimens were kept in a water bath at room temperature to avoid loss of water from the tissue and drying.

Tissue specimen cutting

A surgical skin graft blade (Swann-Morton, Sheffield) was used for specimen cutting.
The skin tissue was in the form of a thin sheet. Hence it was cut into rectangular specimens of dimensions measuring approximately 10 mm in width and 50 mm in length (Figure 4.1). The thickness of the skin tissue was approximately 2 mm as measured by a Vernier-calliper. The tendon tissue had a somewhat circular cross-section with diameter varying between 7 to 12 mm. It was cut to a length of 50 mm. At the bottom of the specimen a rectangular portion was cut for clamping the specimen in between the lower jaws (Figure 4.1).

Since the suture specimens did not have a needle swaged to them, a syringe needle was used for threading instead. A syringe needle (21G1 PrecisionGlide) with inner diameter of 0.495 mm was used. This diameter was slightly greater than the suture diameter by 0.095 mm. The threading process was begun by first inserting this needle into the tissue specimen (Figure 4.2). The maximum usable needle insertion length was 20 mm. This determined the point of insertion which was 20 mm away from the pullout edge. This left 30 mm for clamping below the insertion point.
Figure below shows important information.

![Figure 4.2: Threading the barb into the tissue for preparing the pullout specimen](image)

The needle was pushed into the tissue in a straight line along the center of the tissue, starting from the top face for the skin tissue and the transverse side for the tendon. Figure 4.1 shows the needle entry points for the two types of tissue. Although the needle started from the top face for skin, it passed through the tissue and came out on the other side in a straight line (Figure 4.2). Once outside, a suture with a barb facing opposite to the needle-entry was inserted into the needle. The suture was pulled through so as to bring the barb inside the tissue and at a position 10 mm from the point of entry (Figure 4.2).

This gave a peel away distance or anchoring distance of 10 mm inside the tissue during the suture/tissue pullout test. Note that while the outer diameter of this syringe needle was 0.813 mm, after it was retracted it was assumed that the surrounding tissue would fall back against the suture. Thus there was no tunneling effect through which the suture might just slide out without any barb anchoring.
4.5 Experiments

All the experiments in tensile testing and suture/tissue pullout testing were performed on the MTS ReNew tensile testing machine at Biomedical Textiles (BMT) Laboratory, College of Textiles, NCSU. TestWorks software was used, which in turn was installed on the computer running on Windows 98.

4.5.1 Tensile Testing

Tensile testing of the unbarbed and barbed sutures was performed. The results from this test were also used to verify the prototyping method. The load cell used was of 250 Newton capacity for tensile testing of both unbarbed and barbed sutures. the time to break was approximately 20 seconds. This time was used to determine the testing speed of the equipment.

Unbarbed suture

The unbarbed sutures were tested until failure. The peak load and elongation at this peak load were recorded. The testing parameters were:

- Gauge length : 35 mm
- Clamp type : capstan clamp
- Clamping pressure : 60 psi (pneumatic)
- Testing speed : 2.0 mm per sec

Barbed suture

Since the specimen length for the barbed sutures was only 5 cm, it was not possible to use the regular capstan clamps which required a minimum specimen length of about 10 cm. Therefore a modified setup was used on a zig-zag clamp using a 'Allen-key wrench' to create a capstan effect. The wrench was clamped in the lower jaw. One end of the single barb suture specimen was clamped into the lower jaw along with the wrench. Then two turns were made around the wrench shaft before clamping the specimen into the upper jaw. This setup completely eliminated jaw breaks. All the breaks were in the center where the suture was
barbed. As written above, this setup was not used for unbarbed sutures, because the unbarbed monofilaments had a much higher breaking force.

Figure 4.3: Barb suture specimen mounting for tensile test using capstan clamping effect.

The barbed suture specimens were mounted as shown in Figure 4.3. It should be noted that due to the smaller specimen size, machine and clamp limitations, the suture was out of alignment by about 9.59° as it traveled up to the top clamp. The effective gauge length was 1.2 cm (12mm). This modified clamping setup was used for all the specimens tested, so as to avoid variation or bias between and within the lots tested.

The specimens were loaded until failure. The peak load and the elongation at this peak load were recorded. The testing parameters were:

- Gauge length : 12 mm
- Clamp type : modified zig-zag clamping technique with capstan effect
- Clamp pressure : manual
- Testing speed : 2.0 mm per sec

4.5.2 Single Barb Pressure Point Loading

In the experiment a virtually non-elastic metal wire tip was glued to the tip of the barb using Superglue. This procedure was done under a microscope at 100x.
magnification.

The idea behind this experiment was to be able to measure the loading response of a barb to a pure peeling force. Figure 4.4 shows the specimen ready for the test. In this case the tip of the metal wire is not modified. It is more or less a rounded cylinder at the tip, which is glued to the tip of the barb.

![Figure 4.4: Barb tip glued to rounded wire tip](image)

Figure 4.4: Barb tip glued to rounded wire tip

Figure 4.5 shows a modified approach in shaping the tip of the metal wire. In this case the tip of the metal wire was cut to form a recess into which the barb tip was accommodated and then glued. This extra surface provided more area for glue bonding due to a greater contact surface area. Yellow colored Scotch tape can be seen securing the soldering point until the specimen was mounted on the tensile testing machine prior to loading. A cardboard window was also used to secure the point of soldering. In this latter case the sides of the window were cut after the sample had been mounted on the testing machine.

![Figure 4.5: Barb tip glued to a pointed barbed wire tip](image)

Figure 4.5: Barb tip glued to a pointed barbed wire tip

Figure 4.6 shows pure loading of a single barb on the tensile testing machine. The single barb suture was attached to the flat edge of a brass metal plate clamped
in the lower jaw. The metal wire was clamped in the upper jaw. And as seen in Figure 4.6, the sides of the cardboard window were cut in this case before the loading began.

Figure 4.6: Pure loading of single barb

The load vs displacement is recorded as the test proceeded.

Testing parameters:

– Barb cut angle: 165.76°
– Barb cut depth: 0.15 mm
– Suture diameter: 0.40 mm
– Metal wire diameter: 0.25 mm
– Super glue name: KrazyGlue
– Testing speed: 0.05 mm/sec
4.5.3 Suture/Tissue Pullout Test

The suture/tissue pullout test was performed only on barbed sutures. Two types of tissues used were porcine skin tissue and bovine tendon tissue. The load cell used for testing had 10 Newton capacity.

The testing parameters for both skin and tendon tissue pullout test were:

- Testing speed : 0.75 mm per sec
- Anchoring distance : 10 mm

Skin tissue

The specimens for the skin tissue pullout test were mounted as shown in Figure 4.7.

![Figure 4.7: Specimen mounted ready for a skin tissue pullout test](image)

First the tissue was inserted in the lower jaw and clamped manually by tightening the screw. Then the suture coming out from the other end near to the upper jaw
was tightened and clamped in the center.

The process of loading the specimen began by running the test from the MTS software TestWorks.

**Tendon tissue**

The specimens for the tendon tissue were mounted in a similar manner to those for the skin tissue test (Figure 4.8).

Figure 4.8: Specimen mounted ready for a tendon tissue pullout test.

In this case the tendon specimen had a specially cut bottom area for clamping.
4.6 Finite Element Analysis

The finite element analysis was performed at the High Performance and Grid Computing Center at NC State University, Raleigh, NC.

4.6.1 High Performance Computing Resources

Hardware specifications

The High Performance Computing facility at NC State University was used for running the simulations. The Henry2 system configuration is as follows:

- Processor: Intel Xeon
- Speed: 2.8GHz
- RAM: 4GB
- HDD: 40GB

This cluster is equipped with a total of 131 processors with 4GB RAM each. The academic version of Ansys licence used 'one' processor at a time.

Software specifications

The commercial finite element analysis software called 'ANSYS, version 11.0' was used. Since this was an academic version, it had two types. One was 'ANSYS Academic Research' with unlimited number of nodes. And the second was 'ANSYS Academic Teaching Advanced' with a maximum of 256,000 number of nodes. Due to limited availability of the licence the 'Research' version was off limits most of the time. Therefore the 'Teaching' version was used.

Academic Teaching Advanced version 11.0 had the following specifications:

- Maximum node limit: 256,000
- Number of processors: 1
- Operating system: Linux
Local access

The GUI (graphical user interface) for ANSYS on a HPC (RedHat Linux 64bit machine) was accessed via the 'Virtual Computing Laboratory (VCL)' at NC State University. Thus the software could be accessed on a local computer remotely for a maximum time of '6 hours' in a single run. The configuration for the local computer was:

- Processor: Intel Pentium(R) 4
- Speed: 3 GHz
- RAM: 1 GB

Scripting

A script was written using ANSYS Parametric Design Language (ADPL) to create a batch file. This file contained a sequence of commands that the software would follow to perform the simulation.

During the initial phases of debugging the script, it was important to use ANSYS interactively via the Graphical User Interface (GUI). The VCL allowed this access for '6 hours' at one time. Therefore if the simulation time exceeded '6 hours' then the script was re-edited to shorten the run time.

Once the script ran successfully in the GUI it was then ready to be submitted to the Load Sharing Facility (LSF) - the HPC Linux cluster. These batch files were submitted using LSF commands in another batch file.

4.6.2 Suture material properties

The material properties required for the simulations were measured in our laboratory. They were as follows:

1. General properties
2. Shear relaxation modulus
3. Bulk relaxation modulus
General properties

The initial elastic Youngs modulus (\(E_X = 3.94 \times 10^9\) Pascals) was calculated by drawing a tangent to the stress-strain curve of a unbarbed suture. The testing parameters are those described earlier in the section on unbarbed suture tensile properties. The value for Poisson’s ratio of 0.4 for polypropylene was used [47]. The coefficient of friction of 0.15 for polypropylene suture-on-suture was used for all simulations [23]. A value of suture-on-suture was used because a value for suture-on-tissue was not found in the literature.

Shear relaxation modulus

A new method was developed to measure the shear relaxation modulus of monofilament sutures. Figure 4.9 shows the principle for shearing a monofilament in the longitudinal direction. The basic idea is to have a rectangular cuboid like structure. This cube can be held on one fixed side and a tangential force can be applied to the other side. This will result in the shearing of the cuboid. In the current case, as shown in the inset in Figure 4.9 we can see that there were two cuts, cut-1 and cut-2. This is explained later in detail. These cuts form a cuboid with vertices A,B,C,D,A’,B’,C’ and D’. The idea now is to make one surface stationary with respect to the other. Let this surface be CC’B’B. This surface can be held in a fixed position by the lower part of the monofilament which in turn is fixed by the bottom jaw. This lower part of the monofilament (drawn in red) can be considered as if it was glued or bonded to the surface CC’B’B. Similarly the top surface DD’A’A can be considered to be glued to the upper part of the monofilament drawn in black with a green arrow. This surface DD’A’A can be considered to be the movable surface. And to impart tangential movement to this surface, the upper part of the monofilament was clamped in the upper movable jaw of the tensile testing machine (MTS ReNew).

Now if the specimen described above was to be sheared by moving the upper part of the monofilament upwards (direction shown by the green arrow), shearing of the cuboid would take place. However there would be bending of the specimen also. In order to avoid the bending of the specimen, the sides of the monofilament were restricted to move only radially outward. This could be prevented by using some kind of a sheath around the monofilament. This sheath could be provided
by a syringe-needle that had a diameter slightly larger than the diameter of the monofilament. As shown in Figure 4.9 the wall of the syringe needle helped to keep the monofilament from bending.

Thus a tangential force could be applied to one surface (DD’A’A) of the monofilament-cuboid while the other surface (CC’B’B) was held in a fixed position.

Figure 4.9: Suture specimen geometry for measuring shear relaxation modulus.

In order to prepare the specimen that forms a cuboid as described above, the following mounting procedure for cutting the sutures must be followed (Figure 4.10). The setup consisted of two glass slides, some Scotch tape and markers. One glass slide (bottom) was marked with a black color permanent marker to create the ‘central dark region (CDR)’. This made it opaque. So the light was reflected back. The second slide (top) was marked with a center-line parallel along its width (CL2) and its length (CL1). This was shown by red arrows. A ‘suture-line’ (yellow line) drawn parallel to the central line CL1. The suture-line was in the exact position where the suture monofilament was to be mounted. The line CL2 was used to align the cutting edge of the blade that was mounted in the upper jaw. Before starting the mounting procedure the ‘base center line’ was marked.
To prepare the suture monofilament, a length approximately equal to or less than the length CL1 was cut. Scotch tape was attached at both the ends of the monofilament, and the faces identified with Scotch tape labels: '1' and '2'.

Prior to mounting, it was necessary to place the top glass slide over the bottom one. These slides were taped together by scotch tape to hold them exactly on top of each other (see ‘double’ in Figure 4.10). Once the glass slides had been placed onto the base, the line CL1 was aligned with the base center line. The upper crosshead was lowered so that the cutting edge of the blade just touched the glass slide. CL2 was aligned with the cutting edge of the blade. Use Scotch tape was used to secure the glass slide in position on the base. The specimen marked with Scotch tape was then mounted on the glass slide along the suture-line. Both ends of the suture were taped on the glass slide, making sure that the suture lay flat. This was verified using a backlight. And if there was a gap, than the light reflected by the CDR was visible, and additional Scotch tape would be needed to secure the suture further. The specimen was now ready for the 'first cut'. After successfully cutting the first cut on the side marked '1' on the Scotch tape. The suture was then removed and turned over so that now the side marked '2' was visible on the Scotch tape. The suture was mounted on the suture-line. The suture was then ready to make the 'second cut' exactly opposite to the first cut.
Figure below shows important information.

Figure 4.11: Method of cutting suture specimen

Figure 4.11 shows the results of the cutting procedure. Later image analysis was used to verify the position and depth of the cuts. This imaging procedure was the same as that used for measuring the barb geometry.

To perform the actual test, the specimen was mounted in the tensile testing machine such that the upper part of the monofilament (described earlier) was clamped in the upper jaw, and the lower part of the monofilament was clamped in the lower jaw. The shear modulus was calculated using the relation shown in Figure 4.12

Shear Modulus = \frac{\text{Shear stress}}{\text{Shear strain}} = \frac{(\text{Force}/\text{Area})}{(\text{dx}/\text{Height})}

Figure 4.12: Calculating shear relaxation modulus for suture monofilament

The testing parameters were:

- Displacement: 0.20 mm
- Load cell: 10 Newton
- Syringe needle size: 21G1 (0.495 mm diameter)
- Cut-1 and Cut-2: 0.30 mm
- Distance between cuts: 1.98 mm
- Area of shear surface (AA'D'D): 0.3429 mm² (calculated)
- Time: 30 mins (1800 seconds)
- The effect due the curvature of the cylindrical monofilament was assumed to be negligible

The specimen was held in the displaced condition and the resultant decay force due to shear stress relaxation was measured. The Prony coefficients for shear response were calculated by curve fitting in ANSYS. The results are given in Table 4.5.

<table>
<thead>
<tr>
<th></th>
<th>alpha1</th>
<th>tau1</th>
<th>alpha2</th>
<th>tau2</th>
<th>alpha3</th>
<th>tau3</th>
<th>alpha4</th>
<th>tau4</th>
<th>alpha5</th>
<th>tau5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5.496973e-01</td>
<td>1.190189e+04</td>
<td>1.558405e-01</td>
<td>9.990970e+04</td>
<td>1.554279e-01</td>
<td>4.220923e+02</td>
<td>1.288123e-01</td>
<td>5.490521e+01</td>
<td>1.022214e-02</td>
<td>8.112180e+00</td>
</tr>
</tbody>
</table>

**Bulk relaxation modulus**

A new method was developed to measure the bulk relaxation modulus of monofilament sutures. Figure 4.13 shows the steps involved in the measurement procedure.
Figure 4.13: Measuring bulk relaxation modulus of monofilament sutures

A small cylindrical specimen of the suture monofilament was cut and measured under the microscope. The setup consisted of two metal mounting plates. The top plate had a mounting area (cylindrical hole) with an inner diameter that was equal to the outer diameter of the monofilament suture. In Step-1 this suture cylinder was ready to be placed inside the mounting area. It should be noted that the length 'L' of this specimen was slightly less than the height of the cylindrical mounting area. In Step-2 the specimen was placed inside the mounting area, and the compressing solid metal cylinder was aligned vertically with the suture cylinder. Since the diameters were very small, the metal cylinder was lowered into the upper free space inside the hole. Since the length of the suture cylinder was known and the height of the hole is known, the height of the free space can be calculated. This free space height was used to zero the metal cylinder onto the surface of the suture cylinder inside the mounting area (hole) of the top metal plate. The bottom metal plate was solid through out and it served to close the lower end of the mounting area.

In step-3 the specimen is compressed by a known distance. The change in volume was by longitudinal compression. There was no lateral expansion. This change in volume was used to calculate volumetric strain. The decay of bulk relaxation forces was measured over time.

This setup gave approximately the effect of bulk compression of the monofilament in the longitudinal direction. The bulk relaxation modulus was calculated as shown in Figure 4.14.
Figure below shows important information.

![Diagram](image)

**Bulk Modulus** = \( \frac{\text{Volumetric stress}}{\text{Volumetric strain}} = \frac{P}{(dV/V)} \)

Figure 4.14: Calculating shear relaxation modulus for suture monofilament.

The testing parameters:

- Displacement: -0.20mm
- Load cell: 250 Newton
- Height of mounting area (hole): 0.80 mm
- Diameter of mounting area (hole): 0.4 mm
- Length of the suture cylinder: 0.60mm
- Diameter of the suture cylinder: 0.40 mm
- Time: 30 mins (1800 seconds)
Figure below shows important information.

Figure 4.15: Unbarbed suture bulk relaxation modulus in axial direction.

Figure 4.15 shows the curve for the bulk relaxation modulus for the polypropylene suture that was measured along the axis of the monofilament. The Prony coefficients for shear response were calculated by curve fitting in ANSYS. They are given in Table 4.6.

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>alpha1</td>
<td>4.630237e-02</td>
<td>tau1</td>
<td>1.364961e+02</td>
</tr>
<tr>
<td>alpha2</td>
<td>4.835429e-02</td>
<td>tau2</td>
<td>7.778524e+02</td>
</tr>
<tr>
<td>alpha3</td>
<td>5.244109e-02</td>
<td>tau3</td>
<td>7.778536e+02</td>
</tr>
<tr>
<td>alpha4</td>
<td>7.060477e-02</td>
<td>tau4</td>
<td>1.364962e+02</td>
</tr>
<tr>
<td>alpha5</td>
<td>8.869075e-02</td>
<td>tau5</td>
<td>2.582872e+01</td>
</tr>
</tbody>
</table>

### 4.6.3 Tissue Material Properties

Values for the tissue material properties were used from the literature. The Youngs Modulus for the skin and tendon tissue were used directly. And the relaxation
modulus curves imported in ANSYS for curve fitting were used to calculate the Prony coefficients.

The tendon tissue properties that were used where from human tendon (EX=6.4e8 Pascals). A value for Poisson’s ratio of 0.488 for tendon tissue was selected [91]. The properties of the human tendon were very close to the properties of the bovine tendon. Curve fitting to the stress relaxation spectrum of the tendon tissue was performed in ANSYS (Figure 4.16) [7]. Table 4.7 shows the calculated Prony coefficients for tendon tissue.

![Tendon stress relaxation modulus](image)

**Figure 4.16: Human tendon tissue relaxation modulus** [7]

| Table 4.7: Prony coefficients for tendon tissue relaxation |
|---------------|-----------------|---------------|-----------------|---------------|
| alpha1        | 1.473326e-01    | tau1          | 1.884317e+00    |
| alpha2        | 5.589389e-01    | tau2          | 9.218506e+03    |
| alpha3        | 9.83650e-02     | tau3          | 2.277244e+02    |
| alpha4        | 7.511071e-02    | tau4          | 4.814193e+01    |
| alpha5        | 8.006383e-02    | tau5          | 1.138688e+01    |

The properties for porcine skin tissue were taken from the literature, EX=9e5 Pascals and Poissons-ratio 0.48 [4]. ANSYS was used to fit the data to the stress relaxation curve (Figure 4.17) [69]. And Table 4.8 shows the calculated Prony coefficients for porcine skin tissue.
coefficients for skin tissue.

![Skin : stress relaxation modulus](image)

Figure 4.17: Porcine skin tissue relaxation modulus [69]

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>alpha1</td>
<td>5.987582e-01</td>
</tr>
<tr>
<td>tau1</td>
<td>5.135235e+03</td>
</tr>
<tr>
<td>alpha2</td>
<td>1.788124e-02</td>
</tr>
<tr>
<td>tau2</td>
<td>9.999447e+04</td>
</tr>
<tr>
<td>alpha3</td>
<td>1.916081e-01</td>
</tr>
<tr>
<td>tau3</td>
<td>4.932554e+00</td>
</tr>
<tr>
<td>alpha4</td>
<td>1.164539e-01</td>
</tr>
<tr>
<td>tau4</td>
<td>8.899513e+01</td>
</tr>
<tr>
<td>alpha5</td>
<td>7.529856e-02</td>
</tr>
<tr>
<td>tau5</td>
<td>8.709795e+01</td>
</tr>
</tbody>
</table>

### 4.6.4 Solid Modeling and Meshing

The solid modeling of the barbed suture was done in ANSYS. Scripts were written to develop solid models instantly (see Appendix B). In order to change the geometry the user had to just change the input numbers in the script. It should be noted that some of the line numbers and area numbers remained constant for any geometry. Therefore those numbers were directly used in the script.

It is also important to note that the solid models described in the subsequent sections could be made into a varying range of geometries. The variables such as
cut angle (ca), cut depth (cd) and suture monofilament diameter could be easily varied. A different combination of each of these geometries can be studied using the same script that generates the representative models described below.

In all cases except for the curved configuration a blade was created after the monofilament volume was created. The depth of the penetration of this second volume of the blade created was decided by the cut depth specified at the beginning of the script by the user. At the same time the angle at which the blade was inclined to cut the exact cut angle was controlled by the cut angle the user inputs in the script.

The way a barb was created was by subtraction of this volume of the blade from the volume of the monofilament generated. Therefore the following assumptions were made:

1. The volume of the blade subtracted, deleted the volume of suture monofilament. So it was assumed that this loss of mass of monofilament polymer was negligible. Because in actual cutting of barbs there is no loss of mass and there was only shifting of the mass of polymer as a result of the blade penetration while barb cutting.

2. Since there were very sharp angles formed due to this volume subtraction of the blade, the degree of accuracy may have directly depended on the fineness of the mesh generated may have limited the accuracy of the simulation. In this project there was a maximum limit of 256,000 nodes, which may have limited the accuracy of the simulation.

In all the models the barbs were created with 'zero' twist. This was purposely planned so as to reduce the model complexity and to understand the basic behavior of the barbs.

**Point Pressure Loading of a Barb Tip**

The objective of point loading of a barb tip was to try to understand the mechanism of barb bending before it reached the critical failure load and initiate a peeling along the cut line. Figure 4.18 shows the solid model of a barb.
Figure below shows important information.

![Solid model of single barb for point loading of barb tip](image)

**Figure 4.18:** Solid model of single barb for point loading of barb tip

Figure 4.19 shows the area and the line numbers for a single barbed suture. In the case of point loading, the idea was to apply a load at the tip of the barb. The nodes over which the load was applied approximately correspond to the surface area covered by the super-glue when the tip of the copper metal wire was glued to the tip of the barb.

![Lines and areas of a single barbed suture](image)

**Figure 4.19:** Lines and areas of a single barbed suture

Applying the load to just a single and multiple node gave problems with badly
deformed elements. At the same time applying loads at the line at the tip of the barb also gave errors while computing. Finally the load was applied over an area under the tip of the barb. If this area was too small the same errors continued. So finally, the area was decided based on proportion of the barb length. The area that was used for applying pressure was the area towards the tip of the barb that was created by dividing the area under the barb by a horizontal line created.

The meshing of the solid geometry was done using an element SOLID187, a 10-node tetrahedral structural solid. The criteria for meshing was to be able to mesh the entire volume with a minimum number of errors that would allow the solution to converge. The mesh was finer at the areas of interest such as the tip of the barb and at the cut-line of the barb as seen in Figures 4.20 to 4.22.
Figure below shows important information.

Figure 4.20: Meshed barb: 150° cut angle & 0.12mm cut depth

Figure 4.21: Meshed barb: 160° cut angle & 0.12mm cut depth
Figure below shows important information.

![Meshed barb: 170° cut angle & 0.12mm cut depth](image)

The meshing of the barb was the most difficult part for the entire volume because the cutting of the monofilament volume to create a barb causes the formation of very small angles. Some of these angles are as small as 0.5°.
Single Barb Tissue Pullout

The model for a single barb tissue pullout test was created in three steps. First the barbed suture was created. Then the tissue block was created around this suture. Then the barbed suture volume was subtracted, and this volume was again recreated. Figure 4.23 shows the geometry for this model. The mirror symmetry of the model was used to perform a symmetric analysis of only half of the model.

![Figure 4.23: Straight pullout of single barb anchored in tissue](image)

In Figure 4.23 the barbed suture already has the barb anchored inside the block of tissue. The type of tissue can be changed by changing the properties of the tissue in the input file for the script.
Figure below shows important information.

Figure 4.24: Lines and areas of a anchored single barb in tissue

As shown in Figure 4.24 areas A44, A17 and A45 were fixed to zero displacement. Figure 4.25 shows meshed solid model of a suture tissue pullout test for a single barb.

Figure 4.25: Straight pullout of single barb anchored in tissue
Figure 4.26 shows a magnified view of the mesh at the tip of the barb inside the tissue. The lines along the tip of the barb were divided to create a finer mesh.

Figure 4.26: Straight pullout test of single barb anchored in tissue

Figure 4.27 shows the meshed tissue in the suture tissue pullout test. We can see the sharp part of the tissue extending outwards. This is the part of the tissue which fills the gap under the barb as seen in Figure 4.23.
Figure below shows important information.

Figure 4.27: Magnified view: Anchored tissue

Figure 4.28 is a magnified view of the part of the tissue that fills the gap under the barb. In this area we can see that the mesh is finer. The lines along this part of the volume were also subdivided to create a finer mesh. This same method was used to create a fine mesh inside the barb along the cut-line.
Figure below shows important information.

Figure 4.28: Straight pullout test of single barb anchored in tissue.

Surface-to-surface contact method was used to do the contact analysis between the suture and the surrounding tissue in a suture/tissue pullout test. Four contact pairs were setup as follows, 4.24:

- lower half of the suture monofilament surface (A29) with surrounding tissue surface area (A43)
- upper half of the suture monofilament (A30) with its surrounding tissue (A46)
- lower under-face area (A27) of the barb surface with its surrounding tissue surface area (A42).
- cut-face of the monofilament surface below the under-face of the barb (A28) and its surrounding tissue surface area (A41)

The barbed suture was chosen as a target surface since it was the moving surface that had displacement applied to it. Target surface was responsible for forming a deformable-deformable pair with the tissue surface. Figure 4.29 shows the barbed suture surface meshed with TARGE170 target elements.
The tissue surface forms the contact surface of the deformable-deformable contact pair. Figure 4.30 shows the meshed tissue surface that is surrounding the anchored barb in the tissue.
Figure below shows important information.

Figure 4.30: Contact: Tissue [CONTA174 elements]

4.6.5 New Design : 'Geomcirc'

A new design for a barbed suture was created as a part of virtual prototyping to see if this design has any advantages over the original design. Figure 4.31 shows the solid model which consists of a geometric circular cylinder that is cut through the cut-line. The radius of this circular cylinder is 10% of the cut depth.
Figure below shows important information.

![Figure 4.31: A 'Geomcirc’ barbed suture](image)

This new design was meshed using the same method as described above Figure 4.32 shows the magnified view of the finer mesh at the circular cut line.

![Figure 4.32: A meshed 'Geomcirc’ barbed suture](image)
4.6.6 Boundary conditions

The boundary conditions used in the simulations are described in this section. The detailed boundary conditions for all the simulations are specified in the ADPL script in Appendix-B. The boundary conditions used in the simulations are those that resulted in a successful convergence.

In the case of point loading of barbed suture tip simulations both the cross-sectional areas of the suture monofilament were fixed (zero displacement). A point load at one or serval nodes, keypoints and lines resulted in a persistent error of excessive element distortion. Due to which the solution never converged inspite of making the mesh very fine. Finally, the approach of selecting a small area at the tip of the barb and applying pressure to over this area worked. The area was created by divided the area under the barb by a horizontal line. The proportional position of this line was kept constant for all the geometries. This was done by first dividing the line (L21 before divide, Figure 4.19) into three lines of equal length. The a horizontal line was drawn with the newly created keypoints at the ends of the line at the tip of the barb. Although this creates different resultant areas at the tip of the barb, it was the minimum area required for the simulation to converge. Areas smaller than that cause excessive element distortion and the solution did not converge. A pressure of magnitude 4e6 Pascals was applied.

In case of the suture tissue pullout test, the a mirror symmetry was applied in the plane-YZ (monofilament extruded along z-axis). So only half of the solid model was needed to be meshed, which allowed to use fine mesh along the cut line with more number of elements. The outer three tissue surfaces of the rectangular tissue block were fixed with zero displacement. A displacement of 0.001e-3 meters was applied to the leading (direction in which the barb is pointing i.e. (+)ve z-axis direction) cross-sectional area.
4.7 Statistics

Statistical analysis was performed to analyse the results at 95 or 99 confidence interval.

4.7.1 Student T-test with Unequal Variance

The t-test was used to determine if there were significant differences between the means of any two samples.

4.7.2 Analysis of Variance (ANOVA)

One way analysis of variance was performed to see if there was any significant difference within a group. Two way analysis was performed to test the significance of interaction between the cut angle and cut depth. MS Excel was used for undertaking these calculations.
Chapter 5

Results and Discussion

This chapter focusses on the results from the experiments and the outcomes from the simulations and discusses their relevance to the project.

5.1 Images of Prototyped Barbed Sutures

One image for each of the nine geometries are displayed in this section (100X magnification).

Figure 5.1: 150° at 0.07mm  Figure 5.2: 150° at 0.12mm  Figure 5.3: 150° at 0.18mm

continued ...
5.2 Image Analysis of Prototyped Barbed Sutures

Approximately 700 prepared barbed specimens were viewed, captured and measured for suture monofilament diameter, barb cut angle and barb cut depth using an image analysis system.

5.2.1 Diameter

Figure 5.10 shows the variation in the mean suture diameter with standard error bars for 66 specimens in each of the 9 lots. This diameter was in the range of 0.39 mm to 0.40 mm. Appendix-C shows the scatter plot for individual measurements.
A student t-test showed that the variation in the diameter was overall insignificant at an alpha value of 0.01 (99% confidence interval). However there was a significant difference between the diameters for the lots at 150$^\circ$ and 160$^\circ$ cut angles and at 0.18 and 0.12 mm cut depths. Also there was a significant difference in diameters between the lots having 0.18 and 0.12 mm cut depths at a cut angle of 170$^\circ$.

### 5.2.2 Barb Geometry

The barb geometry measurements included both the cut angle and the cut depth. The tabulated raw data for the barb geometry are given in Appendix 2.

#### Cut angle

The mean ± S.E. cut angle is shown in Figure 5.11. Appendix-D shows the scatter plot for individual measurements. The actual cut angles that were prototyped were in the range as given below:

- 150$^\circ$ : 149.91$^\circ$ to 150.03$^\circ$
- 160$^\circ$ : 160.28$^\circ$ to 160.53$^\circ$
- 170$^\circ$ : 170.20$^\circ$ to 170.60$^\circ$
The differences between lots of different cut angles were significant at an alpha value of 0.01 (99% confidence interval). And at this confidence interval the differences within a lot were not significant, except for cut angle 160° with cut depths 0.07 and 0.12 mm and for cut angle 170° with cut depths 0.12 and 0.18 mm, the differences in the cut angles were significantly different.

![Cut angle variation](image)

Figure 5.11: Mean±S.E. for barb cut angle

**Cut Depth**

The mean ± S.E. cut depth is shown in Figure 5.12. Appendix-E shows the scatter plot for individual measurements.
There was no significant difference at either 95% or 99% confidence intervals between the values of cut depth between lots of different cut angles. And significant difference was observed at the 99% confidence interval between the cut depths within the same lot of cut angle.

The actual cut depths that were prototyped were in the ranges as given below:

- 0.18 : 0.1791 mm to 0.1808 mm
- 0.12 : 0.1188 mm to 0.1194 mm
- 0.07 : 0.0684 mm to 0.0704 mm

### 5.3 Tensile Testing

This section discusses the results from the tensile testing of the suture material.

#### 5.3.1 Elongation at Peak Tensile Load

Figure 5.13 shows the values for the percentage elongation at peak tensile load.
Figure below shows important information.

Figure 5.13: Mean±S.E. for elongation % at peak tensile load

There were significant differences observed within the same cut angle at different cut depths at both 95 and 95% confidence interval, except for cut angle 160° with cut depth of 0.12 and 0.07mm, where the differences were not significant. Further, no significant differences were observed between any two different lots with different cut angles.

The unbarbed suture had significantly higher elongation than the barbed sutures. In the case of unbarbed sutures, the break was catastrophic. The suture broke instantaneously when it reached the peak load. However in the case of the barbed sutures, the break was not instantaneous. All the microfibrils in the individual filaments did not break at the same time. This was apparent from the fibrillation of the suture after breakage. Another explanation may be that all these microfibrils were not loaded equally at the same time. The curve for failure of a barbed suture is shown in Figure 5.14. It shows that the curve rises and falls before it reaches the peak load, and the rises and falls may be associated with the breaking of individual microfibrils.
The elongation at peak load was highest for cut depth 0.07mm, which was followed by cut depth 0.12mm and 0.18mm respectively. The core-sheath composition of a monofilament may be able to explain this behavior. While a monofilament is extruded, the monofilament cools from outside to inside. Hence the polymer i.e. structure near the outside of the monofilament is more crystalline than the core. The core also experiences relatively less drag and hence orientation during the extrusion and drawing processes. This renders the core to be less crystalline and more amorphous.

Hence if making a cut in a monofilament severs the outer more crystalline microfibrils, the load is borne by a smaller fraction of the outer microfibrils. Now as compared to a cut depth of 0.07mm, a cut depth of 0.18mm is more closer to the center of the monofilament (radius = 0.20mm). Therefore the amount of intact core and sheath in the lower cut depth of 0.07mm will be more than that of suture with 0.18mm cut depth. As a result the elongation at peak load values are more for the barbed sutures with a low cut depth of 0.07 mm as compared to a higher cut depth of 0.18mm.

This evident from the peak load values discussed next, where the peak load values for the sutures with 0.07 mm cut depth are highest.
5.3.2 Peak Tensile Load

The peak load results are shown in Figure 5.15.

These peak load results indicate that there was a significant difference between the peak loads experienced by the barbed sutures cut at the same angle with different cut depths at 99% confidence interval. And there was no significant difference between the peak load values at the same cut depth between different cut angles. The greater the cut depth the smaller is the cross sectional area of the monofilament and hence there will be fewer microfibrils available to share the applied load. Therefore, as the cut depth increased, so the peak load values decreased. A 3D plot in Figure 5.16 shows the results of decreasing peak load with increasing cut depth for all three cut angles.
Figure below shows important information.

![Graph showing barbed suture peak tensile load](image)

**Figure 5.16: Barbed suture peak tensile load [Mean±S.E.]**

Another reason for this behavior may also be that at a greater cut depth more crystalline microfibrils are severed along with more microfibrils in the amorphous region. A polymeric suture monofilament is made up of long molecular chains that are parallel to its longitudinal axis. Since after drawing these filaments are in a stressed condition, they are in a high state of energy. Now as such a monofilament is loaded axially, these monofilaments undergo molecular rearrangement to counteract the increasing load in a tensile test. Therefore some of the initial elongation is due to this rearrangement where some molecular chains that were originally slack are straightened out. Therefore it is only after a certain load is reached that the majority of these monofilaments start to bear the load evenly.

In the case of the unbarbed suture monofilaments a state is reached where most of the monofilaments are sharing the load equally. At this point of time these monofilaments are in a straightened and stretched configuration. Most of the microfibrillar structure of the polymer is reoriented along the longitudinal axis. Now as the load reaches the peak breaking load, all these microfibrils reach the break-
ing load together. Therefore all of them break at once. Hence the break of the monofilament suture in unbarbed form, is catastrophic. However in the case of the barbed suture, the case is different. In barbed sutures, some of the microfibrils are already severed by the blade, as it makes a cut to create the barb, while some of the molecular chains and microfibrils remain intact. Therefore when such a barbed monofilament is loaded, some of these microfibrils and molecular chains start bearing the full load earlier and are already reaching their peak breaking load, while there are others that have just started to share the load. Therefore the breaking of a barbed sutures takes place is gradually in steps and does not reach catastrophic failure mode as is the case of the unbarbed suture.

5.4 Suture/Tissue Pullout Testing

This section discusses the results for the barbed suture pullout tests for skin and tendon tissues.

5.4.1 Skin Tissue

The results for the single barb skin tissue pullout load are shown in Figure 5.17.

![Figure 5.17: Peak tensile skin tissue pullout load (mean±S.E.)](image)

Figure 5.17: Peak tensile skin tissue pullout load (mean±S.E.)

| NOTE: How to read the Significance chart: Figure 5.18 shows respective nine points from the plot. In the chart the 1st row: 0.18mm cut depth; 2nd row: 0.12mm cut depth and 3rd row: 0.07mm cut depth & 1st column: 150° cut angle; 2nd column 160° cut angle and 3rd column: 170° cut angle) where blue line
corresponds to a significant difference between the two points at 95% confidence interval and a blank space corresponds to no significant difference.

The barbed suture with cut angle of 170° and cut depth of 0.18mm gave the highest peak load which was significant at 95% confidence interval. All the differences between peak loads at different cut depths were significant except that no significant difference was observed between different cut angles at the same cut depths for cut angles 160° and 170° at both 0.07mm and 0.12mm. And there was no significant difference between cut depths 0.18mm and 0.12mm at 160° cut angle.

This explains that for a soft tissue such as skin, it is easier for the barbs to cut through and anchor themselves into the tissue because the barb with lowest bending modulus, i.e. was the most flexible at the highest peak load. Thus barbs with shallow cuts and longer lengths are more suitable for softer tissue such as skin.

The barbs with cut depths as low as 0.07mm may not be good for skin tissue, since there is limited barb length for anchoring. On the other hand a higher cut depth of 0.18mm but a low cut angle such as 150° is not suitable either. This is because the barb in this case would be too stiff to bend by the forces exerted by the softer skin tissue. This results in the barb eroding the tissue in the pullout test and coming out with minimal peeling. The same situation arose with a cut angle of 160°.

Further the barb with lowest cut angle of 150° and lowest cut depth of 0.07mm showed the lowest peak pullout load compared to 150° at 0.12mm and 160° at 0.07mm; significant at a 95% confidence interval. This means that barbs with a very shallow angle provide less anchoring effect into the tissue. This is explained below.

Assume that a barb encounters a tissue lying in front of it on the monofilament. When such a monofilament is pulled in the direction such that the barb tip engages into the tissue in front of it, the barb tip first penetrates the tissue mass. In the case of a straight pullout or a convex curved pullout of a single barb, the tip would have allowed sufficient tissue to get underneath it to lift the barb further up. While the cut point remains intact, the stress concentration is steadily increasing. Now if the tissue that is underneath the barb lacks sufficient modulus then after a certain point the barb is not going to be lifted further. What will happen after that is
that the barb will stay at that lifted position and start moving forward as it is pulled. And since the resistance offered by the tissue is considerably less than the force required to dislodge or peel the barb from its base at the cut line, it will not bend. Therefore it will tear out the tissue that has managed to get underneath it. Thus the barb will come out of the tissue at a lower load than its normal peeling force.

The interaction between the geometrical factors of cut depth and cut angle together had an effect on the peak pullout load of the skin tissue as suggested by ANOVA. These results are significant at 95% confidence interval.

5.4.2 Tendon Tissue

The results from the tendon tissue pullout test help explain the following things which were significant at 95% confidence interval.

– the peak pullout load increases as the cut angle increases from 150° to 170° for cut depths 0.07mm and 0.12mm which may be due to due progressively better anchoring
– the peak pullout load increases as the cut depth increases with the same cut angle

![Figure 5.19: Peak tensile tendon tissue pull-out load (mean±S.E.)](image)

![Figure 5.20: Chart](image)

The barbed suture with a cut angle of 150° and a cut depth 0.18mm showed the highest pullout load in the tendon tissue (Figure 5.19). Note that the tendon is stronger and less elastic than the skin tissue. The tendon tissue pullout test also revealed an important fact that the polymer polypropylene provides sufficient
barb bending modulus so as to be used in tissues with different moduli ranging from skin to tendon.

In both the tendon and skin tissue pullout tests one can observe that the cut depth of 0.07mm has the least peak pullout load. This points to the fact that longer barbs are absolutely essential for tissue anchoring. Also a barb that is too short it may not be able to survive all the different stages of barb activity once surrounded by tissue. While performing the single/barb tendon tissue pullout test, the following observations were made that explain the mechanical behavior of the barb and how it passes through the 5 stages in its life cycle from initiation to failure.

**Stage-1** The barb tip pierces the tissue.
Criteria: Barb tip sharpness should overcome the tissue penetration force.

**Stage-2** The tissue enters in the space below the barb to lift the barb and start bending of tip.
Criteria: Tissue lifting force should exceed the barb bending force.

**Stage-3** The barb bending continues and propagates towards the end of the cut line.
Criteria: The tissue modulus should be higher than the barb bending modulus to continue.

**Stage-4** Peeling starts
Criteria: The tissue modulus should be higher to sustain bending until the cut point is reached and peeling is initiated.

**Stage-5** Peeling propagates.
Criteria: The force required to propagate peeling equal to or more than the force required to initiated the peeling. Therefore if the barb and tissue combination survived till peel is initiated then it will survive peeling also.

Thus a barb-tissue combination is dependent on the following:

1. barb bending modulus (BBM)
2. modulus of the tissue anchoring the barb (MTAB)

The Barb Bending Modulus (BBM) controls some of the most important stages in the barb pullout process. Given a polymer suture monofilament, the BBM
can be varied by varying the cut depth and the cut angle. This interaction is significant at the 95% confidence interval. Although they both work in tandem, the cut angle primarily controls the bending rigidity of the barb. The cut depth primarily controls the barb base area and hence the peel initiation force.

Thus the ideal barb geometry for a given polymer would be the one that successfully completes stages 1 through 5 as described above. Just having a stronger barb with a large peel initiation force does not necessarily lead to success. For example, if its bending modulus is so high that the tissue fails to reach near the peel initiation point in Stage 4 then the barb will be unable to absorb sufficient energy. This would tear and damage the tissue. On the other hand, a barb with very low bending rigidity is also of little value, because even if it reaches near the peel initiation point, its not going to be able to peel the barb. This is because the force required to bend such a barb will be lower than the force required to peel and dislodge the barb from its base at the cut line.

Another possibility is that even if the barb tip is able to pierce the surrounding tissue, it will bend back in the middle, yield and slip out, instead of bending the entire barb and engage the surrounding tissue.

5.5 Finite Element Analysis

In this section the results from the finite element analysis are discussed.

5.5.1 Point Loading of a Single Barb

The comparison of the experimental and the simulation values for the point loading of the single barb are shown in the Table 5.1.

<table>
<thead>
<tr>
<th>Displacement (mm)</th>
<th>Force (gf)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0053</td>
<td>0.71</td>
</tr>
<tr>
<td>0.0052</td>
<td>0.74</td>
</tr>
</tbody>
</table>

The simulation value is in close approximation with the experimental value by an error of 4%. Since the values of displacement generated were very small (i.e. 0.0052mm) as compared to the maximum point on the experimental curve (i.e.
0.43 mm), the experimental value used above is extrapolated as a value between two points 'A' (displacement = 0.0035 mm; force = 0.444 gf) and 'B' (displacement = 0.0059 mm; force = 0.795 gf) on the experimental curve (Figure 5.21).

Figure 5.21: Metal wire barb tip pull experimental curve.
5.5.2 Effect of Varying the Cut Angle and Cut Depth

A point load was applied to the tip of the barb. Earlier attempts using a point load with single and multiple keypoints and nodes were unsuccessful due to excessive element deformation. Therefore a pressure load was applied at the tip as discussed in the Materials and Methods section. The contour plots of the displacement (UZ) results is shown in Figures 5.22 to 5.30. The contour plots for the shear stress (SYZ) and the principal stress (S3) are shown in the Image-gallery in the Appendix G and H.

![Image Gallery](Image-Gallery-Appendix-G-H.png)
This method of point loading deformed the barb. The displacement of the barb tip due to this deformation was analyzed. As we can see from the Figure 5.31 there is a distinct trend for the pattern of deformation of the barb.

![Figure 5.31: Barb tip displacement at point pressure load](image)

It can be noted that for the same cut depth, as the cut angle increases, the amount of displacement of the barb tip also increases. This may be because at lower cut angles, the length of the barbs at the same cut depth are shorter. Therefore the barbs at the lower cut angle (150°) are stiffer. This difference increases rapidly as the cut angle approaches 170°, because relatively speaking there is a larger increase in the cut length.

Now, at the same cut angle, as the cut depth increases the length of the barb also increases. This increase in length makes the barb more flexible. Therefore as seen in Figure 5.31, the displacement of the barb tip decreases. This decrease in the displacement of the barb tip is more rapid at the higher cut angle of 170°. The drop in the displacement of the barb tip is however less at the lower cut angle of 150° because there is an increase in barb stiffness.

Thus we can say that, at the same cut depth, as the barb angle increases from 91° to 179°, so the flexibility of the barb increases. The effect of an increase or decrease in cut depth has a more pronounced effect as angles increase from 91° to 179°.

Figures 5.32 to 5.34 show the effect on the peeling stress in the z direction of varying the cut angle at the same cut depth for the same applied point pressure
load at the tip of the barb.

Figure 5.32: Effect of cut angle on cut line stresses at 0.07mm cut depth.

Figure 5.33: Effect of cut angle on cut line stresses at 0.12mm cut depth.
Figure below shows important information.

Figure 5.34: Effect of cut angle on cut line stresses at 0.18mm cut depth

The peeling stress (SYZ) at the cut line increases with increasing cut angle. This may be due to the increase in cut length. And as discussed earlier, the effect of increasing cut angle is more pronounced than the effect of increasing cut depth on the displacement of the barb. This means that the barb becomes more flexible with increasing cut angle at the same cut depth, as compared to increasing cut depth at the same cut angle.

Therefore there is more transfer of stress to the cut line at the base of the barb with a more flexible barb due to more bending. Hence at any cut depth, a higher cut angle will always generate more peeling stresses along the cut line. This also means that such a barb will also reach the maximum peeling stress earlier and hence peel earlier.

Next we discuss the effect on the peeling stress of the varying cut depth at the same cut angle.
Figure below shows important information.

Figure 5.35: Effect of cut depth on cut line stresses at 150° cut angle.

Figure 5.36: Effect of cut depth on cut line stresses at 160° cut angle.
are no observable differences in peeling stress (SYZ) at the cut-line with varying cut depth. This may be because the applied point pressure load at the tip of the barb causes deflection of only the tip of the barb, and not deformation of the entire barb. Therefore these cut line stresses have not yet reached their maximum to initiate peeling of the barb. If the barb tip would have been displaced in such a way that the entire barb deformed, then a difference in the variation of the maximum peeling stress would have been observed along the cut line.
5.5.3 New Design 'Geomcirc'

An alternative and novel concept for the design of a barbed suture has been conceived. This design referred to as 'Geomcirc' is predicted to give superior performance (Figure 4.31). Although the barb has not yet been prototyped, the simulations reveal that it has a higher energy absorption capacity than the original design. Under the same applied point (pressure) load at the tip of the barb, the displacement of the tip in the new design is higher by up to 13.98% at 150° and up to 3.96% at 170°, Figures 5.38 and 5.39.

![Original vs. New design [160°]](image)

Figure 5.38: Displacement (UZ) of new and original designs

![New Design](image)

Figure 5.39: Increased resiliency of new design
The novel design involves the inclusion of a circular cut-line at the base of the barb which redistributes the stresses. This means that barbs with this new design will have a higher peeling resistance as a greater force will be required to initiate a peeling action. The circular cut-line gives the base of the barb a spring-like action which absorbs more energy before peeling is initiated.

A design like this one could be used to change the behavior of the barb by changing its geometry without changing the polymer properties. The polymers with higher moduli have always been advantageous for making barbed sutures. This is because the barbs stand out move from the monofilament surface, have better tissue penetration and hence better tissue anchoring. However, they have a limitation as to the maximum force they can withstand before they start to peel. Due to their stiff nature there are high stress concentrations along the cut-line. This increased stress concentration means an increased risk of barb rupture due to peeling. With the new design there is a possibility to increase this safety margin by up to 13.98%.

![Peeling stress (SYZ)](image)

Figure 5.40: SYZ: New[c-150-07-10]; Original[150-07] at 0.07mm

Figures 5.40 to 5.42 show the SYZ stress (peeling stress) along the cut line of the original design and for the new design at a 160° cut angle. We can see that the stresses generated along the cut line are lower in the new design for the same applied point load at the tip of the barb.
Figure below shows important information.

Figure 5.41: SYZ: New[c-150-07-10]; Original[150-07] at 0.12mm

Figure 5.42: SYZ: New[c-150-07-10]; Original[150-07] at 0.18mm

[Note: c-160-07-10 or 160-07 :: c=new design; 160=cut angle (degrees); 07=cut depth (mm); 10=radius of geometric circular cylinder at cut line having radius equal to 10% of cut depth.]

As discussed earlier, as the flexibility of the barb increases due to increasing the cut angle at the same cut length the likelihood of the original barb getting peeled off increases. However the flexibility introduced by this new design is different.
It does not induce flexibility by increasing the cut length, it does so by keeping the cut length constant. So for in the new design, if the flexibility increases, this does not mean that there is a greater likelihood of the barb getting peeled. we can see from Figure 5.40 that the stress concentration along the cut line is lower than for the original design. The most important factor that allows us to keep the advantages of increased flexibility with the reduced risk of barb peeling is inherent to the new design that allows a re-distribution of the forces along the cut line of the barb.

Figure 5.43: 'Geomcirc': Vector plot(displacement) [ca:160°. cd:0.07mm]
When a comparison is made between the spread of displacement vectors for 'Geomcirc' in Figure 5.43 with the conventional design Figure 5.44, we can observe that in new design the displacement due to applied point-pressure, has reached the cut-line. This may be due to elastic and spring-like displacement of barb. Such a barb is also good for anchoring. Because as the barb tip penetrates deeper into the tissue, the barb accommodates this tissue by moving backwards (direction of displacement vector). And then once the penetration is complete such that the tissue has reached and filled the circular cut-line space, then the barb can 'snap-back' on the tissue holding it locked into place.
Figure below shows important information.

Figure 5.45: 'Geomcirc': Peeling stress (SYZ) (ca:160°, cd:0.07mm)

Figure 5.46: Original: Peeling stress (SYZ) (ca:160°, cd:0.07mm)

In order to understand the re-distribution of the stresses along the barb for the new and original designs we can refer to Figures 5.45 and 5.46. The max-
imum negative compressive stress just on top of the original barb tip (blue &
dark blue) in Figure 5.46 has stresses in the range of -0.19e7 to -0.10e7 Pascals.
Now in the new design the applied point-pressure at the tip of the barb is redis-
tributed, which reduces the maximum level of peeling stresses. In Figure 5.45 for
the new ‘Geomcirc’ design these compressive stresses are in the range of -0.17e7
to -0.79e6 Pascals. Similarly, the positive stress along the cut-line is reduced from
0.65e6 Pascals in the original design to 0.17e6 Pascals. In addition, it can be seen
that the area of stress concentration (dark blue in Figure 5.46) has been reduced
considerably by the new design (Figure 5.45).

5.5.4 Tendon and Skin Tissue Pullout Test Simulations

This section describes the skin and tendon tissue pullout test simulations. It
is important to note that in the simulations all the barbs are assumed to have
100% anchoring in the surrounding tissue. Also that the surrounding tissue has
pushed the barb back into the monofilament such that the gap that remains (due
to deletion of blade volume) is negligible.

The results from the tendon tissue pullout simulation are shown in Figure 5.47.
As the cut angle increased from 150° to 170° the maximum shear stress (SINT)
decreased. Except that at cut depth of 0.07 for cut angle 160° this stress level
peaked. At a constant cut depth as the cut angle increased, the barb became
more flexible. Therefore it was easy for the barb to bend. Hence for an applied
constant displacement for all geometries, the barb with higher cut angle was the
most flexible and hence generated the lowest maximum shear stress.
Figure below shows important information.

![Tendon tissue pullout simulation (SINT)](image)

Figure 5.47: Tendon tissue pullout test simulation

...This meant that the force required to peel such a compliant barb was lower than a barb that was stiffer i.e. in case of a completely anchored barb.

[NOTE: In the ANSYS simulation figures that follow it should be noted that SMN and SMX are the minimum and maximum values for the plotted items and not stress.]
The tendon tissue near the cut-line, i.e. at the base of the barb, starts to move first. Later the displacement involves the surrounding tendon tissue as eventually the barb tip begins to move. This is evident from Figure 5.48 where the displacement flow is from base to tip of the barb at maximum displacement.

In the case of skin tissue (Figure 5.49) a trend similar to that for tendon tissue was observed (Figure 5.47).
Figure below shows important information.

![Skin tissue pullout simulation](image)

Figure 5.49: Skin tissue pullout test simulation

However it can be seen from Figure 5.50 that the skin tissue at the base of the barb has higher stress than at the tip since the base moves first.

![UZ: Skin tissue & barb](image)

Figure 5.50: UZ: Skin tissue & barb (ca:150°. cd;0.07mm)

This means that in both tendon and skin tissue the base of the barb moves first and the tip of the barb moves last. Comparing Figure 5.48 with Figure 5.50 we can see the extent of the displacement of the surrounding tissue, with the softer
skin tissue being displaced more. Also we can see that in skin tissue the entire barb has reached the maximum displacement stress (shown in red), whereas in the case of tendon tissue the stress is lower and only reaches close to maximum when the whole suture reaches its maximum displacement. This again helps explain that if the tissue surrounding the barb is tougher (i.e. has a higher modulus) then there is more tissue resistance. Hence more force is required to displace the barb through the same distance.

Further to the above discussion, it can also be noted in Figure 5.48 that when the suture on the left hand side reaches the maximum applied displacement (in red), the tip of the barb reaches a lower displacement below (yellow and light orange). This may cause the barb to bend such in a way that the barb tip experiences a positive displacement in the direction UY (Figure 5.51). The lifting of the barb tip (i.e. the UY displacement), is greater for the barb being pulled in tendon tissue (0.33e-7m seen as light orange in Figure 5.51 at barb tip) as compared to the skin tissue (0.40e-8m seen as red in Figure 5.52 at barb tip).

Figure 5.51: UY: Tendon tissue under barb (ca:150°, cd:0.07mm)
Figure below shows important information.

![Image](image.png)

**Figure 5.52**: UY: Skin tissue under barb (ca:150°, cd:0.07mm)

Therefore from Figures 5.51 and 5.52 we can say that in a suture tissue pullout test, the barb tip starts to move outwards and away from the monofilament axis as the test begins. This may be a primary interaction of the barb and the surrounding tissue once they are in contact, engaged and loaded.

Finally we can compare the maximum shear stress (SINT), generated in the case of both the skin and tendon pull-out simulation in Figure 5.53.
Figure below shows important information.

![Tendon vs. Skin Tissue Pullout Simulation](image1)

**Figure 5.53: Simulation comparison: Skin vs. Tendon tissue**

We can see from Figure 5.53 that the maximum shear stresses generated in the case of the tendon tissue pullout test are much higher than those for the skin tissue test. This may again help explain that the higher the modulus of the tissue, the higher is the deformation of the barb and the higher is the stress generated.

Finally if we look at the peeling stresses along the cut-line of a barb during a suture/tissue pullout test we can see in which tissue the barb will fail first.

![Tendon vs. Skin (0.07)](image2)

**Figure 5.54: SYZ: skin [s-160-07] & tendon [t-160-07](cut depth 0.07mm)**
In Figures 5.54 and 5.55 we can see that the peeling stresses generated along half of the cut line. In the case of the tendon tissue test the stresses are higher than those produced in the skin tissue pullout test. The direction of stress for the tendon tissue test depends on the cut depth i.e. whether it is at 0.07mm or at 0.18mm.

If look at the displacement vector plot along the barb we can visualize the localised direction of displacement. In Figure 5.56 we can see the vectors (in orange) at the contact surface between the barb and the tissue. The direction of these vectors varies from the cut-line or base up to the tip of the barb. Near the cut-line they are at a very small angle to the z-axis (along with displacement), and towards the tip of the barb this angle increases. At the tip of the barb direction of these vectors is pointing upwards. This means that when the maximum displacement is reached, the barb tip begins to move upwards into the surrounding tissue rather than starting to bend.
Figure below shows important information.

Figure 5.56: Displacement - symmetry-cut side (ca:150º. cd:0.07mm)

Figure 5.57: Direction of displacement - LEFT side (ca:150º. cd:0.07mm)

In Figure 5.57 we view the same barb from the other side of the symmetrical boundary condition. This shows the vectors on the surface as opposed to the cross-sectional symmetrical side view discussed in Figure 5.56.

Figure 5.57 shows the direction of displacement in the 'wake of the barb' i.e. the volume of the barb that transcends into the suture monofilament. Contact between
the barb and the surrounding tissue has created a wave of displacement that goes beyond the barb itself. The vectors show that the entire mass of the monofilament at and above the cut line begins to move away from the z-axis and upwards along the y-axis. Thus this part of the suture is going to experience a build up of compressive forces due to bending of the barb. This can be further explained by Figure 5.58, where we see that it is the tip of the barb that has experienced the least displacement (in dark blue), whereas other parts of the suture have reached maximum displacement (red on the scale).

![Figure 5.58: Wake of the barb (ca:150°. cd:0.07mm)](image)

The tip of the barb moved approximately 22.7% less than the maximum displacement and similarly, the base of the barb experienced 9.8% lesser displacement. So there was a definite difference between the displacement of the barb and the rest of the monofilament suture. This difference may be one of the important factors that is responsible for barb failure due to fracture at the weakest shear line.

Although this suture was prepared with a cut depth of 0.18mm, Figure 5.58 shows the actual fracture along such a shear line. This can be considered as an amplification of the phenomenon of shear line fracture. The shear here was due to bending of the barb while it passed over a metal surface and made a 90° turn, while at the same time being under the tension of the suture thread line. So, at the bending point, the suture monofilament can be assumed to have experienced different
strains across its diameter. The strain increased from inside out and reached a maximum at the outermost surface of the monofilament where it bent.

Figure 5.59: Barb fracture: Tensile & bending effect (ca:150°, cd:0.18mm)

In Figure 5.59 the barb must have experienced a different displacement than the remaining suture which caused it to shear fracture from the cut line in the axial direction. In the tendon tissue simulation (Figure 5.58) this difference was approximately 2.73%. Finally, it should be noted that a monofilament suture has a varying modulus across its diameter which may add to the effect of shear-line fracture.

While a barb is experiencing differential displacement, the surrounding tissue is also undergoing change. Figure 5.60 shows the vector plot for the displacement of the tendon tissue at maximum displacement of the barbed suture in the suture/tissue pullout test.
Figure below shows important information.

![Tendon tissue behavior in a pullout test (ca:150°, cd:0.07mm)](image)

**Figure 5.60**: Tendon tissue behavior in a pullout test (ca:150°, cd:0.07mm)

In Figure 5.60 we can see that as the barb is moving in a positive z-direction, so does the tissue. This movement of the tissue is spread over its entire surface that is underneath the barb. The tip of the tissue (located at the cut line of the barb) being easier to displace compared to the base of the tissue (located near the tip of the barb) because of its small volumetric mass. This can be seen more clearly from the side view shown in Figure 5.61 where the length of the green vector arrows corresponds to the extent of displacement.
Figure below shows important information.

Figure 5.61: Tendon tissue behavior in a pullout test (ca:150°, cd:0.07mm)
Finally in Figure 5.62 we can see in 3 dimensions the simulated tendon tissue pullout test.

Figure 5.62: Tendon tissue behavior in a pullout test (ca:150°, cd:0.07mm)

5.5.5 Limitations of FEA

The following are the limitations of the current FEA study:

– In case of the point pressure loading, although the pressure applied under the barb is the same. It was applied over different areas for each geometry. Therefore the resultant force is different for each of the geometries. At the same time it should be noted that if different forces were applied to create a same resultant force over varying areas, then the difference in the UZ displacements increased.

– In the case of the experiment measuring the shear relaxation modulus of the monofilament, it is possible that the shear load may not have been isolated. And the structural extension of the suture monofilament itself may have affected the values.

– The experimental value of the point pressure metal wire pullout load that was compared with the simulation value may have been prone to errors. This is because it was difficult for the current tensile testing machine to measure
a displacement as small as 0.005mm accurately, although it showed it on the display for up to 4 decimal places. Therefore the value of 4% approximation between the simulation results and the experimental results contains some error.

– An assumption was made in all the finite element simulations that the barb was not standing out as it naturally would, and that the surrounding tissue had pushed the barb back into the monofilament. Again it should be noted that in the actual case, if the tissue were to push a barb back into the monofilament, then there would be no residual gap below the barb. This gap however exists in the model.

– All the materials were assumed to be isotropic, even though it is well known that polypropylene suture material possesses an anisotropic structure and mechanical properties.

– A value for friction between two sutures was used instead of the value for friction between suture and tissue.

– The effect of a mesh fineness may have influenced the results of the FEA models. It would be helpful in future to study this interrelationship between the fineness of the mesh and the outcome of the Model.

### 5.5.6 Benefits of the FEA study

The following are the benefits of the current FEA study:

– A user friendly script was written to generate, mesh and run FEA simulations for barbs of all possible geometries with either the original design or the ‘Geomcire’ design.

– Since this was the first ever simulation study of surgical barbed sutures, many limitations were uncovered which can be overcome in future.

– New methods have been developed to estimate the constants of surgical suture for the FEA model such as the shear relaxation modulus and bulk relaxation modulus. These models can be further perfected to give more accurate values.

– Most importantly the actual requirements of computational resources and time are now understood.
– The solutions to many of the errors that arose during several attempts to converge the simulations have been understood. And should these errors occur in future, the solutions are already known.

– A parametric comparison of the trends in the results from varying the barb geometry indicated important findings.

– The contact analysis of the suture and tissue were successfully simulated.

– For the first time it was possible to visualize how a viscoelastic barb moves and performs at low displacement within a 3D tissue bed.
Chapter 6

Conclusions

The preparation, experimentation and simulation of the barbed sutures has helped understand the mechanical behavior of the barbs both when stressed individually and when surrounded by different tissues. The following are the main conclusions from this study and they respond to the 6 primary objectives listed in Chapter 1:

1. A new prototyping method has been successfully developed to cut barbs on monofilament sutures with precisely controlled geometries and frequencies.

2. A complete block experimental design was undertaken to cut barbs with 3 different cut angles (150°, 160° and 170°) and 3 different cut depths (0.07, 0.12 and 0.18 mm). The dimensional and mechanical properties of all 9 lists were measured and the findings are listed below

   a) Suture monofilament diameter: At 95% confidence interval there was no significant difference between the diameters for suture for prototyping. Except a significant difference was observed between 150° and 160° cut angles at 0.18 and 0.12mm cut depth. Also significant difference was observed between lots of 0.18 and 0.12mm cut depth for 170° cut angle. The suture monofilament diameter was in the range of 0.39 mm to 0.40.

   b) Elongation at peak tensile load: at 95% confidence interval, significant difference was found between the barbs with same cut angle and different cut depth. Except for 160° cut angle between 0.18 and 0.12 mm

   c) Peak tensile load: at 95% confidence interval, significant significant difference was found between barbs at same cut angle and different cut
depths. No significant difference was found between barbs at different cut angles at same cut depth.

(d) Skin tissue pullout test, Peak load: at 95% confidence interval, the peak load for cut angle 170° and cut depth 0.18mm was significantly higher than the rest of the geometries. And the lowest peak load was recorded for 150° cut angle and 0.07mm cut depth.

(e) Tendon tissue pullout test, Peak load: at 95% confidence interval, the barb with cut angle 150° and cut depth 0.18mm was the highest than the rest. The lowest value for peak load was recorded for barb with cut angle 150° and cut depth 0.07mm.

(f) Overall at 95% confidence interval the cut depth of 0.07mm resulted in the least value of peak load in the suture/tissue pullout force test. And the cut depth of 0.18 gave highest peak load.

(g) Tissue specific barb geometry under experimental anchoring conditions is as follows:
   – Skin: 170° cut angle and 0.18mm cut depth
   – Tendon: 150° cut angle and 0.18mm cut depth

3. a 3D solid model for a single barb was successfully created and meshed after optimization. Finite element simulation was successfully performed on the barb. The simulation result was in close approximation with the experimental result of the metal wire pullout test with an error of 4%.

4. 3D solid models for testing effects of varying cut angle and cut depth were successfully created, meshed and analyzed using finite element simulation converged results for a point pressure load at the tip of the barb.

5. 3D virtual suture/tissue pullout test for skin and tendon tissue using contact elements in finite element analysis successfully converged.

6. A virtual prototype of a new design of barbed surgical suture called ‘Geomcirc’ was designed and tested using point pressure loading boundary conditions in finite element analysis. The solution converged.

Specific conclusions related to the various activities during the study are listed below:
6.1 Prototyping

1. The new prototyping method can be successfully used to make barbed suture.

2. In the current method, the force required for a blade to cut into a monofilament suture and create a barb increases sharply as the cut angle approaches 170°.

3. Suture line tension has to be optimum to maintain accuracy and precision

4. Erosion of the blade profile may cause error in cut depth. So a high quality steel blade should be used.

5. Additional tensioners should be used to maintain the monofilament in contact with cutting base.

6.2 Experiments and Simulations

1. There is loss in breaking load and elongation of a suture due to barbing a suture

2. At constant cut depth, as cut angle increases,
   (a) the barb experiences more displacement when a point pressure load is applied at its tip
   (b) the barb becomes more flexible

3. At constant cut angle, as cut depth increases,
   (a) the barb flexibility does not increase much
   (b) the ability of the barb to anchor increases as cut length increases while the stiffness stays the same

4. In a suture/tissue pullout test, the softer the tissue, there is:
   (a) less deformation of the barb
   (b) less of a tendency for the barb tip to move away from the monofilament axis (UY displacement)
   (c) A barb with a higher cut angle and lower cut depth should be used, if 100% anchoring is possible.

5. Tissue holding capacity of a barbed suture depends on
   (a) ability of the barb to anchor. This in turn depends on,
i. the sharpness and rigidity of the barb tip to initially penetrate into the tissue
ii. the rigidity of the barb body to maintain a straight path into the tissue without bending or buckling
iii. the tissue modulus. If the tissue modulus is lower than that for the suture polymer this is good for better penetration and hence increases the chance of better anchoring.

(b) right combination of cut angle and cut depth
i. if the tissue is easy to penetrate (as in healthy tissue) and has a low modulus then a higher cut angle (170°) and lower cut depth (0.07mm) may be used
ii. if the tissue is difficult to penetrate (as in scarred tissue) and has a very low modulus, then a lower cut angle (160°) and a higher cut depth (0.18mm) may be used
iii. if the tissue is easy to penetrate and has a high modulus, then a lower cut angle (150°) and a medium cut depth (0.12mm) may be used to avoid slipp off
iv. if the tissue is difficult to penetrate and also has a high modulus, then a lower cut angle (150°) and a medium cut depth (0.12mm) may be used.

(c) force required to initiate peeling.
(d) initial elastic flexibility of the barb before permanent deformation sets in. This may increase the fatigue life of the barb. Since it can absorb cyclic waves in the tissue, by redistributing the forces along the cut-line and not letting them reach the threshold peeling initiation load.

6. A circular cut line design in 'Geomcirc' redistributes the stress concentration along the cut line.

7. The 'Geomcirc' design can redistribute the stresses produced by displacements upto 13% more than the original design

8. Since the polymer structure in the suture monofilament is oriented in its axial direction, in most cases, the barbs peel along the length

9. As long as the breaking load of the suture monofilament is more than the force required to initiate peeling and maintain peeling, the loss in the suture
monofilament’s tensile strength due to barbing is acceptable. That is if it can still withstand the tensile force while suturing a tissue.

10. Contact analysis reveals that the softer the tissue under the barb, the greater the displacement of this tissue due to compressive loading by the barb.

11. In point pressure loading of a barb tip, at a constant cut depth, as the cut angle decreases (from 170° to 150°) the peeling stresses at the cut line are reduced.

12. In point pressure loading of a barb tip, at a constant cut angle, as the cut depth decreases (from 0.18mm to 0.07mm) no particular trend of either increase or decrease in the peeling stress along the cut-line was observed.

13. Virtual prototyping and testing using finite element analysis helps identify the areas of stress concentration in the barbed suture and develop improved designs.
Chapter 7

Future Work

The work from the single barb can be taken a step further to perform virtual prototyping of multiple barbs in a curved suture, Figures 7.1 to 7.3. The current script automatically generates this curved suture when the user inputs number of barbs, cut angle and cut depth.

Figure 7.1: Curved suture

Figure 7.2: Meshed curved suture
Figure below shows important information.

![Image](image_url)

Figure 7.3: Magnified view of meshed barb in curved suture

Further research can be done into assessing the fatigue behavior of monofilament sutures and barbed suture to understand the effects of number of cycles to failure and peel initiation. It will particularly help understand this if the suture were to be used to suture pulsating artery for example. The following are the experiments that can be performed on the Dynamic Mechanical Analyzer (DMAQ800) to understand the behavior of the barb under dynamic loading:

1. For non-absorbable suture polymers
   
   (a) For monofilament suture
      
      i. Frequency spectrum at constant amplitude 37°C of monofilament
      ii. Amplitude spectrum at constant frequency at 37°C of monofilament
      iii. Cycles loading of monofilament in different modes: uni-axial, bending, twisted or their combinations
      iv. Change in elastic modulus, breaking strength of monofilament due the above three experiments
   
   (b) For barbed suture
      
      i. Frequency spectrum at constant amplitude 37°C of barb
      ii. Amplitude spectrum at constant frequency at 37°C of barb
      iii. Cyclic loading of barb and entire suture with barb, in different modes: uni-axial, bending, twisted or their combinations
iv. Cycles to failure for point loading of a single barb of different polymers

v. Cycles to failure for a barb anchored in the tissues of different types

vi. Change in elastic modulus, breaking strength of barbed suture due to the specified number of cycles

vii. Change in the peel initiation and peel propagation force

2. For absorbable suture polymers

   (a) repeat all the experiments for non-absorbable polymers at different levels of degradation of polymers at physiological pH ranging from acid to neutral to basic.

Parameter Range: The following parameters is just a range which may be easily exceeded depending upon the type of clinical condition or a non-clinical application:

1. Specimen length: 2mm or depending upon fixture or specimen length
2. Frequency spectrum: 0.01 to upto 100 Hz
3. Frequency (if constant): 1 Hz (equivalent to heart rate)
4. Amplitude spectrum: 0 to upto 100% of yield point (i.e. at elastic limit) or more than that depending upon the application or clinical condition
5. Amplitude (if constant): 1% of elastic limit
6. Materials: absorbable and non absorbable polymers
7. pH: 1 (acidic as gastric fluid) to 7.4 (blood)

In order to perform fatigue simulations using finite element analysis in ANSYS, a Transient analysis will be need to be performed.

It will also be interesting to do a time and material property dependent finite element model the absorbable barbed suture to incorporate the factor of chemical stability. Because depending upon a particular in-vivo environment the suture is subject to, the rate of degradation will be vary and so will the material properties.

At the same time the core sheath effect of the monofilaments can be modeled. In order to perform such a simulation the varying properties of the monofilament suture across the diameter would be needed to be incorporated.
The same technology of making barbed sutures can be extended to making a metal barb as shown in Figure 7.4. This means that the current technology can be for creating a barb like surface on a material on a spectrum of materials from polymers to metals.

Thus this technology can also be used in developing other medical devices where anchoring is required.

Lastly, from a Food and Drug Administration (FDA) perspective of the safety and long term durability of barbed suture, the above listed questions may help address the points of interest listed below:

1. Loss in strength due to barbing

2. Loss in strength of a absorbable sutures during resorption

3. Barb and hence the suture slippage when physiological overloaded

4. Clinical conditions such as fibrosis

5. Bacterial infection due to more surface areas. And also due to area under the barb which serves as a nidus for bacterial growth.
Bibliography


Center for Tribology, Inc., 2008.


[26] Leung J. C. Barbed suture technology: Recent advances. 

[27] Leung J. C. Barbed suture technology: Recent advances. 
Medical Textiles 2004, Advances in Biomedical Textiles and Healthcare Products, Conference 


[29] Leung J. C., Ruff G., and Kaplan A. Suture anchor and method. United 


[71] Brustein M., Pellegrini J., Choueka J., Heminger H., and Mass D. Bone suture anchors versus the pullout button for repair of distal profundus tendon


[83] Dattilo P. P., King M. W., and Leung J. C. Tissue holding performance of


[117] Lo I. K. Y., Burkhart S. S., and Athanasiou K. Abrasion resistance of
Appendices
APPENDIX A

The following is the list of abbreviations used:

– Prototyping
  * AG: adjustable guided
  * BSIC: barbed suture imaging clamp
  * CCP: critical cutting point
  * CDR: central dark region
  * CES: concaving effect of suture
  * CL 1,2: center-line 1,2
  * CZ: cutting zones
  * DBB: distance between barbs
  * DWZ: dead weight zone
  * EN: edge-ninety
  * ET-1,2: elastic tensioner-1,2
  * G-1,2,3: guide 1,2,3
  * GR: glue-region
  * HF: horizontal force
  * HFS: horizontal force stabilizer
  * RL: reverse lock
  * TK: turnable knob
  * TSS: transverse (cylindrical) steel shaft
  * TUC: take-up cylinder

– Finite Element Analysys - ANSYS
  * FX, FY, FZ: Force (Newton) in X-axis, Y-axis and Z-axis direction respectively
  * UX, UY, UZ: Displacement (Meters) in X-axis, Y-axis and Z-axis direction respectively
  * SXY, SYZ, SXZ: Shear stress (Pascals) in XY-plane, YZ-plane and XZ-plane respectively
  * S1, S2, S3: Principle stress (Pascals) in X-axis, Y-axis and Z-axis direction respectively
* SMN, SMX: Minimum and maximum of a plotted item, 
  (FX,FY,FZ,UX,UY,UZ,SXY,SYZ,SXZ,S1,S2,S3)
* EX: Initial elastic modulus (Young’s modulus)
* DA: displacement over area
* K: keypoints
* N: node
* L: line
* A: area
* V: volume
* ET: element
* PRXY: Poisson’s ratio
* MP: material property
* VMESH: mesh volume
* AMESH: mesh areas
* LESIZE: resize line
* VSEL: select volume
* LREFINE: refine line
* ALLSEL: select all
* SMRTSIZE: smart size

– High Performance Computing - HPC
* ADPL: ANSYS parameteric design language
* GB: giga bytes
* GHz: giga hertz
* GUI: graphical user interface
* HDD: hard disk drive
* LSF: load sharing facility
* RAM: random access memory
* VCL: virtual computing laboratory
APPENDIX B

! SIMULATING :: TENDON SUTURE/TISSUE PULLOUT TEST FOR A SINGLE BARB

!Single barb - cut angle

!Ansys Command Listing

! VARYING - cut angle, ca

! CONSTANT - cut depth, cd

/CLEAR

/TITLE, Tensile loading of size-0 polypropylene barbed suture

/PREP7

SHPP,ON,ALL !activates element shape checking

/UNITS.SI !*** iii EXTREMELY IMPORTANT TO NOTE THIS "SI" ***** !!!

!SI = MKS system

! where, Force is Newton; Mass is Kilogram; Length is Meter; Time is Sec

! Temperature is Kelvin

!PLEASE ENTER REQUIRED 'Cut Angle' (in degrees)

! between 90\(\degree\) - 180

ca= 170 ! cut angle later converted to radians in calculations

cd=0.00018 !0.00018 worked ! cut depth (meters)

mdia=0.00040 ! monofilament diameter (meters)

! Creating a monofilament suture

xc=0

yc=0

monolength = 0.002!(meters) <<< variable *** GaugeLength ***

length=monolength – (monolength \* 0.40)
ir=0
or=mdia/2
cllr=0.002 ! clearance top and side outside filament
repo=cllr/tan(ca*3.14/180)
!CYL4, XCENTER, YCENTER, RAD1, THETA1, RAD2, THETA2, DEPTH
CYL4, xc,yc,ir,,or,,mono
!Creating a blade
! K, NPT, X, Y, Z
!top edge outside filament
xpos=or+cllr
ypos=or+cllr
zpos=length/2
xpos1=xpos
ypos1=ypos
!bottom sharp edge inside filament
ang=(ca-90)
c=cos(ang*3.14/180)
Hyp=(cd+(ypos-or))/c
lc = Hyp
!lc=cd/c
*IF,lc,LT,0.0, THEN
lc=lc*(-1)
*ENDIF
Yor = ypos
Ycd = or - cd
Zor = zpos
!Zcd = ??, therefore
x=lc*lc - (Ycd-Yor)*(Ycd-Yor)
*IF, x, LT, 0.0, THEN
x = x * (-1)
*ENDIF

Zcd = SQRT(x) + Zor

Zcd_n = length/2!re – positioning

K, 24, (or + 0.002), Ycd, Zcd_n! changemntometers
K, 25, -(or + 0.002), Ycd, Zcd_n! changemntometers

zpos_n = Zcd_n – (clr/tan(ca * 3.14/180))! re – positioning

K, 20, xpos1, ypos1, zpos_n
K, 21, xpos1, ypos1, zpos_n + 0.0005! 0.0002 changedto 0.0005
K, 22, -xpos1, ypos1, zpos_n
K, 23, -xpos1, ypos1, zpos_n + 0.0005! 0.0002 changedto 0.0005

A, 20, 21, 23, 22
A, 20, 21, 24
A, 22, 23, 25
A, 20, 24, 25, 22
A, 21, 24, 25, 23

! VA, A1, A2, A3, A4, A5, A6, A7, A8, A9, A10
VA, 5, 6, 7, 8, 9
! VSBV, NV1, NV2, SEPO, KEEP1, KEEP2
VSBV, 1, 2

! ***
! Creating 'tissue'
! ***

mth = monolength – (monolength * 0.10)! (mm) thicknessoftissue
mx = xc + or + 0.1e-3
my = yc + or + 0.1e-3

! mz = xc + length ! iii might create problem... put 'zero' directly instead of xc
mz = xc
K,101,mx,-my,mz+(monolength * 0.10)
K,102,mx,my,mz+(monolength * 0.10)
K,103,-mx,my,mz+(monolength * 0.10)
K,104,-mx,-my,mz+(monolength * 0.10)
K,105,mx,-my,mz+mt
K,106,mx,my,mz+mt
K,107,-mx,my,mz+mt
K,108,-mx,-my,mz+mt
A,101,102,103,104
A,105,106,107,108
A,101,102,106,105
A,104,103,107,108
A,102,103,107,106
VA,3,5,6,7,8,9
! make a hole in the plate
!h_dia = or + 0.001e - 3
!CYLIND,0,h_dia, mz, mz+mt!CYLIND, RAD1, RAD2, Z1, Z2, THETA1, THETA2
!subtract volume
!VSBV,1,3,SEPO,KEEP,KEEP !VSBV, NV1, NV2, SEPO, KEEP1, KEEP2
VSBV,1,3,SEPO,KEEP,keep
VDELE,1,,1 !VDELE, NV1, NV2, NINC, KSWP
!************************************************
***CREATING AREA TO CUT THE VOLUMES
!************************************************
outd=1e-3
K,501,0,outd,-outd
K,502,0,-outd,-outd
K,503,0,outd,(length+outd)
K,504,0,-outd,(length+outd)
A,501,503,504,502 !creates A3

!VSBA, NV, NA, SEPO, KEEPV, KEEPA
VSBA,all,3 !should create volumes 4,6 1,5

!VDELE, NV1, NV2, NINC, KSWP
VDELE,1,5,4,1 ! deletes volumes and below

!!!*************MODEL IS DIVIDED INTO HALF **********

! ********

! Selecting ELEMENTS adding MATERIAL properties (polypropylene)

! ********

ET,1,SOLID187
MP,EX,1,3.94e9 ! breaking modulus (Pa=N/m²)
MP,PRXY,1,0.40 ! Poisson’s ratio (assumed) !from literature
MP,DENS,1,1900 ! Density in kg/m³ (i.e. 0.9 grams/cc)
MP,MU,1,0.15 ! Coefficient of friction of suture (from literature)

!********************* add viscoelastic properties below

!Define Material

! the time in seconds (secs) and modulus in Pascals (N/m²)

! ***

tbft,fcase,1,new,pvhe,polypropylene ! PVHE refers to Prony Viscohypoelastic)
tbft,fadd,1,visco,pshar,5
tbft,fadd,1,visco,pbulk,5
tbft,fadd,1,visco,shift,none
tbft,fcase,1,fini
tbft,eadd,1,sdec,shear-rlx.exp
tbft,eadd,1,bdec,bulk-rlx.exp
tbft,set,1,case,polypropylene,,1,1 ! Initialize the 1st coefficient to 0

tbft,set,1,case,polypropylene,,2,10 ! Initialize the 2nd coefficient to 10

tbft,set,1,case,polypropylene,,3,100

tbft,set,1,case,polypropylene,,4,1000

tbft,set,1,case,polypropylene,,5,100000

!***

! solve only for shear

tbft,set,1,case,polypropylene,,tref, 294.26

tbft,set,1,case,polypropylene,,comp,pshea

tbft,solve,1,case,polypropylene,,,,

tbft,fset,1,case,polypropylene,,comp,pshea

! solve for bulk

tbft,set,1,case,polypropylene,,tref, 294.26

tbft,set,1,case,polypropylene,,comp,pbulk

tbft,solve,1,case,polypropylene,,,,

tbft,fset,1,case,polypropylene,,comp,pbulk

! solve for all

tbft,solve,1,case,polypropylene,,comp,pvhe

tbft,solve,1,case,polypropylene,,,,

tbft,fset,1,case,polypropylene,,comp,pvhe

! ***

! print

tbft,list,1

! Write to TB command or database

tblis,all,all

! ****

! MESHING

! ****
VSEL,S,VOLU,,4 !qiMONOFIL

LESIZE,09,,60,,,,0 !along length
LESIZE,6,,3,,,,0
LESIZE,7,,3,,,,0
LESIZE,2,,3,,,,0
LESIZE,3,,3,,,,0
LESIZE,49,,20,,,,0 !¡¡cut-line ¡!!! Spacing ratio !!!¡¡¡
LESIZE,50,,30,,,,0 !¡¡barb-line
LESIZE,51,,30,,,,0 !¡¡barb\textsubscript{mono} – line
SMRTSIZE,4,......,ON,ON,4,1 ! smart size
MAT,1
VMESH,4 ! suture volume is 3 **

ALLSEL

!******* define tissue material properties **********

VSEL,S,VOLU,,6

LESIZE,74,,20,,,,0 !¡¡tis-cut-line ¡!!! Spacing ratio !!!¡¡¡¡¡
LESIZE,76,,30,,,,0 !¡¡tis-barb-line
LESIZE,75,,30,,,,0 !¡¡tis-barb\textsubscript{mono} – line
LESIZE,70,,40,,,,0 !top line at origin
LESIZE,71,,15,,,,0 !top line away
LESIZE,83,,3,,,,0 !¡¡edge circles
LESIZE,84,,3,,,,0
LESIZE,77,,3,,,,0
LESIZE,78,,3,,,,0
LESIZE,29,,60,,,,0 !¡¡along length

!SMRTSIZE,1
SMRTSIZE,4,......,ON,ON,4,1 ! smart size

! for human(similar to bovine stated in literature) tendon tissue
MP,EX,2,6.4e8 ! Pa! initial elastic modulus (Young’s) *** (MPa)

MP,PRXY,2,0.488 ! Poisson’s ratio (assumed) ! from literature

! Define tissue viscoelastic material

! normalized shear/tenesile stress relaxation modulus (MPa/MPa)

! ***

! ***

tbft,fcase,2,new,pvhe,polypropylene ! PVHE refers to Prony Viscohypoelastic)

tbft,fadd,2,visco,pshear,5

tbft,fadd,2,visco,shift,none

tbft,fcase,2,fini

tbft,eadd,2,sdec,shear-rlx-tendon.exp

tbft,set,2,case,polypropylene,,1,1 ! Initialize the 1st coefficient to 0

tbft,set,2,case,polypropylene,,2,10 ! Initialize the 2nd coefficient to 10

tbft,set,2,case,polypropylene,,3,100

tbft,set,2,case,polypropylene,,4,1000

tbft,set,2,case,polypropylene,,5,100000

! ***

! solve only for shear

tbft,set,2,case,polypropylene,,tref,294.26

tbft,set,2,case,polypropylene,,comp,pshea

tbft,solve,2,case,polypropylene,,,,

tbft,fset,2,case,polypropylene,,comp,pshea

! print

tbft,list,2

! ***

! Write to TB command or database

tblis,all,all

MAT,2 ! Turns on Material type 2
tissue surface meshing by tri before vmesh

VMESH, 6 ! tissue ***

ALLSEL

/pnum, mat, 1 ! turning on the material color shading
eplot

! ***** PAIRING OF TARGE/CONTAC BEGINS ************

! target surface (barb)

! ET, ITYPE, Ename, KOP1, KOP2, KOP3, KOP4, KOP5, KOP6, INOPR
ET, 2, TARGE170 ! surface to surface contact element
ET, 3, CONTA174 ! TISSUE ! USING CONTA174 ! !!! SURFACE TO SURFACE

! R, 3, , 1e-40, , 1e-10, , 6e-5

! KEYOPT, 3, 2, 1 ! PENALTY
KEYOPT, 3, 5, 3 ! close gap/reduce penetration with auto CNOF
KEYOPT, 3, 8, 1 ! ignore spurious contacts
! KEYOPT, 3, 9, 0 ! include both init
! KEYOPT, 3, 10, 5 ! each iteration FKN
! KEYOPT, 3, 12, 0 ! standard contact

! ***** PAIR - ONE begins ************

TYPE, 2 ! activate this element i.e. numbered '2' for CONTA174
real, 2

ALLSEL
ASEL, S, AREA, 27 ! BARB-underside
nsla, s, 1 ! NSLA, Type, NKEY
esurf
TYPE, 3
REAL, 2

ALLSEL
ASEL, S, AREA, 42 ! TISSUE
nsla, s, 1 ! NSLA, Type, NKEY
esurf

******PAIR - ONE ends **********

******PAIR - TWO begins **********

TYPE,2 ! activate this element i.e. numbered '2' for CONTAC174
real,3
ALLSEL
ASEL,S,AREA,,30
nsla, s, 1 ! NSLA, Type, NKEY
esurf
TYPE,3
REAL,3
ALLSEL
ASEL,S,AREA,,46
nsla, s, 1 ! NSLA, Type, NKEY
esurf

******PAIR - TWO ends **********

******PAIR - THREE begins **********

TYPE,2 ! activate this element i.e. numbered '2' for CONTAC174
real,7
ALLSEL
ASEL,S,AREA,,29
nsla, s, 1 ! NSLA, Type, NKEY
esurf
TYPE,3
REAL,7
ALLSEL
ASEL,S,AREA,,43
nsla, s, 1 ! NSLA, Type, NKEY
esurf

!******PAIR - THREE ends ********

!******PAIR - FOUR begins ********

TYPE,2 ! activate this element i.e. numbered '2' for CONTAC174
real,5

ALLSEL

ASEL,S,AREA,,28

nsla, s, 1 ! NSLA, Type, NKEY
esurf

TYPE,3

REAL,5

ALLSEL

ASEL,S,AREA,,41

nsla, s, 1 ! NSLA, Type, NKEY
esurf

!******PAIR - FOUR ends ********

!!!!!!!! TARGE+CONTAC PARING DONE ********

ALLSEL

!***** !!! VERY IMPORTANT !!! *****

!**REFINE - contact mesh area for tissue and barb **

!AREFINE, NA1, NA2, NINC, LEVEL, DEPTH, POST, RETAIN

!AREFINE, 16, 19, 1, 4, 1, !i[TISSUE

!AREFINE, 42, , 2, 2, !i[TISSUE

!AREFINE, 27, , 2, 2, !i[BARB

!AREFINE, 46, , 2, 2, !i[TISSUE

!AREFINE, 30, , 2, 2, !i[BARB

!AREFINE, 43, , 2, 2, !i[TISSUE
!AREFINE, 29, , , 2, 2.,!BARB
!AREFINE, 28, , , 2, 1.,!BARB
**********************
/VIEW,1,1,1,1
allsel
FINISH

/SOLU ! Enter solution phase
NLGEOM,ON ! Nonlinear geometry on
NSUBST,10,1000,1 ! 20 load steps
OUTRES,ALL,ALL ! Output data for all load steps
AUTOTS,ON ! Auto time-search on
LNSRCH,ON ! Line search on
NEQIT,1000 ! 1000 iteration maximum
!CNVTOL,F, ,0.10,2,1e-12
ANTYPE,0 ! Static analysis

!**APPLYING SYMMETERY BOUNDARY CONDITIONS!****
DA,24,SYMM !BARB-mono
DA,40,SYMM !TISSUE-top+barb
DA,36,SYMM !TISSUE-bottom

!*****************************************************************
DA,44,all ! Constraining tissue block at '4' sides **
DA,45,all ! double check area numbers !!! ***
DA,48,all
DA,47,all

! dof of barbed suture on open only in z-direction
DA,26,UX,0 ! instead of '0'/zero !DA, AREA, Lab, Value1, Value2
DA,26,UY,0 ! '2' = area at other end of fil. where disp is applied
DA,25,UX,0 ! '1' = area at the base of monofil. at origin
DA,25,UY,0
!strain=0.005 !0.05
!displ=strain*length
! below.... "0.03e-3" WORKs !!
DA,26,UZ,0.001e-3 ! Displace the other end in z-direction by 1.2mm ***
!SFA,2,,PRES,-0.005e6
SOLVE ! solve the resulting system of equations
FINISH ! finish solution
! ***
! POST PROCESSING
! ***
!/POST1
!PLDISP,2 ! Plot Deformed shape
!PLVAR,3,,,,,,,,,, ! Plot Axial Stress,,PRES,-0.005e6
!SIMULATING :: PRESSURE POINT LOAD AT THE TIP OF THE SINGLE BARB

!Single barb - cut angle

! VARYING - cut angle, ca

! CONSTANT - cut depth, cd

/CLEAR

/TITLE, Tensile loading of size-0 polypropylene barbed suture

/PREP7

SHPP,ON,ALL !activates element shape checking

/UNITS,SI !*** iii EXTREMELY IMPORTANT TO NOTE THIS ”SI” ***** !!!

!SI = MKS system

! where, Force is Newton; Mass is Kilogram; Length is Meter; Time is Sec

! Temperature is Kelvin

!PLEASE ENTER REQUIRED ’Cut Angle’ (in degrees)

! between 90¡ca¡180

ca= 170 ! cut angle later converted to radians in calculations

cd=0.00018 ! cut depth (meters)

mdia=0.00040 ! monofilament diameter (meters)

! Creating a monofilament suture

xc=0

yc=0

length= 0.002 ! (meters) variable *** Gauge Length ***

ir=0

or=mdia/2

cllr=0.002 ! clearance top and side outside filament

repo=cllr/tan(ca*3.14/180)

!CYL4, XCENTER, YCENTER, RAD1, THETA1, RAD2, THETA2, DEPTH
CYL4, xc, yc, ir, or, length !default Theta1=0 and Theta2=360 degrees

! Creating a blade
! K, NPT, X, Y, Z
!
!top edge outside filament
xpos=or+cllr
ypos=or+cllr
zpos=length/2
xpos1=xpos
ypos1=ypos
!
!bottom sharp edge inside filament
ang=(ca-90)
c=cos(ang*3.14/180)
Hyp=(cd+(ypos-or))/c
lc = Hyp
!lc=cd/c
*IF, lc, LT, 0.0, THEN
lc=lc*(-1)
*ENDIF
Yor = ypos
Ycd = or - cd
Zor = zpos
!Zcd = ??, therefore
x=lc*lc - (Ycd-Yor)*(Ycd-Yor)
*IF, x, LT, 0.0, THEN
x=x*(-1)
*ENDIF
Zcd = SQRT(x) + Zor

\[ Z_{cd_n} = \frac{\text{length}}{2} \text{re} - \text{positioning} \]

K,24,(or+0.002),Ycd,Zcd,\text{!changing meters}

K,25,-(or+0.002),Ycd,Zcd,\text{!changing meters}

z\text{pos}_n = Z_{cd_n} - (\text{clr} / tan(c \times 3.14 / 180)) \text{!re} - \text{positioning}

K,20,xpos1,ypos1,z\text{pos}_n

K,21,xpos1,ypos1,z\text{pos}_n + 0.0005!0.0002\text{!changed to 0.0005}

K,22,-xpos1,ypos1,z\text{pos}_n

K,23,-xpos1,ypos1,z\text{pos}_n + 0.0005!0.0002\text{!changed to 0.0005}

A,20,21,23,22

A,20,21,24

A,22,23,25

A,20,24,25,22

A,21,24,25,23

!VA, A1, A2, A3, A4, A5, A6, A7, A8, A9, A10

VA,5,6,7,8,9

! VSBV, NV1, NV2, SEPO, KEEP1, KEEP2

VSBV,1,2

! Divide lines before meshing

LDIV,21, , ,3,0 \text{!dividing line 21 into 3 lines to create lines 21, 11 and 12}

LDIV,11, , ,3,0 \text{!then divide line 11 into 3 lines to create 11, 13 and 14}

!L,13,14, !create line L15 at tip to divide A10 int A5 and A3(13,15)

!LDIV,15, , ,5,0 \text{!to create keypoints 24 to 27 + 13\text{!}14}

!LDIV,13, , ,10,0 \text{!to create keypoints 15 to 23 at tip}

L,11,12,

ASBL,10,15,,KEEP \text{!creates area A5 and A3}
ET,1,SOLID187

MP,EX,1,3.94e9 ! breaking modulus (Pa=N/m²)

MP,PRXY,1,0.40 ! Poisson’s ratio (assumed) !from literature

MP,DENS,1,900 ! Density in kg/m³ (i.e. 0.9 grams/cc)

! ********************* add viscoelastic properties below

!Define Material

! the time in seconds (secs) and modulus in Pascals (N/m²)

! ***

tbft,fcase,1,new,pvhe,polypropylene ! PVHE refers to Prony Viscohypoelastic)
tbft,fadd,1,visco,pshear,5

tbft,fadd,1,visco,pbulk,5

tbft,fadd,1,visco,shift,none

tbft,fcase,1,fini

tbft,eadd,1,sdec,shear-rlx.exp

tbft,eadd,1,bdec,bulk-rlx.exp

tbft,set,1,case,polypropylene,,1,1 ! Initialize the 1st coefficient to 0

tbft,set,1,case,polypropylene,,2,10 ! Initialize the 2nd coefficient to 10

tbft,set,1,case,polypropylene,,3,100

tbft,set,1,case,polypropylene,,4,1000

tbft,set,1,case,polypropylene,,5,100000

!***

! solve only for shear

tbft,set,1,case,polypropylene,,tref, 294.26
tbft, set, 1, case, polypropylene,, comp, pshea

! solve for bulk

tbft, set, 1, case, polypropylene,, tref, 294.26

tbft, set, 1, case, polypropylene,, comp, pbulk

tbft, solve, 1, case, polypropylene,,

tbft, fset, 1, case, polypropylene,, comp, pbulk

! solve for all

tbft, solve, 1, case, polypropylene,, comp, pvhe

tbft, solve, 1, case, polypropylene,,

tbft, fset, 1, case, polypropylene,, comp, pvhe

! ***

! print

tbft, list, 1

! Write to TB command or database

tblis, all, all

!***********************

! ****

! MESHING

! ****

LESIZE, 10,,,30,,,0

LESIZE, 09,,,30,,,0

LESIZE, 20,,,45,,,0

LESIZE, 5,,,3,,,0

LESIZE, 6,,,3,,,0
LESIZE,7,,3,,,,0
LESIZE,8,,3,,,,0
LESIZE,1,,3,,,,0
LESIZE,2,,3,,,,0
LESIZE,3,,3,,,,0
LESIZE,4,,3,,,,0
!SMRTSIZE, SIZLVL, FAC, EXPND, TRANS, ANGL, ANGH, GRATIO, SMHLC, SMANC, MXITR, SPRX

!SMHLC=ON ¿¿¿ small hole coarsening - supresses refinement that causes very small edges

!SMANC=ON ¿¿¿ small angle coarsening - restricts refinement in tight corners

!MXITR=4 ¿¿¿ max. no. of sizing iterations

!SIZLVL=DEFA ¿¿¿ changed to DEFA (default of '6') from '1'

!EXPND=0.5 ¿¿¿ a mesh with smaller elements on the interior

!MOPT,TIMP,6

SMRTSIZE,4,,3,,,,ON,ON,4,1 ¡¡¡ smart size

MAT,1 ¡¡¡ somehow this line got deleted !!! watchout !

VMESH,all

FINISH

! ***

! SOLVING

! ***

/SOLU ! Enter solution phase

ANTYPE,STATIC ! Static analysis

NLGEOM,ON ! Nonlinear geometry on

!NSUBST,5,100,1 ¡ 5 load steps

NSUBST,5 ¡ increased number of substeps
OUTRES, ALL, ALL ! Output data for all load steps

NEQIT, 100 ! 100 iteration maximum

ARCLEN, ON, 1/5, -1

CNVTOL, F, , 0.10, 2, 1e-12
!CNVTOL, U, , 0.20, 2, 1e-12

ESCHECK, ESEL, WARN, 1

ALLSEL

DA, 1, all ! Constrain area 1

DA, 2, all

ACEL, ,, 9.8

!DL, 26, UZ, -0.1183e-3 ! in meters

!DL, 27, UZ, -0.1183e-3 ! DISP on LINE

SFA, 3, PRES, 4e6

SOLVE ! solve the resulting system of equations

FINISH ! finish solution
This the script for the model shown the future work

!SOLID MODEL :: CREATING A CURVED BARBED SUTURE FOR A TISSUE PULLOUT TEST

!Single barb - suture

! VARYING - cut depth, cd

! CONSTANT - cut angle, ca

/CLEAR

/PREP7

!PLEASE ENTER REQUIRED 'Cut Depth' (in mm)

! between 90¡ca¡180

c = 120 ! 167 ! cut angle ! iii CONSTANT

cut\_depth = 0.25

mdia=1 ! monofilament diameter

cd=(mdia/2)-cut\_depth!cut\_depth! << VARYING

w = .5 ! width of the BLADE

! Creating a monofilament suture

Ac = 5 ! iii Radius of the arc

xc=0

yc=0

!length=5

ir=0

or=mdia/2

!(or+1) is used in accordance with the usage below

alm = (or+1)*TAN((90-ca)*3.14/180)

! see image staroint.jpgforderivation

!alm = (or+5)*((90-ca)*3.14/180) !arc\_length\_monofilament
alo = (Ac)*(angle)* (3.14/180)!length \, \text{origin}

Therefore, 'alm’ has to be equal to ‘alo’

\text{angle} = alm/(Ac \times (3.14/180))!radians

\text{angle} = angle*ad \times 180/3.14!degrees

\text{lag1} = angle*ad180 - ((180 - ca) + 90)

!! BE SURE TO CHECK THICKNESS OF THE BLADE BELOW !!!!

\text{lag2} = \text{lag1} + 1 !\, \text{lag1}+ (.01 \times 3.14/180)

\text{start} = 20

\text{end} = 180

\text{increment} = 20

!IMPORTANT !!!

!BOPTN,KEEP,YES

!CYL4, XCENTER, Yadjx = ((2 * w) + mdia)* (cos(2 * 3.14/180))

\text{CENTER}, \text{RAD1}, \text{THETA1}, \text{RAD2}, \text{THETA2}, \text{DEPTH}

\text{CYL4}, \text{xc}, \text{yc}, \text{ir}, 0, or, 360,

*GET,Acir,AREA,0,NXTH,,,,

*SET,Acir,1

\text{K}, 100000, 0, 0, 0

\text{K}, 101000, 0, 0, -Ac !\, \text{defining the plane of the arc}

\text{K}, 102000, (Ac*2), 0, 0

LARC,10000,102000,10100,5

!*GET, Par, Entity, ENTNUM, Item1, IT1NUM, Item2, IT2NUM

!*GET,AneW,AREA,,NXTL,,,,

!*SET,AneW,10,

! VDRAG, NA1, NA2, NA3, NA4, NA5, NA6, NLP1, NLP2, NLP3, NLP4, NLP5, NLP6

VDRAG,1,,,,,,5,,,,,,cd=0.3 ! cut depth ! \text{VARYING}
K,201,10,0.5
L,201,10200
VDRAG,6,14
!NUMSTR,VOLU,1000
VADD,ALL
!NUMSTR,VOLU,DEFA
*GET,Vtemp,VOLU,1,NXTH,,
*SET,Vtemp,2 SET monofil VOL
!*GET,tem(DOTX-1)
!pA,AREA,10,NXTH,,
! ***NUMSTR,VOLU,3000************
! *******************
! *******************

! Getting the x, y, z coordinates
! derived from
!/**/**/**
!xpos=(a + r*cos(teta*3.14/180))+2
!ypos=or+2
!zpos=-((b + r*cos(teta*3.14/180))+2)
! SINCE:::::
! THE DAEMN *DO command does not work as it should

r=Ac
a=Ac
b=0
*DIM,X,ARRAY,1000
*DIM,Y,ARRAY,1000
*DIM,Z,ARRAY,1000
! 111111111111111 4004, 4006
*DIM,Xx,ARRAY,1000
*DIM,Yy,ARRAY,1000
*DIM,Zz,ARRAY,1000
*DO,DOTX,start deg,end deg, increment deg
K,DOTX,((a + (r+w)*COS(DOTX*3.14/180)),(cd),... 
-((b + (r+w)*SIN(DOTX*3.14/180)))
*GET,X(DOTX),KX,DOTX,LOC,..
*MSG,INFO,X(DOTX)
X(DOTX) =
! KDELE, NP1, NP2, NINC
KDELE,DOTX,..
*ENDDO

*DO,DOTX,start deg,end deg, increment deg
K,DOTX,((a + (r-w)*COS(DOTX*3.14/180)),(cd),... 
-((b + (r-w)*SIN(DOTX*3.14/180)))
*GET,Xx(DOTX),KX,DOTX,LOC,..
*MSG,INFO,X(DOTX)
Xx(DOTX) =
KDELE,DOTX,..
*ENDDO
! I am just for Y-coord here
*DO,DOTX,start deg,end deg, increment deg
K,DOTX,((a + (r+w)*COS(DOTX*3.14/180))),(cd),...
-((b + (r+w)*SIN(DOTX*3.14/180)))
*GET,Y(DOTX),KY,DOTX,LOC,,
*MSG.INFO,Y(DOTX)
Y(DOTX) =
KDELETE,DOTX,;
*ENDDO

*DO,DOTX,start\_deg,end\_deg, increment\_deg
K,DOTX,((a + (r-w)*COS(DOTX*3.14/180))),(cd),...
-((b + (r-w)*SIN(DOTX*3.14/180)))
*GET,Yy(DOTX),KY,DOTX,LOC,,
*MSG.INFO,Yy(DOTX)
Yy(DOTX) =
KDELETE,DOTX,;
*ENDDO

*DO,DOTX,start\_deg,end\_deg, increment\_deg
K,DOTX,((a + (r+w)*COS(DOTX*3.14/180))),(cd),...
-((b + (r+w)*SIN(DOTX*3.14/180)))
*GET,Z(DOTX),KZ,DOTX,LOC,,
*MSG.INFO,Z(DOTX)
Z(DOTX) =
KDELETE,DOTX,;
*ENDDO

*DO,DOTX,start\_deg,end\_deg, increment\_deg
K,DOTX,((a + (r-w)*COS(DOTX*3.14/180))),(cd),...
-((b + (r-w)*SIN(DOTX*3.14/180)))
*GET,Zz(DOTX),KZ,DOTX,LOC,,;
261

*MSG,INFO,Zz(DOTX)
Zz(DOTX) =
KDELE,DOTX,,
*ENDDO
! 111111111111¿¡¿¡¿¡¿4004, 4006
! ¡¡¡¡ *******************,k,dotx**¿¿
! ¡¡¡¡ *********************¿¿
*DIM,L,ARRAY,1000
*DIM,M,ARRAY,1000
*DIM,N,ARRAY,1000
! 2222222222222¡¿¡¿¡ 4021 , 4031
*DIM,Ll,ARRAY,1000
*DIM,Mm,ARRAY,1000
*DIM,Nn,ARRAY,1000
*DO,DOTX,startd eg, endd egree, incrementd egree
K,DOTX,((a + (r+w)*COS((DOTX-lag1)*3.14/180))),...
(or+1),-((b +(r+w)*SIN((DOTX-lag1)*3.14/180)))
*GET,L(DOTX),KX,DOTX,LOC,,,
*MSG,INFO,L(DOTX)
L(DOTX) =
!KDELE, NP1, NP2, NINC
KDELE,DOTX,,
*ENDDO
*DO,DOTX,startd eg, endd egree, incrementd egree
K,DOTX,((a + (r-w)*COS((DOTX-lag1)*3.14/180))),...
(or+1),-((b + (r-w)*SIN((DOTX-lag1)*3.14/180)))
*GET,Ll(DOTX),KX,DOTX,LOC,,,


*MSG,INFO,L1(DOTX)
L1(DOTX) =
KDELE,DOTX,,
*ENDDO

! I`am just for Y-coord here

*DO,DOTX,start_deg,end_deg,increment_deg

K,DOTX,((a + (r+w)*COS((DOTX-lag1)*3.14/180))),...
(or+1),-((b + (r+w)*SIN((DOTX-lag1)*3.14/180)))
GET,M(DOTX),KY,DOTX,LOC,,
*MSG,INFO,M(DOTX)

M(DOTX) =
KDELE,DOTX,,
*ENDDO

*DO,DOTX,start_deg,end_deg,increment_deg

K,DOTX,((a + (r-w)*COS((DOTX-lag1)*3.14/180))),...
(or+1),-((b + (r-w)*SIN((DOTX-lag1)*3.14/180)))
GET,Mm(DOTX),KY,DOTX,LOC,,
*MSG,INFO,Mm(DOTX)

Mm(DOTX) =
KDELE,DOTX,,
*ENDDO

*DO,DOTX,start_deg,end_deg,increment_deg

K,DOTX,((a + (r+w)*COS((DOTX-lag1)*3.14/180))),...
(or+1),-((b + (r+w)*SIN((DOTX-lag1)*3.14/180)))
GET,N(DOTX),KZ,DOTX,LOC,,
*MSG,INFO,N(DOTX)

N(DOTX) =
KDELE,DOTX,,
*ENDDO

*DO,DOTX,start, deg, end, degree, increment, degree

K,DOTX,((a + (r-w)*COS((DOTX-lag1)*3.14/180))),,...
(or+1),-((b + (r-w)*SIN((DOTX-lag1)*3.14/180)))
*GET,Nn(DOTX),KZ,DOTX,LOC,,
*MSG,INFO,Nn(DOTX)

Nn(DOTX) =
KDELE,DOTX,,
*ENDDO

! 222222222222¿¡¿¡¿¡¿4021, 4031

*DIM,S,ARRAY,1000
*DIM,T,ARRAY,1000
*DIM,U,ARRAY,1000

! 33333333¿¡¿¡¿¡¿ 4022 , 4032
*DIM,Ss,ARRAY,1000
*DIM,Tt,ARRAY,1000
*DIM,Uu,ARRAY,1000

*DO,DOTX,start, deg, end, degree, increment, degree

K,DOTX,((a + (r+w)*COS((DOTX-lag2)*3.14/180))),,...
(or+1),-((b + (r+w)*SIN((DOTX-lag2)*3.14/180)))
*GET,S(DOTX),KX,DOTX,LOC,,
*MSG,INFO,S(DOTX)

S(DOTX) =
!KDELE, NP1, NP2, NINC
KDELE,DOTX,,
*ENDDO
*DO,DOTX,start_deg,end_deg,increment_deg
K,DOTX,((a + (r-w)*COS((DOTX-lag2)*3.14/180))),....
(or+1),-((b + (r-w)*SIN((DOTX-lag2)*3.14/180)))
*GET,Ss(DOTX),KX,DOTX,LOC,,, *
*MSG,INFO,Ss(DOTX)
Ss(DOTX) = KDELE,DOTX,, *
*ENDDO ! I'am just for Y-coord here

*DO,DOTX,start_deg,end_deg,increment_deg
K,DOTX,((a + (r+w)*COS((DOTX-lag2)*3.14/180))),....
(or+1),-((b + (r+w)*SIN((DOTX-lag2)*3.14/180)))
*GET,T(DOTX),KY,DOTX,LOC,,, *
*MSG,INFO,T(DOTX)
T(DOTX) = KDELE,DOTX,, *
*ENDDO

*DO,DOTX,start_deg,end_deg,increment_deg
K,DOTX,((a + (r-w)*COS((DOTX-lag2)*3.14/180))),....
(or+1),-((b + (r-w)*SIN((DOTX-lag2)*3.14/180)))
*GET,Tt(DOTX),KY,DOTX,LOC,,, *
*MSG,INFO,Tt(DOTX)
Tt(DOTX) = KDELE,DOTX,, *
*ENDDO

*DO,DOTX,start_deg,end_deg,increment_deg
K,DOTX,((a + (r+w)*COS((DOTX-lag2)*3.14/180))),...
(or+1),-((b + (r+w)*SIN((DOTX-lag2)*3.14/180)))
*GET,U(DOTX),KZ,DOTX,LOC,,
*MSG,INFO,U(DOTX)
U(DOTX) =
KDELE,DOTX,,
*ENDDO

*DO,DOTX,start deg,end deg,increment deg
K,DOTX,((a + (r-w)*COS((DOTX-lag2)*3.14/180))),...
(or+1),-((b + (r-w)*SIN((DOTX-lag2)*3.14/180)))
*GET,Uu(DOTX),KZ,DOTX,LOC,,
*MSG,INFO,Uu(DOTX)
Uu(DOTX) =
KDELE,DOTX,,
*ENDDO

! iiiii
! 33333333iiciici 4022 , 4032
! iii *** iciici

!iciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciiciic
K,4021,L(DOTX),M(DOTX),N(DOTX)

ccos = \cos(\text{angle} \times 3.14/180)

ssin = \sin(\text{angle} \times 3.14/180)

K,4031,((Ll(DOTX)\times ccos)+(Nn(DOTX)\times ssin)),...
Mm(DOTX),((-Ll(DOTX)\times ssin)+(Nn(DOTX)\times ccos))

K,4022,S(DOTX),T(DOTX),U(DOTX)

K,4032,((Ss(DOTX)\times ccos)+(Uu(DOTX)\times ssin)),...
Tt(DOTX),((-Ss(DOTX)\times ssin)+(Uu(DOTX)\times ccos))

!¿¡¿¡¿¡¿¡¿¡¿¡¿¡¿¡

!NUMSTR, Label, VALUE

NUMSTR,AREA,2000

A,4021,4022,4032,4031
A,4021,4031,4006,4004
A,4022,4032,4006,4004
A,4021,4022,4004
A,4031,4032,4006

NUMSTR,AREA,DEFA

NUMSTR,VOLU,3000


NUMSTR,VOLU,DEFA

*GET,MonoVOLU,VOLU,0,NXTH,,,,
VSBV,MonoVOLU,3000

*ENDDO
APPENDIX C: Variation in Diameter

The following are the scatter plots for the variation in the suture monofilament diameter used for barbed suture prototyping.

Figure 0.5: Variation in diameter for Figure 0.6: Variation in diameter for 150° 160°

Figure 0.7: Variation in diameter for 170°
APPENDIX D: Variation in Cut Angle

The following are the scatter plots for the variation in the cut angle of the barbed suture samples prototyped.

Figure 0.8: Variation in cut angle 150°

Figure 0.9: Variation in cut angle 160°

Figure 0.10: Variation in cut angle 170°
APPENDIX E: Variation in Cut Depth

The following are the scatter plots for the variation in the cut depth of the barbed suture samples prototyped.

Figure 0.11: Variation in cut depth

Figure 0.12: Variation in cut depth

Figure 0.13: Variation in cut depth
APPENDIX F: Point load - UZ

Point load - UZ

Figure 0.14: 150° at 0.07mm

Figure 0.15: 150° at 0.12mm

Figure 0.16: 150° at 0.18mm

Figure 0.17: 160° at 0.07mm

Figure 0.18: 160° at 0.12mm

Figure 0.19: 160° at 0.18mm

Figure 0.20: 170° at 0.07mm

Figure 0.21: 170° at 0.12mm

Figure 0.22: 170° at 0.18mm
APPENDIX G: Point load - SYZ

Point load - SYZ

Figure 0.23: 150° at 0.07mm
Figure 0.24: 150° at 0.12mm
Figure 0.25: 150° at 0.18mm

Figure 0.26: 160° at 0.07mm
Figure 0.27: 160° at 0.12mm
Figure 0.28: 160° at 0.18mm

Figure 0.29: 170° at 0.07mm
Figure 0.30: 170° at 0.12mm
Figure 0.31: 170° at 0.18mm
APPENDIX H: Point load - S3

Point load - S3

Figure 0.32: 150° at 0.07mm
Figure 0.33: 150° at 0.12mm
Figure 0.34: 150° at 0.18mm

Figure 0.35: 160° at 0.07mm
Figure 0.36: 160° at 0.12mm
Figure 0.37: 160° at 0.18mm

Figure 0.38: 170° at 0.07mm
Figure 0.39: 170° at 0.12mm
Figure 0.40: 170° at 0.18mm
APPENDIX I: Skin - UZ (isometric)

Skin - UZ (isometric)

Figure 0.41: 150° at 0.07 mm
Figure 0.42: 150° at 0.12 mm
Figure 0.43: 150° at 0.18 mm

Figure 0.44: 160° at 0.07 mm
Figure 0.45: 160° at 0.12 mm
Figure 0.46: 160° at 0.18 mm

Figure 0.47: 170° at 0.07 mm
Figure 0.48: 170° at 0.12 mm
Figure 0.49: 170° at 0.18 mm
APPENDIX J: Skin - UZ

Skin - UZ

Figure 0.50: 150° at 0.07mm
Figure 0.51: 150° at 0.12mm
Figure 0.52: 150° at .18mm

Figure 0.53: 160° at 0.07mm
Figure 0.54: 160° at 0.12mm
Figure 0.55: 160° at .18mm

Figure 0.56: 170° at 0.07mm
Figure 0.57: 170° at 0.12mm
Figure 0.58: 170° at .18mm
APPENDIX K: Skin - UY

Skin - UY

Figure 0.59: 150° at 0.07mm
Figure 0.60: 150° at 0.12mm
Figure 0.61: 150° at .18mm

Figure 0.62: 160° at 0.07mm
Figure 0.63: 160° at 0.12mm
Figure 0.64: 160° at .18mm

Figure 0.65: 170° at 0.07mm
Figure 0.66: 170° at 0.12mm
Figure 0.67: 170° at .18mm
APPENDIX L: Skin - SYZ

Skin - SYZ

Figure 0.68: 150° at 0.07mm
Figure 0.69: 150° at 0.12mm
Figure 0.70: 150° at .18mm

Figure 0.71: 160° at 0.07mm
Figure 0.72: 160° at 0.12mm
Figure 0.73: 160° at .18mm

Figure 0.74: 170° at 0.07mm
Figure 0.75: 170° at 0.12mm
Figure 0.76: 170° at .18mm
APPENDIX M: Skin - S3

Skin - S3

Figure 0.77: 150° at 0.07mm
Figure 0.78: 150° at 0.12mm
Figure 0.79: 150° at 0.18mm
Figure 0.80: 160° at 0.07mm
Figure 0.81: 160° at 0.12mm
Figure 0.82: 160° at 0.18mm
Figure 0.83: 170° at 0.07mm
Figure 0.84: 170° at 0.12mm
Figure 0.85: 170° at 0.18mm
APPENDIX N: Tendon - UZ (isometric)

Tendon - UZ (isometric)

Figure 0.86: 150° at 0.07mm
Figure 0.87: 150° at 0.12mm
Figure 0.88: 150° at 0.18mm

Figure 0.89: 160° at 0.07mm
Figure 0.90: 160° at 0.12mm
Figure 0.91: 160° at 0.18mm

Figure 0.92: 170° at 0.07mm
Figure 0.93: 170° at 0.12mm
Figure 0.94: 170° at 0.18mm
APPENDIX O: Tendon - UZ

Tendon - UZ  
cut depth = 0.07mm; 0.12mm; 0.18mm
APPENDIX P: Tendon - UY

Tendon - UY
cut depth = 0.07mm; 0.12mm; 0.18mm

Figure 0.104: 150° at 0.07
Figure 0.105: 150° at 0.12
Figure 0.106: 150° at 0.18

Figure 0.107: 160° at 0.07
Figure 0.108: 160° at 0.12
Figure 0.109: 160° at 0.18

Figure 0.110: 170° at 0.07
Figure 0.111: 170° at 0.12
Figure 0.112: 170° at 0.18
APPENDIX Q: Tendon - SYZ

Tendon - SYZ
cut depth = 0.07mm; 0.12mm; 0.18mm

Figure 0.113: 150° at 0.07
Figure 0.114: 150° at 0.12
Figure 0.115: 150° at .18

Figure 0.116: 160° at 0.07
Figure 0.117: 160° at 0.12
Figure 0.118: 160° at .18

Figure 0.119: 170° at 0.07
Figure 0.120: 170° at 0.12
Figure 0.121: 170° at .18
APPENDIX P: Tendon - S3

Tendon - S3
cut depth = 0.07mm; 0.12mm; 0.18mm

Figure 0.122: 150° at 0.07  Figure 0.123: 150° at 0.12  Figure 0.124: 150° at .18

Figure 0.125: 160° at 0.07  Figure 0.126: 160° at 0.12  Figure 0.127: 160° at .18

Figure 0.128: 170° at 0.07  Figure 0.129: 170° at 0.12  Figure 0.130: 170° at .18
APPENDIX S: Matlab Imaging

The main file below is followed by a function file 'makelist.m' The Figure 3.17 was used for this program.

% Code for measuring cut angle, cut depth and calculating cut length

% The MEGA loop ¡¡ begins! ¡¡

ti = 5;

gg = 0;

% Calling multiple image files within a directory

list = makelist;

list

% kkk = list3

for out = 1:1:10

kkk = listout

for mega = 1:1:ti

RGB = imread(kkk);

I = rgb2gray(RGB);

threshold = graythresh(I);

BW = im2bw(I,threshold);

imshow(BW)

dim = size(BW);
col = round(dim(2)/2);
row = find(BW(:,col),1);
connectivity = 8;
num_points = 500;
contour = bwtraceboundary(BW, [row, col], 'N', connectivity, num_points);
imshow(RGB);
hold on;
plot(contour(:,2),contour(:,1),'g','LineWidth',2);
x = contour(:,2); y = contour(:,1);
QQ = [x,y];

% whos
% First find the lowest 'y-cord' in 'y'
% REMEMBER :: top left corner is (0,0)
for i=2:1:500
if y(i-1)¿y(i)
    highest_y = y(i-1);
    lowest_y = y(i);
for j=2:1:500
    if highest_y < y(j-1):
        highest_y = y(j - 1);
        aq = j;
    end
end
end
end
end
highest_y
lowest_y

plot(x(aq),highest_y,'*')%<<< Hoorey! this is the CUTPOINT!!!

% Now we increase 'x-coord' from 'x(aq)' onwards till 'y' becomes constant
% aq
for k=aq:1:500
if y(k)¿= y(k-1)
temp=y(k);
% well! this no. tells a group size with same value of 'y'
% And it works only at '10' ! TOO SENSITIVE, might not work for
% other images ¡¡¡¡ check!
WHY=10;
slope = (y(k) - y(k-WHY))/(x(k) - x(k-WHY));
if slope == 0
sq=k-WHY;
y_s = y(sq);
break;
end
end
end
end
% x(sq)
% y_s
plot(x(sq),y_s,'*')

% plot(672,490,'*')
plot (x(sq),highest_y,'*')%<<< That's for the cut depth!
% CALIBRATION SETTINGS ¡¡¡ Important !!!!!
pix = 340
% Please DOUBLE CHECK THE ABOVE CALIB 'pix' VALUE !!!!
% Can use 'ImageJ' to get the 'pix' VALUE

% pLC = sqrt((x(aq) - x(sq))^2 + (highest_y - ys)^2);
Lc = (pLC * 1)/pix

pCd = sqrt((x(sq) - x(sq))^2 + (ys - highest_y)^2);
Cd = (pCd * 1)/pix

pac = sqrt((x(aq) - x(sq))^2 + (highest_y - highest_y)^2);
a_c = (pac * 1)/pix;

theta = acos(Cd/Lc)*(180/3.14); %¡¡¡ in degrees
Ca = (90+theta)
alc(mega) = Lc+gg; %¡¡ array storing Lc

acd(mega) = Cd+gg; % ¡¡ DON'T FORGET TO REMOVE 'gg' !!!!!!!!!!
aca(mega) = Ca+gg;

gg=gg+100;
sp_n_o(mega) = mega;
end
alc
acd
aca

% STATISTICAL ANALYSIS
% Here we will find:
% Mean, Std. dev., Std. Error
% for Lc, Cd, Ca

sLC = 0; sCd = 0; sCa = 0;
for z=1:1:mega
\[ s_{lc} = s_{lc} + alc(z); \]
\[ s_{cd} = s_{cd} + acd(z); \]
\[ s_{ca} = s_{ca} + aca(z); \]
end
\[ m_{lc} = s_{lc}/\text{mega}; \]
\[ m_{cd} = s_{cd}/\text{mega}; \]
\[ m_{ca} = s_{ca}/\text{mega}; \]
% Std.dev.
\[ df_{lc} = 0; df_{cd} = 0; df_{ca} = 0; \]
for \( zz = 1:1:\text{mega} \)
\[ df_{lc} = df_{lc} + (alc(zz) - m_{lc}); \]
\[ df_{cd} = df_{cd} + (acd(zz) - m_{cd}); \]
\[ df_{ca} = df_{ca} + (aca(zz) - m_{ca}); \]
end
\[ sd_{lc} = \sqrt{df_{lc}/\text{mega}}; \]
\[ sd_{cd} = \sqrt{df_{cd}/\text{mega}}; \]
\[ sd_{ca} = \sqrt{df_{ca}/\text{mega}}; \]
\[ se_{lc} = sd_{lc}/\sqrt{\text{mega}}; \]
\[ se_{cd} = sd_{cd}/\sqrt{\text{mega}}; \]
\[ se_{ca} = sd_{ca}/\sqrt{\text{mega}}; \]
\[ \text{mean} = [m_{lc}, m_{cd}, m_{ca}] \]
\[ \text{sd} = [sd_{lc}, sd_{cd}, sd_{ca}] \]
\[ \text{se} = [se_{lc}, se_{cd}, se_{ca}] \]
\%
\% WRITING TO EXCEL
\%
%M = 0;alc(mega);acd(mega);aca(mega);

% Create some column headers for the data
ColHeaders = 'Sample number','Specimen number'...
'Cut length (mm)';'Cut depth (mm)';'Cut angle (degrees)';

% Now write the data into the first sheet of a new spreadsheet
% s = xlswrite('bg eo.xls', M, 1, 'A2');
% xlswrite('bg eo.xls', sample_no', 1, 'C2 : C6')
% xlswrite('bg eo.xls', sp_no', 1 + out, 'B2 : B6')
% xlswrite('bg eo.xls', alc', 1 + out, 'C2 : C6')
% xlswrite('bg eo.xls', acd', 1 + out, 'D2 : D6')
% xlswrite('bg eo.xls', acd', 1 + out, 'E2 : E6')
% Add the column headers
% xlswrite('bg eo', ColHeaders, 1 + out, 'A1 : E1');
% rowheaders='Mean', 'Std.Dev.', 'Std.Err.';
% xlswrite('bg eo.xls', rowheaders', 1 + out, 'B7 : B9');
% Writi’n the stats
% xlswrite('bg eo.xls', mean, 1 + out, 'C7 : E7')
% xlswrite('bg eo.xls', sd, 1 + out, 'C8 : E8')
% xlswrite('bg eo.xls', se, 1 + out, 'C9 : E9')
% Writi’n the sample number
% xlswrite('bg eo.xls', out, 1 + out, 'A2 : A2')
alc=0;acd=0;aca=0;sic = 0; scd = 0; sda = 0; dfic = 0; dfd = 0; dfa = 0;
mean=0;sd=0;se=0;gg=0;
end

%**makelist.m***

function list=makelist
% returns a list of files (in a cell array named list), made interactively
exit=0; % The program quits when exit=1
list=;
while (exit == 0)

% SET UP DISPLAY
wd=pwd; % current directory
disp(['Current directory ' wd]);
sz=size(list,1);
if (sz);
disp(‘ ’); disp(['CURRENT LIST: ' num2str(sz) ' entries: ' list1 ' ... ' listend])
else
disp(‘List: 0 entries’)
end
choices=’MENU:’; ’s=show list’; ’i=Info about image’;...
’d(or ls)=dir’; ’sk=skip’; ’c=cut’;...
’ec=include’; ’x=erase list start over’;...
’cd=change directory’; ’e=edit’;
disp(char(choices))
beep

% GET INPUT FROM USER
inp=input (’Type base name (wild cards OK) (ENTER=use current list),’,’s’);
switch inp
    case ” % ENTER pressed, time to quit program (unless list is empty)
        clc;
        if (isempty(list)); exit=1; end
    case ’i’ % get information about file(s) in list
prompt=['Which number? (1-` num2str(sz)`; ENTER=all)'];

inp=input(prompt,'s');

if isempty(inp);
    for j=1:sz
        try
            info=imfinfo(listj)
        catch; disp (['Error reading ' listj])
        end;
    end;
else
    try
        info=imfinfo(liststr2num(inp))
    catch; disp (['Error reading ' listinp])
    info
    end;
end

case 'cd' % change directory
[f picpath]=uigetfile('*.*','Pick any file in Directory');
cd (picpath) % change to new directory

case 's' % show list
clc
disp(char(list))
input ('Press ENTER');

case 'ls' % display all files in this directory
ls
disp('Press ENTER'); pause
case 'd' % display all files in this directory

dir; disp('Press ENTER'); pause

case 'c' % Cut files from list that contain string

c=input('Omit if it contains string - type string (ENTER=abort)','s');
if (isempty(c));
nn=1; list2=;
for j=1:length(list);
if isempty(findstr(c,listj));list2(nn)=list(j);nn=nn+1;end
end
end
list=list2';

case 'cc' % CCut files from list that do NOT contain string

c=input('Include if it contains string - type string (ENTER=abort)','s');
if (isempty(c));
nn=1;list2=;
for j=1:length(list);
if findstr(c,listj); list2(nn)=list(j); nn=nn+1; end
end
end
list=list2';

case 'sk' % skip files

inp=input('Take how many, skip how many? (ENTER= 1 1)','s');
[n1 n2]=strtok(inp,' '); % strtok splits inp at spaces
% e.g., '1 3' becomes '1' and '3'. Still strings, not numbers
if (isempty (n1)); n1='1'; n2='1';end
nn=0; n1=str2num(n1); n2=str2num(n2);list2=;
for j=1:n1+n2:size(list,1)
for k=1:n1
    nn=nn+1;
    try; list2(nn)=list(j+k-1);
    catch; nn=nn-1; end
end
end

list=list2';

case 'x' % erase list
    list=[];
    case 'e'
    dlmwrite('junk.txt',char(list),")
    edit 'junk.txt' %
    input ('Press ENTER when done','s')
    list=textread('junk.txt','%s');
    otherwise % something was entered
    structlist=dir(inp); % DIR returns a structure (4 fields: name, date, byes, isdir)
    celllist=structlist.name; % make cell array
    celllist=celllist'; % 1 row becomes 1 column
    list=[list; celllist]; % append to old list
end % switch inp
end % while exit==0