DEVELOPMENT OF NEW TREATMENT MODALITIES FOR KIDNEY/URETER STONES

A Dissertation
Presented to
The Graduate Faculty of The University of Akron

In Partial Fulfillment
Of the Requirements for the Degree
Doctor of Philosophy

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August 2015
DEVELOPMENT OF NEW TREATMENT MODALITIES FOR KIDNEY/URETER STONES

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ABSTRACT

The number of people suffering from urolithiasis (formation of kidney stones) has increased over the past few decades. Ureteroscopic stone extraction devices are effective and ubiquitous tools in the management of urolithiasis. These devices, however, have the potential to cause injury to the ureter. Avulsion and perforation of the ureter as a result of excessive forces on the extraction device are the most serious complications of this treatment. Moreover, effective management of kidney stones depends on their size, location, and composition. In this dissertation, different treatment modalities for kidney stone disease are discussed.

In the first part of this dissertation, analysis of the peristaltic movement, which drives the urine from the kidneys to the bladder through the ureter, is presented. More specifically, different sizes and types of kidney stones are modeled inside the ureter and their effects on the urine flow and pressure on the ureter wall are studied. It is concluded that in addition to the stone size, different stone shapes result in different pressures on the ureter wall.

In the second part of this dissertation, a kidney basket prototype with a force sensor has been developed. This device was built based on the measured injury forces during basketing, using two different setups, a benchtop model and an ex-vivo porcine ureter. The force sensor provides instantaneous visual force measurements imposed on the ureter wall.
wall during stone extraction, and thereby, aids in reducing the risk of complications by highlighting the safety and hazardous extraction forces.

The tests were performed in conjunction with the Division of Urology, Southern Illinois University, School of Medicine, Springfield, IL. The results obtained from these tests were consistent with injury forces reported in the literature. The designed prototype, together with the stone analysis performed in this study could potentially lead to an improvement in the treatment of urolithiasis and enhance patient outcomes.
ACKNOWLEDGEMENTS

I would like to express my special appreciation to my advisor Dr. Ajay Mahajan for his leadership, direction and encouragement throughout the entirety of this research. I would also like to thank and acknowledge my co-advisor Dr. Abhilash Chandy for his insightful comments, time and guidance on this research. My sincere thanks to Dr. Bradley Schwartz and Dr. Thomas Tieu, at the Southern Illinois University, School of Medicine, Division of Urology, Springfield, IL, for their support and guidance in this project.

Special thanks to Dr. Bing Yu, Dr. Rouzbeh Amini and Dr. Jutta Luettmers-Strathman for their support as members of my dissertation committee and for all their comments and suggestions which helped to complete this work. I would like to thank Stephan Paterson the engineering technician in the machine shop for his guidance in building the prototype.

I would like to give special thanks to my family. Words cannot express how grateful I am to my parents and sisters for all of their love and support. Last but not least, I would like to express a very special appreciation to my beloved husband who has always been a source of strength and inspiration throughout my work.
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABSTRACT</td>
<td></td>
<td>iii</td>
</tr>
<tr>
<td>ACKNOWLEDGMENT</td>
<td></td>
<td>v</td>
</tr>
<tr>
<td>LIST OF TABLES</td>
<td></td>
<td>xi</td>
</tr>
<tr>
<td>LIST OF FIGURES</td>
<td></td>
<td>xii</td>
</tr>
<tr>
<td><strong>CHAPTER</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I – INTRODUCTION</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1.1 Computational Modeling and Simulation of the Human Ureter</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1.2 Stone Extraction Force Measurements</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>1.3 “Smart Device” Design with Force Feedback</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>1.4 Scope of Dissertation</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>II – ANATOMY AND PHYSIOLOGY OF THE HUMAN URINARY TRACT</td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>2.1 Introduction</td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>2.2 Anatomy of the Urinary System</td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>2.3 Physiology of the Ureter</td>
<td></td>
<td>8</td>
</tr>
<tr>
<td>2.4 Conclusion</td>
<td></td>
<td>12</td>
</tr>
<tr>
<td>III – COMPUTATIONAL MODELING OF THE URETER</td>
<td></td>
<td>14</td>
</tr>
<tr>
<td>3.1 Introduction</td>
<td></td>
<td>14</td>
</tr>
<tr>
<td>3.2 Peristaltic Movement in the Ureter</td>
<td></td>
<td>14</td>
</tr>
</tbody>
</table>
3.3 Modeling the Peristaltic Movement............................................. 19
3.4 Formulation of the Fluid............................................................. 21
3.5 Analysis of the Ureter with no Stone.......................................... 24
  3.5.1 Mesh and Step Time Independence Test................................. 25
  3.5.2 Analysis of the Pressure Contours and Velocity Vectors.......... 30
  3.5.3 Pressure Gradient Magnitudes along the Ureter Axis............... 39
  3.5.4 Analysis of the Shear Stresses on the Wall............................ 42
  3.5.5 Analysis of the Axial Velocity Profiles................................. 44
  3.5.6 Analysis of the Pressure Profiles......................................... 46
3.6 Analysis of Different Sizes of a Stone Type in the Ureter.............. 48
  3.6.1 Analysis of the Pressure Contours and Velocity Vectors........... 49
  3.6.2 Pressure Gradient Magnitudes along the Ureter Axis............... 60
  3.6.3 Analysis of the Shear Stresses on the Wall............................ 64
  3.6.4 Analysis of the Axial Velocity Profiles................................. 67
  3.6.5 Analysis of the Pressure Profiles......................................... 69
3.7 Analysis of Different Types of Stone in the Ureter...................... 71
  3.7.1 Analysis of the Pressure Contours and Velocity Vectors.......... 72
  3.7.2 Pressure Gradient Magnitudes along the Ureter Axis............... 83
  3.7.3 Analysis of the Shear Stresses on the Wall............................ 87
  3.7.4 Analysis of the Axial Velocity Profiles................................. 90
  3.7.5 Analysis of the Pressure Profiles......................................... 92
3.8 Conclusion.................................................................................. 94
IV – PERFORATION AND AVULSION FORCE MEASUREMENTS............. 95
4.8.2 Ex-vivo Porcine Ureter Test Results

4.8.2.1 Maximal Average Force (MAF) Results

4.8.2.2 Maxime Time (\(T_m\)) and Rise Time (\(T_r\)) Results

4.8.2.3 Work Results

4.8.3 Bench Top Test MAF Values vs. Ex-vivo Test MAF Values

4.8.4 Discussion on the Measured Forces

4.9 Training Device Design

4.9.1 Retraction Basket Preparation

4.9.2 Circuit Preparation

4.9.3 Training Device Bench Top Test

4.10 Conclusion

V – DESIGN OF A SMART DEVICE

5.1 Introduction

5.2 Instrumentation in the Ureteroscopy

5.2.1 Stone Migration Devices

5.2.2 Stone Forceps

5.2.3 Stone Baskets

5.2.3.1 Complication of Basketing

5.3 Design of the “Smart Device”

5.3.1 Force Measurement Methods

5.3.1.1 Load Cell Force Measurement

5.3.1.2 Spring Force Measurement

5.3.2 Proposed Device Description
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.4 Prototype Bench Top Test</td>
<td>145</td>
</tr>
<tr>
<td>5.5 Prototype Test Results</td>
<td>151</td>
</tr>
<tr>
<td>5.6 New Design of the Device</td>
<td>156</td>
</tr>
<tr>
<td>5.7 Conclusion</td>
<td>157</td>
</tr>
<tr>
<td>VI – CONCLUSION AND FUTURE WORK</td>
<td>158</td>
</tr>
<tr>
<td>6.1 Summary</td>
<td>158</td>
</tr>
<tr>
<td>6.2 Future Work</td>
<td>160</td>
</tr>
<tr>
<td>BIBLIOGRAPHY</td>
<td>162</td>
</tr>
<tr>
<td>APPENDICES</td>
<td>173</td>
</tr>
<tr>
<td>APPENDIX A. FORCE SENSOR</td>
<td>174</td>
</tr>
<tr>
<td>APPENDIX B. DATA ACQUISITION SYSTEM</td>
<td>178</td>
</tr>
<tr>
<td>APPENDIX C. PROTOTYPE DRAWINGS</td>
<td>189</td>
</tr>
<tr>
<td>APPENDIX D. USER DEFINE FUNCTION CODE</td>
<td>194</td>
</tr>
<tr>
<td>APPENDIX E. FORCE MEASUREMENT PROTOCOLS</td>
<td>197</td>
</tr>
<tr>
<td>APPENDIX F. FLOW OF FLUID OVER CYLINDER IN ANSYS FLUENT</td>
<td>200</td>
</tr>
<tr>
<td>Table</td>
<td>Page</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>3.1. Boundary condition in the steady state and the transient simulation</td>
<td>23</td>
</tr>
<tr>
<td>3.2. Wall shear stress peak values at the beginning of the peristalsis for different stone sizes</td>
<td>65</td>
</tr>
<tr>
<td>3.3. Wall shear stress peak values at the beginning of the peristalsis for different stone types</td>
<td>88</td>
</tr>
<tr>
<td>4.1. The maximum time and rise time results in the ex-vivo porcine ureter test</td>
<td>125</td>
</tr>
<tr>
<td>5.1. The average maximum values of each region</td>
<td>155</td>
</tr>
</tbody>
</table>
## LIST OF FIGURES

<table>
<thead>
<tr>
<th>Figure</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.2. Cross-sectional view of the ureter [3]</td>
<td>7</td>
</tr>
<tr>
<td>2.3. Example of ureteroogram in a healthy dog ureter (pressure (mmHg) versus time (s)) [7]</td>
<td>9</td>
</tr>
<tr>
<td>2.4. Videomicroscopy of a ureter peristaltic motion in rats [9]</td>
<td>9</td>
</tr>
<tr>
<td>2.5. Upper urinary tract contractions begin at the pelvis–kidney junction. Kidneys were bisected as shown in (a) to expose the inside of the organ (b and c). At higher power (c), the pelvis-kidney junction (PKJ) can be seen. Bisected kidneys were analyzed by real-time video microscopy and contractile activity was recorded (d-g) [13]</td>
<td>11</td>
</tr>
<tr>
<td>2.6. Blocks of tissue represented successively to illustrate luminal change through an Artist’s representation of the full range of luminal change [11]</td>
<td>12</td>
</tr>
<tr>
<td>3.1. Model of the ureter with radius r, (b) Peristaltic movement model on ureter wall with wave amplitude of a, total height (R), speed of wave (c), and the wavelength (λ)</td>
<td>20</td>
</tr>
<tr>
<td>3.2. The geometry and initial computational structured mesh for the ureter model</td>
<td>24</td>
</tr>
<tr>
<td>3.3. Geometry of the ureter wall in different times of wave movement</td>
<td>25</td>
</tr>
<tr>
<td>3.4. Pressure gradient magnitude along axis for 15K, 25K, and 50K mesh element sizes at time T</td>
<td>27</td>
</tr>
<tr>
<td>3.5. The percentage of errors between the 25K and 50K mesh elements</td>
<td>28</td>
</tr>
<tr>
<td>3.6. Pressure gradient magnitude on axis for time step sizes of 0.01s, 0.05 s, and</td>
<td></td>
</tr>
</tbody>
</table>
3.7. The percentage of errors between the time step size 0.01s and 0.05s.

3.8. Pressure contour (a) and the velocity vectors (b) of the model solved in the steady state case.

3.9. Ureteral pressure contours during peristaltic movement at (a) T/4, (b) T/2, (c) 3T/4, (d) T.

3.10. Urine velocity vector plot showing ureteral back flow development following the contraction wave at the beginning of peristalsis.

3.11. Urine velocity vector plots at (a) T/4, (b) T/2, (c) 3T/4, (d) T.

3.12. Urine velocity vectors at T/4. Four different regions of a, b, c and d were defined on the ureter and were zoomed in.

3.13. Urine velocity vectors at T/2. Four different regions of a, b, c and d were defined on the ureter and were zoomed in.

3.14. Urine velocity vectors at 3T/4. Four different regions of a, b, c and d were defined on the ureter and were zoomed in.

3.15. Urine velocity vectors at T. Four different regions of a, b, c and d were defined on the ureter and were zoomed in.

3.16. Ureteral streamlines during peristaltic wave propagation (a) T/4 (b) 3T/4.

3.17. Pressure gradient magnitude along the ureter axis at (a) T/4, (b) T/2, (c) 3T/4, and (d) T.

3.18. Wall shear stress during peristaltic movement at (a) T/4, (b) T/2, (c) 3T/4, (d) T.

3.19. Axial velocity profiles versus the distance from the ureteral axis on the twelve defined profiles at (a) T/4, (b) T/2, (c) 3T/4, (d) T.

3.20. Ureteral pressure profiles versus the distance from the ureteral axis at the twelve defined profiles at (a) T/4, (b) T/2, (c) 3T/4, (d) T.
3.21. Different sizes of kidney stones (calculi) [80] .................................................. 48

3.22. Geometry of two different sizes of cylinder stone. Stone of size 1x1mm (top) and stone size 2x2 mm (bottom) .......................................................... 49

3.23. Pressure contours of the steady state solved ureter model. From top to bottom are the no stone ureter, 25% blockage and 50% blockage ........................................ 50

3.24. Pressure contours of the steady state solved ureter model. From top to bottom are the no stone ureter, 25% blockage and 50% blockage ................................. 50

3.25. Pressure contours at T/4 (a) ureter with no stone, (b) ureter with stone 1x1mm, (c) ureter with stone 2x2 mm ................................................................. 52

3.26. Velocity vectors during peristaltic movement at T/4 (a) ureter with no stone, (b) ureter with stone 1x1mm and (c) ureter with stone 2x2 mm ..................................... 53

3.27. Pressure contours at T/2 (a) ureter with no stone, (b) ureter with stone 1x1mm, (c) ureter with stone 2x2 mm ................................................................. 54

3.28. Velocity vectors during peristaltic movement at T/2 (a) ureter with no stone, (b) ureter with stone 1x1mm and (c) ureter with stone 2x2 mm ..................................... 55

3.29. Pressure contours at 3T/4 (a) ureter with no stone, (b) ureter with stone 1x1mm, (c) ureter with stone 2x2 mm ................................................................. 56

3.30. Velocity vectors during peristaltic movement at 3T/4 (a) ureter with no stone, (b) ureter with stone 1x1mm and (c) ureter with stone 2x2 mm ............................... 57

3.31. Pressure contours at T (a) ureter with no stone, (b) ureter with stone 1x1mm, (c) ureter with stone 2x2 mm ................................................................. 58

3.32. Velocity vectors during peristaltic movement at T (a) ureter with no stone, (b) ureter with stone 1x1mm and (c) ureter with stone 2x2 mm ............................... 59

3.33. Pressure gradient magnitude at the beginning of the peristalsis. The ureter with no stone is plotted in dark blue, 25% blockage case in red, 50% blockage case in purple and the 60% blockage case in light blue. (a) pressure gradient along the axis (b) pressure gradient from 20 – 40 mm which the stones are placed .................................................. 61

3.34. Pressure gradient magnitudes along ureter axis (blue curve: ureter with no stone, red curve: 25% blockage, green curve: 50% blockage) at (a) T/4, (b) T/2,
3.35. Wall shear stress for the three different status of ureter at the beginning of peristaltic. (dark blue: the ureter with no stone, red: 25% blockage, purple: 50% blockage and green 65% blockage).

3.36. Wall shear stress for the three cases (blue curve: ureter with no stone, red curve: 25% blockage, green curve: 50% blockage) at (a) T/4, (b) T/2, (c) 3T/4 and (d) T.

3.37. Ureteral axial velocity profiles during peristaltic for the three different cases (blue curve: ureter with no stone, red curve: 25% blockage, green curve: 50% blockage) at (a) T/4, (b) T/2, (c) 3T/4 and (d) T.

3.38. Ureteral pressure profiles during peristaltic wave propagation at (a) T/4, (b) T/2, (c) 3T/4, (d) T. (blue curve: ureter with no stone, red curve: 25% blockage, green curve: 50% blockage).

3.39. Different types of kidney stones [111].

3.40. Different types of stones in ureter, cylinder (top), circle (middle) and triangle (bottom).

3.41. Pressure contours of different shapes of stones in the ureter and the ureter with no stone in the steady state simulation.

3.42. Velocity vectors of different shapes of stones in the ureter and the ureter with no stone in the steady state simulation.

3.43. Pressure contours at T/4 (a) the ureter with cylindrical stone, (b) the ureter with spherical stone, (c) the ureter with conical stone.

3.44. Velocity vectors during peristaltic movement at T/4 (a) the ureter with cylindrical stone, (b) the ureter with spherical stone, (c) the ureter with conical stone.

3.45. Pressure contours at T/2 (a) the ureter with cylindrical stone, (b) the ureter with spherical stone, (c) the ureter with conical stone.

3.46. Velocity vectors during peristaltic movement at T/2 (a) the ureter with cylindrical stone, (b) the ureter with spherical stone, (c) the ureter with conical stone.
3.47. Pressure contours at 3T/4 (a) the ureter with cylindrical stone, (b) the ureter with spherical stone, (c) the ureter with conical stone.

3.48. Velocity vectors during peristaltic movement at 3T/4 (a) the ureter with cylindrical stone, (b) the ureter with spherical stone, (c) the ureter with conical stone.

3.49. Pressure contours at T (a) the ureter with cylindrical stone, (b) the ureter with spherical stone, (c) the ureter with conical stone.

3.50. Velocity vectors during peristaltic movement at T (a) the ureter with cylindrical stone, (b) the ureter with spherical stone, (c) the ureter with conical stone.

3.51. Pressure gradient magnitude at the beginning of the peristalsis. Pressures of ureter with no stone are plotted in blue, cylindrical stone in red, spherical stone in green and conical stone in pink. (a) pressure gradients along the axis (b) pressure gradients from 20 – 40 mm which the stones are placed.

3.52. Pressure gradient magnitudes along ureter axis (the ureter with no stone is plotted in dark blue, cylindrical stone in red, spherical stone in green and the conical stone in pink) (a) T/4, (b) T/2, (c) 3T/4, (d) T.

3.53. Wall shear stress at the beginning of the peristaltic movement for the different shapes of stones. (the ureter with no stone is plotted in dark blue, cylindrical stone in red, spherical stone in green and the conical stone in pink).

3.54. Wall shear stress for the different cases (the ureter with no stone is plotted in dark blue, cylindrical stone in red, spherical stone in green and the conical stone in pink) at (a) T/4, (b) T/2, (c) 3T/4 and (d) T.

3.55. Ureteral axial velocity profiles during peristaltic for the four different cases (the ureter with no stone is plotted in dark blue, cylindrical stone in red, spherical stone in green and the conical stone in pink) at (a) T/4, (b) T/2, (c) 3T/4 and (d) T.

3.56. Ureteral pressure profiles during peristaltic wave (the ureter with no stone is plotted in dark blue, cylindrical stone in red, spherical stone in green and the conical stone in pink) at (a) T/4, (b) T/2, (c) 3T/4, (d) T.

4.1. A formed stone in the ureter [86].
4.2. Different types of urinary system stone [81]…………………………………….. 99

4.3. Extracorporeal Shock Wave Lithotripsy (ESWL) [84]………………………… 101

4.4. Ureteroscopy procedure. A basket will be used to retract the stone [87]…….. 102

4.5. Percutaneous Nephrolithotomy (PCNL) procedure [93]……………………… 103

4.6. Ureteral avulsion due forceful basketing [112]……………………………….. 105

4.7. Extraction of a ureteral stone with a basket, ureteroscopic view of a ureteral stone (top left), Passage of the closed basket between stone and ureteral wall (top right), opened basket is manipulated around the stone (middle left), closing of the basket (middle right), passage of the ureteral stone through the distal narrow ureter (bottom left), ureteroscopic view of the ostium with perforation after forceful extraction of the stone (bottom right) [111]…………………………………….. 106

4.8. Low force load cell (OMEGA® LCL-010 Series thin beam) [147]……………… 108

4.9. Calibration setup of the sensor on the optic table…………………………….. 108

4.10. Block diagram of the calibration and data acquisition system…………………. 109

4.11. Bench top test of load cell force measurement test…………………………… 110

4.12. Ex-vivo porcine kidney with an intact ureter. A stricture was made and the stone was placed proximal to the stricture……………………………………………………….. 110

4.13. Withdrawal system with load cell attached to the external end basket……… 111

4.14. Withdrawal system and ureteroscope, Basket is advanced through an opening on the ureteroscope (a), Stone was detected and trapped inside the basket and the withdrawal system was pulled back (b)………………………………………………………. 112

4.15. Calibration curve of the load cell OMEGA® LCL…………………………….. 114

4.16. Output force of surgeon 3 in proximal ureter (bench top test). Each run is assigned with a color. The safe, Cautious (perforation), and dangerous (avulsion) regions are shown in the figure………………………………………………………. 115

4.17. Maximal Average Forces in safe region……………………………………….. 116
4.18. Maximal Average Forces in cautious (perforation) region

4.19. Maximal Average Forces in dangerous (avulsion) region

4.20. Maximal Average Forces in the three regions

4.21. Standard deviation of G1, G2 and, G3 in green, yellow and red regions

4.22. Output force for surgeon 3 in proximal ureter (porcine test)

4.23. Maximal Average Forces in safe region

4.24. Maximal Average Forces in cautious region

4.25. Maximal Average Forces in safe and cautious regions

4.26. Standard deviation of G1, G2 and, G3 in green and yellow regions

4.27. Average T(max) values in green and yellow regions

4.28. Average T(rise) values in green and yellow regions

4.29. Average of works done in green (safe) and yellow (cautious) regions

4.30. Maximal average forces in safe region for load cell test and ex-vivo test

4.31. Maximal average forces in cautious region for load cell test and ex-vivo test

4.32. A kidney basket attached to the force sensor and platform

4.33. Schematic of LT1101 instrumentation amplifier. The outputs of the load cell were connected to pins 3 and 6

4.34. Schematic of LT1101 amplifier (a), Circuit design for the different range of applied forces (b)

4.35. The green LED is on in safe applied forces (a), the yellow LED went on when the applied forces exceed to perforation (cautious) force region (b) The red LED went on with forces exceeding into avulsion region forces (c)

5.1. Accordion (Percsys) stone trapping device (a) device passes the stone, (b) it
controls the movement of stones and widens ureter for enhanced visualization of stone (c) it prevents the fragmented stones from migration [121]................. 138

5.2. Graspit forceps (Boston Scientific), constructed of serrated nitinol [124]............. 139

5.3. Dormia helical stone baskets (Boston Scientific, Natick, MA, USA) [124]........... 140

5.4. NCircle (Cook Urological, 1.5 F) the earliest tipless nitinol basket [151]............. 140

5.5. Complete avulsion of the ureter wall due extra force on the basket (a), perforation in ureter during basketing (b) [132, 133]................................. 142

5.6. Load cells, (a) Strain gauge under load, (b) Button style compression load cells [138]................................................................. 144

5.7. Full-bridge strain gauge circuit [138]................................................. 145

5.8. Schematic of the force sensor handle (front view)....................................... 146

5.9. Spring calibration setup............................................................................. 146

5.10. Proposed sensor handle (a) Cook NCircle kidney basket [151], (b) prototype attached to Cook® Medical basket.................................................... 148

5.11. Force sensor calibration setup............................................................... 149

5.12. Bench top testing setup.......................................................................... 150

5.13. Prototype attached to the load cell (white arrow shows the pullback applied force direction)........................................................................ 150

5.14. Spring calibration curve.......................................................................... 151

5.15. Force sensor calibration curve............................................................... 151

5.16. Output force results of the bench-top test in safe region (green)................. 152

5.17. Output force results of the bench-top test in cautious (yellow).................... 153

5.18. Output force results of the bench-top test in dangerous (red)...................... 154
5.19. Recorded force regions in the bench-top testing................................. 155
5.20. New design of the "smart device".......................................................... 156
A.1. OMEGA ® LCL Series thin beam load cells.......................................... 174
A.2. Schematic of load cell mounting kit.................................................... 175
A.3. The load cell and mounting kit drawing diagram............................... 176
A.4. LT1101 amplifier schematic............................................................... 177
A.5. Connection of the wires of the load cell to the LT1101 amplifier.......... 177
B.1. DI-710 Data acquisition system.......................................................... 178
B.2. Different ways to transfer SD data files.............................................. 180
B.3. Rear panel schematic of DI-710............................................................ 181
B.4. Front panel schematic of DI-710.......................................................... 181
B.5. Channel bar....................................................................................... 182
B.6. Channel bar selection or deselection tab.......................................... 183
B.7. Non-overlapped display.................................................................... 184
B.8. Overlapped display............................................................................ 184
B.9. Specifying a sample rate................................................................. 185
B.10. Specifying gain.............................................................................. 186
B.11. Recording waveforms in disk......................................................... 186
B.12. Recording mode in WINDAQ display............................................ 187
B.13. Full memory usage mode in data recording................................... 188
C.1. The handle of the prototype……………………………………………….. 190
C.2. The connector screw between the handle and the basket………………….. 191
C.3. Spring and swivel holder…………………………………………………… 192
C.4. Screw to fix the spring to the rear part of handle………………………….. 193
E.1. Load cell bench top test protocol……………………………………………… 198
E.2. Ex-vivo porcine force measurement test………………………………………. 199
F.1. Schematic of the problem ……………………………………………………… 201
F.2. (a) Grid display (b) zoomed in the cylinder part of grid display ……….. 201
F.3. Lift coefficient report plot ……………………………………………………… 203
F.4. Static pressure contours ……………………………………………………… 204
F.5. Contours of vorticity magnitude ……………………………………………… 204
F.6. Contours of streamline function ……………………………………………… 205
CHAPTER I
INTRODUCTION

The urinary system, also known as the renal system, consists of different organs whose main function is to produce and excrete urine. It also plays a vital role in maintaining the composition of the body fluids [1]. There are a number of common urinary system disorders that can occur. Examples of these disorders include cancers of the urinary tract, incontinence (inability to control urine flow), kidney stones, kidney failure, and urinary tract infections [2]. Urinary tract stone disease (urolithiasis) is a major health care problem due to its high prevalence and incidence. There are different therapeutic approaches for urinary tract stones depending on their size, location and anatomical variations of the urogenital tract. Different treatment modalities for the urinary tract stone disease are discussed in this dissertation.

1.1 Computational Modeling and Simulation of the Human Ureter

Ureters are tube shape organs in the urinary system which connect the kidneys to the bladder and transport the urine along with train of waves called peristaltic movement. The term peristalsis stems from the Greek word *peristaltikos*, which means clasping and compressing. A medical definition of peristalsis in Merriam Webster’s is “Successive waves of involuntary contraction passing along the walls of a hollow muscular structure and forcing the contents onward” [3].
Peristaltic motion is produced by successive waves of contraction in elastic, tubular structures which push their fluid or fluid-like contents forward [4]. The fluid flow in the ureter is sometimes accompanied by solid particles such as calculi (urinary tract stone) which affect the peristaltic movement [5, 6].

Mathematical modeling is used in biomechanics to study numerous dynamic systems. Biofluid mechanics is that part of biomechanics which describes the kinematics and dynamics of body fluids in humans, animals and plants. Modern biofluid mechanics helps to measure and analyze the fluid flow in the blood vessels, the respiratory system, the lymphatic system, the gastrointestinal system, the urinary system and many other physiological systems. Findings are important for clinical applications such as artificial organs, treatment methods, vascular vessel development, design of medical tools, and fabrication of material membranes for orthopedics, among others. Mathematical modeling of peristaltic transport deals with a prescribed train of sinusoidal waves moving with constant speed on the flexible boundaries of a tube (simulating the ureter). The idea is to study how the fluid flows due to action of the peristaltic motion of the wall. The fluid could flow in a ureter with or without urinary stones. The effect of different sizes and shapes of stones are studied on the flow of the urine and on the ureter wall. Studying the effects of different sizes and shapes of calculi on the urine flow and the ureter wall could potentially impact the treatment decisions for this disease. In the following chapters, these approaches are explored and analyzed under some assumptions.

1.2 Stone Extraction Force Measurements

Ureteroscopy has a prominent role in treatment of the urinary tract stones [7]. Basketing is the most common method for removing the ureteral stones. However, this
procedure may sometimes cause complications such as mucosal injury, false passage, ureteral perforation, ureteral rupture, stricture, inability to remove the device and, ureteral avulsion [8]. These complications can lead to increased operating room time and cost and in some cases may have severe and lasting consequences. Excessive applied forces in retrieval of the stones during basketing are the greatest risk factor in the perforation and/or avulsion of the ureter [9]. An effective way to avoid such serious complications may be to prevent them by providing a visual feedback of the applied forces during stone extraction. In this dissertation, the ureteral perforation and avulsion forces were measured by two different test set ups. An electronic training system was built and tested based on the injury causing forces. Three different LED lights were assigned for safe, cautious (perforation) and dangerous (avulsion) applied forces. This system could be used in the training of the less experienced urologists on the extraction forces. This force training might decrease the risk of injury to the ureter at the time of treatment.

1.3 Design of a Smart Device with Force Feedback

In the ureteroscopic treatment method, when feasible, basketing is considered to be the most rapid means of removing a ureteral stone [10]. Much of the efficacy depends on the quality of the modern disposable stone baskets, which have improved stone extraction techniques [11]. Many new baskets have been introduced with capabilities for manipulation and deflection, and others have intricate wire designs. This evolution in instrumentation has substantially expanded the indications for and use of basketing in urology. A stone basket may be used not only to extract stones but also to obtain tissue from a lesion or to engage a foreign body located within the upper urinary tract. However, stone basketing does have the potential to cause ureteral injury. The greatest
A risk factor for ureteral injury appears to be attempts to remove a stone that is too large to be retrieved in one piece with the use of extra force [12]. A "smart device" was designed which provides instantaneous feedback of the applied forces during extraction. Regions of injury and safe forces are defined on the device which would be a visual cue for the surgeon during stone extraction.

1.4 Scope of Dissertation

In order to provide the technically oriented reader with some elementary knowledge of the anatomy and physiology of the ureter, Chapter 2 introduces the basics of the urinary system. Detailed analysis of peristaltic flow fluid in a ureter with and without urinary stones are given in Chapter 3. In Chapter 4 the measurements of the injury forces to the ureter are presented. A training device was built and tested based on the measured forces. In chapter 5 the design of the "smart device" is presented. Finally, conclusions and recommendations for future work are presented in Chapter 6. The appendices are attached at the end of the dissertation.
CHAPTER II
ANATOMY AND PHYSIOLOGY OF THE HUMAN URINARY TRACT

2.1 Introduction

This dissertation deals with studying and understanding the role of calculi (stony concretions in the urinary system) in the human urinary system and developing methodologies that lead to enhanced patient safety in the removal of stones. In order to provide the technically oriented reader with some elementary knowledge of the anatomy and physiology of the ureter, this chapter introduces the basics of the urinary system.

The Urinary System is a group of organs in the body which filters out excess fluid and other substances from the bloodstream. The substances are filtered out from the body in the form of urine. Urine is a liquid produced by the kidneys, collected in the bladder and excreted through the urethra. Urine flows from the kidneys to the bladder through the ureters by peristaltic action of the ureteral wall [13]. It is known that peristaltic transport is an effective method to move fluid. It is one of the major mechanisms for fluid transport in many biological systems. Anatomy and physiology of the human urinary system and the ureter physiology is presented in this chapter.

2.2 Anatomy of the Urinary System

The urinary system eliminates waste products from the body and maintains fluid/salt balance. Other aspects of urinary system function include regulating the concentrations of various electrolytes in the body fluids and maintaining normal pH of the blood [13]. This
system can be divided in two sections, the upper part (the kidneys and the ureter) and, the lower part (the bladder and the urethra) as shown in Fig. 2.1.

![Components of the urinary system](image)

Fig. 2.1. Components of the urinary system [14].

In the upper urinary tract, the kidneys are a pair of bean-shaped entities that are the primary organs of the urinary system. The kidneys are located at the rear wall of the abdominal cavity just above the waistline, and are protected by the ribcage. In these organs, urea is removed from blood through tiny filtering units called nephrons. Urine is secreted in the nephrons, and after that, it is collected in the papillae (Fig. 2.1) and flows through the lesser and greater calyces into the renal pelvis. The renal pelvis is a funnel-shaped tube which forms the entrance to the ureter. Both calyces and the renal pelvis show peristaltic contractions. The ureters are tubes that carry urine from the kidneys to the urinary bladder [14]. The propulsion of urine in the ureter is accomplished by peristaltic (pumping) contractions moving in the distal direction. In the human adult, the ureter acquires a length of about 25-30 cm, the left ureter being slightly longer. The ureteral diameter, including the muscular coat, varies from 4-10 mm, while the diameter
of the lumen in the relaxed phase varies from 2 - 6 mm. The ureter wall is composed of several layers [2]. The luminal surface of the ureteral wall is composed of a transitional Epithelium Propia (EP), and a Lamina Propia (LP), consisting of a relatively thick layer of well-vascularized and well innervated connective tissue. The rest of the wall is composed of smooth muscle and connective tissue (Tunica Muscularis (TMu)) [15]. This section is composed of smooth muscle bundles separated by abundant loose connective tissue that ease the peristaltic contractions, as shown in Fig. 2.2.

Fig. 2.2. Cross-sectional view of the ureter [15].

In the lower urinary tract, the urinary bladder which temporarily stores the urine is a hollow distensible sac whose volume can be adjusted by varying the contractile state of the smooth muscle within. This organ is connected to the outside of the body through the urethra. On its anterior border lies the pubic symphysis and, on its posterior border, the vagina (in females) and the rectum (in males). The urinary bladder can hold approximately 17 to 18 ounces (500 to 530 ml) of urine, however, the desire to urinate is usually experienced when it contains about 150 to 200 ml. When the bladder fills with
urine (about half full), the stretch receptors send nerve impulses to the spinal cord, which then sends a reflex nerve impulse back to the sphincter (muscular valve) at the neck of the bladder, causing it to relax and that allows the flow of urine into the urethra. The internal urethral sphincter is involuntary. The urine in the bladder also helps regulate the body temperature. The urethra is a muscular tube that connects the bladder with the outside of the body. The function of the urethra is to remove the urine from the body. It measures about 1.5 inches (3.8 cm) in a woman but up to 8 inches (20 cm) in a man [16].

2.3 Physiology of the Ureter

The muscles of the ureter through their peristaltic movement propel the urine into the bladder. This movement occurs only as a reflex phenomenon in response to the entrance of the urine, a few drops every three-quarters of a minute, or in consequence of direct irrigation. This movement initiates with the origin of electrical activity at pacemaker sites located in the proximal portion of the urinary collecting system. The urine between two contraction waves takes the form of a bolus which is propelled distally until it enters the bladder. The velocity of conduction in the ureter ranges from 2 to 6 cm/s [17].

By watching radiopacified urine propagating along the ureter, peristaltic movement has been studied. By measuring the changes in pressure of the ureter, the peristaltic was studied [18]. The pressures were measured using electronic strain gauge pressure sensors that were attached to the inserted catheters into the ureter. “Uremetrogram” is the act of measuring and recording the pressure variations with time in the ureter by these sensors. An example of uremetrogram is shown in Fig. 2.3 [19, 20].
Fig. 2.3. Example of uremetrogram in a healthy dog ureter (pressure (mmHg) versus time (s)) [20].

In another study imaging of the ureteral peristaltic function was presented. Videomicroscopic imaging of ureteral peristalsis was used on rats during cystometry. The velocity of peristaltic wave, frequency, bolus length, and direction of bolus propagation were derived by image processing using indigo carmine for contrast. The velocity was obtained by measuring the time taken for a bolus to travel along a calibrated distance (see Fig. 2.4) [21].

As shown above, this procedure was done by first selecting the two video frames, shown as inserts, one denoting the time the bolus is at the start at the Pelvic Ureter Junction (PUJ) (1) and the other frame showing the bolus located at approximately in the

Fig. 2.4. Videomicroscopy of the ureter peristaltic motion in rats [21].
region of the cranial abdominal vessels (2). The two images were then arithmetically added and the distance between them measured. In this sample, a velocity of 10.41 mm/s was evaluated based on the distance of 5.10 mm and time difference of 0.49 s between both bolus frames. In another recent study, direct video-microscopic examination of ureter showed that contractile waves always initiated at the pelvis-kidney junction (PKJ) and then moved distally through the renal pelvis and then down the ureter (Fig. 2.5). In Fig. 2.5 (b, c) the cortical (c), medullary (m) and papillary (pa) zones are visible in bisected kidneys as well as the renal pelvis (p) and ureter (u). Peristaltic waves occurred 4–9 times/min and always initiated at the PKJ (Fig. 2.5 (e) arrow). As can be seen in Fig. 2.5 (f), contractions move distally (arrow) toward the ureteral-pelvic junction and then down the ureter (arrow, Fig. 2.5 (g)) [22, 23]. To analyze electrical activity in explants, changes in the membrane potential were detected using the voltage-sensitive dye RH237. Explants were loaded with the dye and changes in the intensity of fluorescence signals across the upper urinary tract were recorded over time. Results of these studies showed that spontaneous electrical excitation initiates at the PKJ and propagates distally in a coordinated wave-like manner [23].
Fig. 2.5. Upper urinary tract contractions begin at the pelvis–kidney junction. Kidneys were bisected as shown in (a) to expose the inside of the organ (b and c). At higher power (c), the Pelvis-Kidney Junction (PKJ) can be seen. Bisected kidneys were analyzed by real-time video microscopy and contractile activity was recorded (d-g) [23].

The ureteral lumen is suggested to be spherical based on radiographic observations. However, anatomic illustrations suggested the luminal outline to be stellate. The shape of the lumen during the passage of a wave was studied and the mucosal section of the lumen during peristalsis was analyzed [24]. The ureteral lumen with an inserted catheter during peristalsis was studied in dogs. The caliber of the catheter was shown to influence both contractile amplitude and basal pressure level of the ureter. In one case, an increase in the catheter size from 3.6 Fr. to 5 Fr. resulted in a 5 mmHg (0.6 Kpa) rise in basal pressure with a simultaneous increase of 35 mmHg (4.6 Kpa) in peak pressure amplitude. It was noted that in the absence of the catheter the lumen appears to vary between a totally collapsed configuration (Fig. 2.6) to an almost spherical shape [24]. In a study, it was
shown that the collapsed empty ureter of the dog has its epithelial surfaces in contact in a stellate configuration [25]. In progressive opening of the tube the surfaces separate first to a square or diamond-shaped lumen and only with full dilation is a spherical interior achieved.

Fig. 2.6. Blocks of tissue represented successively to illustrate luminal change through an Artist’s representation of the full range of luminal change [25].

2.4 Conclusion

One of the major functions of the Urinary system is the process of eliminating waste products of metabolism and other materials that are of no use, from an organism. The upper and lower urinary tracts and their functions were discussed.

The Peristaltic motion that consists of successive sequence of contractions along a muscular tube and is the driving force behind many critical functions in the human body was presented in this chapter. The next chapter will deal with the medical problems associated with the urinary system, with a special emphasis on stone formation, and the
state-of-the-art in stone removal. The peristaltic movement will be modeled in the ureter and will be analyzed by the presence of different types of kidney stones.
CHAPTER III
COMPUTATIONAL MODELING OF THE URETER

3.1 Introduction

Peristaltic pumping, the transport of a fluid in a tube due to waves of contraction, is fundamental to many physiological flows. Peristaltic contractions in the ureters are responsible for the passage of urine from the kidneys to the bladder [26]. The peristalsis of urine through the ureter can sometimes be accompanied by entities such as kidney stones. The common treatment for these entities is to let them pass out naturally, if they are small enough, or retract them using kidney baskets if they cannot pass out naturally. By studying the effect of different geometries and sizes of stone, one can have a better understanding on the dynamics of the obstructed ureter. This study could potentially lead to a change in treating the stones based on the effects they have on the ureteral wall. A patient can be sent home for more follow-up, if the formed stone in ureter is not an immediate risk, or be treated immediately.

3.2 Persitaltic Movement in the Ureter

Interest in peristaltic flow has been inspired by its relevance to biological processes, and its potential for industrial and medical applications. From the analytical point of view, fluid transport by peristaltic motion has received some attention in the literature. The main objectives were to characterize the basic fluid mechanics of the process and, in particular, to find the pressure gradients that are generated by the wave, the flow behavior
in the tube or channel due to peristalsis, and the conditions for trapping or reflux. The main parameters for the problem of peristaltic transport are determined by the governing differential equation as well as the boundary conditions. The amplitude, wave number and the Reynolds number are defined as follows:

- The amplitude ratio, $\varphi$, is the relation of the wave amplitude to the tube radius or channel width. It determines the relative degree of geometric occlusion.
- The wave number or wall slope, $\varepsilon$, is the relation of the tube radius or channel width to the wavelength. It is related to the slope and curvature of the wall.
- The Reynolds number, $Re$, is the ratio of the inertial to the viscous forces.

These parameters are considered during the modeling of peristalsis. The results of these investigations led to diverse mathematical models. The main purpose was to describe the physical system by a set of mathematical equations, and after that, solve them to establish relationships between the different variables.

The main requirement of studying the peristaltic flow consists of solving the conservation of mass, momentum and energy equations. In most of the literature, analysis begins by assuming that the fluid is either Newtonian or non-Newtonian. This assumption means that a constitutive equation is employed in modeling the relationship between the stress tensor, pressure and velocity gradients. The equations of conservation of mass and momentum with the constitutive equation for a Newtonian fluid yield the famous Navier-Stokes equations, which are the main mathematical statements to be satisfied by a fluid as it flows. Early analyses of peristaltic motion were simplified by introducing approximations such as periodic, sinusoidal wave trains in infinitely long tubes or channels, small wavenumbers, or low Reynolds numbers [27-34].
Burns and Parkes considered the peristaltic flow of a viscous fluid through axial symmetric pipes and symmetrical channels [35]. Low Reynolds number and long wavelengths assumptions were made. It was noted that an increase in velocity slip parameter decreases the peristaltic and retrograde pumping regions. A small amplitude ratio was assumed and the effect of pressure gradient was investigated. Shapiro et al. [36] investigated the problem of peristaltic flow of a viscous incompressible fluid for plane and axisymmetric geometries. The Reynolds number was considered small to neglect inertial effects, and a long wave approximation was adopted as well. The effect of the amplitude ratio was studied. It was reported that for a given amplitude ratio, the theoretical pressure rise per wavelength, decreases linearly with an increase in the flow.

The problem of peristaltic flow of a viscous incompressible fluid in a two-dimensional geometry was studied by an asymptotic method assuming small wavenumbers, and solutions up to second-order were presented [34]. Relations between the applied pressure gradient and backward flow were presented. A viscous incompressible flow induced by long peristaltic waves of arbitrary shape in an axisymmetric tube was studied [29]. It was shown that the high pressure gradients result in more backflow in the ureter as the result of peristalsis.

Normally, urine flows only down from the kidneys to the bladder; the abnormal condition in which the flow returns from the bladder to the ureter or from the ureters to the kidneys is called vesicoureteral reflux. Trapping of the fluid as the cause of reflux and peristalsis waves were investigated [36, 37]. Agreement between experimental values and theoretical results were reported. Reflux near the wall could manifest itself in adverse pressure gradients. The problem of peristaltic transport of a fluid under zero Reynolds
number and long wavelength approximation was reported in [38]. In this study the reflux at the inlet of the ureter was analyzed and trapping conditions with different wave speeds were reported [38].

By assumptions such as long wavelength and low Reynolds number, the influence of the heat transfer coefficient on the peristaltic flow was investigated [39]. It was noticed that increasing the heat generation parameter increases the size of the trapped bolus. The heat generation parameter increases the peristaltic pumping and temperature. In another study, the peristaltic transport of a specific type of liquid which is electrically conducting was also studied [40]. The ureteral geometry was taken to be a two-dimensional channel having electrically insulated walls. In the analysis, an inertia-free flow and a long wavenumber were assumed. It was reported that an increase of magnetic field and a material parameter increases the resistance in the central part of the channel. [40].

Due to the complexity of urine transport in the ureter, the mathematical simulations of ureteral flow have been restricted to very simple (two-dimensional) geometries, assumptions and boundary conditions. The problem of peristaltic flow in a two-dimensional channel for an incompressible Newtonian fluid was studied [31]. The Navier-Stokes equations were formulated in a stream function-vorticity form. Equations were solved numerically using a finite difference technique and the velocity, pressure and stress fields were traced. Reflux conditions were studied for small and large Reynolds number.

A numerical finite-difference technique to investigate peristaltic flow in a spherical cylindrical tube was employed in a study [40]. Peristaltic flow with different parameter values was investigated. Pumping efficiency was studied, and a greater
efficiency for cylindrical tubes than for two-dimensional plane channels was reported. The results showed that for flow with isolated boluses, the pressure/flow relation was determined by active and passive properties of the tube undergoing peristalsis and not by the outlet load condition. In [32] the peristaltic pumping for an incompressible Newtonian fluid in a spherical tube was studied. A finite volume (FV) method was employed in solving the incompressible Navier-Stokes equations in primitive variable formulation. Parameter values were: Reynolds number between 0.01–100 and wave amplitudes of 0–0.08. Trapping conditions were calculated for different combinations of the parameters. It was noted that by increase in the amplitude of the peristaltic wave, the pressure profiles change significantly and the velocity increases at the compression wall movement.

Experimental studies of peristaltic motion started in 1971 in a planar two-dimensional geometry [42]. A sinusoidal traveling wave was imposed on a flexible membrane to model peristalsis. A series of tests were carried out for three different width-to-height ratios and two different amplitude ratios. Weinberg et al. studied experimentally the problem of peristaltic pumping [43]. Measurements of the mean flow and pressure were made. Visualization of trapping and reflux were investigated by using dyed fluid. Experimental results were compared with analytical approximations and showed a great agreement. Comparison between experimental and theoretical results were reported in a two dimensional ureteral models with different diameters and length [44-46]. The effects of wave amplitude, amplitude ratio, and Reynolds number were reported in some experimental studies [47, 48]. By increase in the amplitude of the imposed wave, the pressure profiles changed along the axis of the ureter. The number of
waves in the experimental tests was shown to have effect on the trapping and the reflux problem in the ureter.

Hung and Brown [49] studied experimentally the motion of a solid particle in two-dimensional peristaltic flow; different particle sizes were investigated. It was reported that changes in the amplitude and form of the wave have significant effects on the particle motion [49]. The peristaltic transport of a macroscopic particle in a two-dimensional channel using the lattice Boltzmann method was studied. The effect of variation of the relevant dimensionless parameters of the system on the particle transport was investigated and the streamlines showed the movement of the particles and the trapping in the ureter due to the peristaltic movement [50]. An immersed boundary framework was presented in [51] to study peristaltic transport of a macroscopic solid particle in a viscoelastic fluid governed by a Navier-Stokes/Oldroyd-B model. Numerical simulations of peristaltic pumping as a function of Weissenberg number were presented. It was noted that the presence of viscoelasticity impedes the forward motion of the particle, and enhances the backward motion. It was shown that complex stress patterns evolve in the peristaltic channel, and the patterns were also influenced by the presence of the particle.

3.3 Modeling the Persitaltic Movement

Mathematical modeling of peristaltic transport deals with a prescribed train of waves moving with constant speed on the boundaries. The ureter could be considered a two-dimensional axisymmetric tube. *In-vivo* morphometric data of ureter and the peristaltic movement were used in the ureteral model [52]. In an adult human, typical ureteral dimensions (radius and length), as suggested for biomechanical modeling by
Boyarski et al. [53], are of the order of $R = 2-8 \text{ mm}$, $L = 120-350 \text{ mm}$. The range of physiological velocity of peristaltic is reported to vary from $c = 2 - 6 \text{ cm/s}$ [54]. In this study the urine is assumed to be laminar, homogenous, Newtonian, viscous and incompressible with constant density of $\rho = 1050 \frac{kg}{m^3}$ and viscosity of $\mu = 1.3 \text{ cP}$ at 298 K.

Fig. 3.1 illustrates the two dimension axisymmetric ureter model (on top) and the sine wave peristaltic movement defined on the wall of the ureter.

![Fig. 3.1](image)

(a)

(b)

Fig. 3.1. (a) Model of the ureter with radius $r$. (b) Peristaltic movement model on ureter wall with wave amplitude of (a), total height (R), speed of wave (c), and the wavelength ($\lambda$).
The ureter length and radius were assumed to be \( r = 4 \text{ mm} \) and \( L = 300 \text{ mm} \) respectively. The peristalsis movement was assumed to be a sinusoidal wave with a physiological velocity of 2 cm/s on the boundary of the model (Fig. 3.1). The displacement at the ureter walls is given by

\[
d(z,t) = \pm a \sin kz \sin \omega t
\]  

(3.1)

Where \( a \) is the amplitude of displacement (1.5 mm), \( k = \pi / L \) is the wave number, and \( \omega \) is the frequency.

Two geometrical ratios are defined. The first is the amplitude ratio, \( \phi = \frac{a}{R} \), which is the amplitude of the wave divided by the total height (plane geometry) or radius (axisymmetric geometry). The range of \( \phi \) is from zero to one, where \( \phi = 0 \) corresponds to a channel or tube with parallel straight walls and \( \phi = 1 \) to a channel whose walls touch the minima. The second ratio \( \delta = \frac{R}{\lambda} \) is the wavenumber, which is the ratio of the total radius or height divided by the wavelength, so it represents the number of repeating units of a propagating wave.

Due to pulsatile flow, two different dimensionless numbers can be considered, the Reynolds number and the Womersley number. The Womersley number is defined as the ratio of the unsteady forces to the viscous forces, whereas the Reynolds number is defined as the ratio of the inertial forces to the viscous forces. The Womersley number \( (W_o) \) describes to what extent unsteady effects matter in pulsatile flows.

\[
W_o = d \left( \frac{\alpha}{\nu} \right)
\]  

(3.2)
where $\omega$ is the frequency of the pulse, $d$ is the diameter of the tube, and $\nu$ is the kinematic viscosity of the fluid. The Reynolds number is defined as:

$$\delta \text{Re} = \frac{\rho c R}{\mu} \left( \frac{R}{\lambda} \right)$$  \hspace{1cm} (3.3)

Where $\rho$ is the density, $\mu$ is the dynamic viscosity, and $\lambda$ is the wavelength of the defined wave. Since $\text{Re}$ is the well-known Reynolds number, the product $\text{Re} = \delta \text{Re}$ will be referred as the modified Reynolds number.

3.4 Formulation of the Fluid

The governing equations used for the fluid domain are the Navier–Stokes and Continuity equations which can be presented in cylindrical coordinates as follows:

$$\frac{1}{r} \frac{\partial (rv_r)}{\partial r} + \frac{\partial (v_z)}{\partial z} = 0$$ \hspace{1cm} (3.4)

r component:

$$\rho \left( \frac{\partial v_r}{\partial t} + v_r \frac{\partial v_r}{\partial r} + v_z \frac{\partial v_r}{\partial z} \right) = -\frac{\partial P}{\partial r} + \rho g_r + \mu \left[ \frac{1}{r} \frac{\partial}{\partial r} \left( r \frac{\partial v_r}{\partial r} \right) - \frac{v_r}{r^2} + \frac{\partial^2 v_r}{\partial z^2} \right]$$ \hspace{1cm} (3.5)

z component:

$$\rho \left( \frac{\partial v_z}{\partial t} + v_r \frac{\partial v_z}{\partial r} + v_z \frac{\partial v_z}{\partial z} \right) = -\frac{\partial P}{\partial z} + \rho g_z + \mu \left[ \frac{1}{r} \frac{\partial}{\partial r} \left( r \frac{\partial v_z}{\partial r} \right) + \frac{\partial^2 v_z}{\partial z^2} \right]$$ \hspace{1cm} (3.6)

where $P$ is the static pressure, and $\rho$ and $\mu$ represent density and dynamic viscosity of the fluid respectively. The boundary conditions for the fluid region in the steady state and the transient cases are shown in Table.3.1.
Table. 3.1. Boundary condition in steady state and the transient simulation.

<table>
<thead>
<tr>
<th>Geometry</th>
<th>Boundary Conditions</th>
</tr>
</thead>
</table>
| Inlet    | at $z=0$, $P=P_{in}=0.3$ Pa [62]  
$\frac{dV_z}{dz}=0$, $V_r=0$ |
| Outlet   | at $z=L=300$ mm, $P=P_{out}=0$ Pa  
$\frac{dV_z}{dz}=\frac{dV_r}{dz}=0$ |
| Symmetry | zero normal gradient and velocity,  
$\frac{dV_z}{dr}=0$, $\frac{dV_r}{dr}=0$, $V_r=0$ |
| Wall     | no slip, no penetration,  
$r=R$ (4mm, top wall), $V_z=0$ in steady state  
$D(z,t) = \pm a \sin kz \sin \omega t$, $V_r = \frac{Dd}{Dt} = \frac{\partial d}{\partial t} + V \cdot \nabla d$ in transient |

The ureter was modeled and the model was solved numerically using the commercial Computational Fluid Dynamics (CFD) solver package ANSYS FLUENT. The ANSYS CFD solvers are based on finite volume method which is a numerical method for solving partial differential equations that calculates the values of the conserved variables averaged across the volume (cells).

The ureter model was meshed and the mesh convergence analysis examining flow parameters with coarse and fine meshes were checked that the numerical results are independent of mesh density. For a reliable convergence of the fluid equations, the iteration tolerance was set to $10^{-6}$ for all variables. After the analysis of the time step size independence test, this value was set to be 0.01s. The simulation was run first for one period of time and continued to run for five period in which the percentage of errors between the periods were less than 0.1%.
The SIMPLE (Semi-Implicit Method for Pressure-Linked Equations) scheme was used in pressure-velocity coupling method. Gradients were set to be discretized using the least square cell based method. Pressures were calculated using a standard scheme while the second order upwind scheme was used for momentum. These settings are believed to be accurate and less costly [58].

3.5 Analysis of the Ureter with No Stone

The two dimension axisymmetric ureter model was created and meshed in the ANSYS software as shown in Fig. 3.2.

![Fig. 3.2. The geometry and initial computational structured mesh for the ureter model.](image)

The fluid domain was initially meshed with 25,000 structural quadrilateral 2-D solid axisymmetric type elements. The fluid and the structure cells were all defined as axisymmetric, so that they supposedly extended circumferentially. The movement of the wall and the boundary conditions were defined and the model was solved numerically using FLUENT. Each bolus of urine was reported to be approximately 60 mm in length [55]. Based on the defined frequency of the sine wave and the bolus length, the peristaltic time would be 6s for each period in our study. The time step size and the number of time steps were assumed to be 0.01s and 3,000 respectively. Fig. 3.3 illustrates four different
times of the ureter wall movement which the fluid parameters will be discussed. At the
times of $T/4$ and $3T/4$ the ureteral wall is compressing and expanding.

Fig. 3.3. Geometry of the ureter wall in different times of wave movement.

3.5.1 Mesh and Step Time Independence Tests

For numerical simulations, three meshes of element number 15,000 (coarse),
25,000 (assumed), and 50,000 (fine) were chosen. Diffusion-based smoothing was
assumed for the dynamic mesh. In this method the mesh motion is governed by the
diffusion equation:

$$\nabla.(\nabla \vec{U}) = 0$$

(3.7)
where $\mathbf{U}$ is the mesh displacement velocity and $\gamma$ is the diffusion coefficient. On deforming boundaries, the boundary conditions are such that the mesh motion is tangent to the boundary (i.e. the normal velocity component vanishes). The Laplace equation (3.6) then describes how the prescribed boundary motion diffuses into the interior of the deforming mesh. The diffusion coefficient $\gamma$ in equation (3.6) can be used to control how the boundary motion affects the interior mesh motion. A constant coefficient means that the boundary motion diffuses uniformly throughout the mesh. This mesh deforming method produces a better quality mesh than other smoothing methods such as spring-based method (the edges between any two mesh nodes are idealized as a network of interconnected springs) [60].

The ureter model with three different mesh element sizes was solved and the results for pressure gradient magnitude along axis (at time $T=6s$) are compared and shown in Fig. 3.4. The errors between the three different mesh sizes were calculated to be less than 0.1%. Fig. 3.5 illustrates the percentage of the errors between the 25K and 50K mesh element models.
Fig. 3.4. Pressure gradient magnitude along symmetry for 15K, 25K, and 50K elements sizes at time T.
Fig. 3.5. The percentage of errors between the 25K and 50K mesh elements.

As the errors between 25K and 50K mesh elements were smaller than the errors between the 15K and 25K mesh elements, a mesh size of 25K mesh elements was chosen and a time step size independence study was conducted until the numerical solution did not show any change in the results. Fig. 3.6 illustrates the pressure gradient magnitude along axis for three time step sizes of 0.01s, 0.05s, and 0.001s. The results were different by less than 1.1% therefore the time step size was defined to be 0.01s. Fig. 3.7 illustrates the errors between the time step size 0.01s and 0.05s. A time step size of 0.01s was chosen for the simulation.
Fig. 3.6. Pressure gradient magnitude on axis for time step sizes of 0.01s, 0.05 s, and 0.001 s at T.
Fig. 3.7. The percentage of errors between the time step size 0.01s and 0.05s.

3.5.2 Analysis of the Pressure Contours and Velocity Vectors

At the beginning, the ureter model was solved in the steady state case (without moving boundaries) with a convergence iteration tolerance of $10^{-6}$ and the pressure contours and the velocity vectors were plotted (Fig. 3.8). Then the model of the peristaltic movement (moving boundaries) was solved numerically and Fig. 3.9 shows the pressure contours in the ureter during the peristaltic at $T/4$, $T/2$, $3T/4$ and $T$. 
Fig. 3.8. Pressure contour (a) and the velocity vectors (b) of the model solved in the steady state case.
Fig. 3.9. Ureteral pressure contours during peristaltic movement at (a) T/4, (b) T/2, (c) 3T/4, (d) T.

A high pressure gradient can be seen following the contractions in the wall which is much higher than the total pressure gradient in the ureter (as shown in Fig. 3.9 (a)) which is in good agreement with Weinberg’s observations. He reported that the maximum ureteral luminal pressure during peristalsis occurs at the time of contraction [43]. Low pressures were seen at times T/2 and T where there is no expansion and
contraction in the wall of the ureter. The high pressure gradients cause recirculation regions in those areas. The pressure gradient also creates a flow in the opposite direction of the peristaltic wave motion that can be verified by fluid velocity vectors.

Fig. 3.10 illustrates the velocity vectors at the beginning of the peristaltic motion. Backflow can be seen at the inlet of the ureter which is consistent with the previous studies on the peristaltic movement and it is consistent with the results reported in literature [61, 62]. The urine velocity vector plot shows that there are consistent stagnation points from which urine retrogrades to its proximal part. The results indicated that the urine velocity is maximum after the contraction (neighboring the centerline) which leads to a high velocity jet flow there. Fig. 3.11 shows the velocity vectors of different times (T/4, T/2, 3T/4, T) in the peristaltic movement.
Fig. 3.10. Urine velocity vector plot showing ureteral back flow development following the contraction wave at the beginning of peristalsis.

Fig. 3.11. Urine velocity vector plots at (a) T/4, (b) T/2, (c) 3T/4, (d) T.

Figures 3.12 through 3.15 illustrate the velocity vectors in different part of the ureter during peristaltic in more detail. As can be seen from these figures there are recirculation regions formed against the jet flow in different parts of the ureter especially near the bolus peak (Fig. 3.12 (b), (c)). Higher velocities in velocity vector plots
correspond to lower pressures in the pressure contour plots (Fig. 3.9 (b) and Fig. 3.13). Fig. 3.13 and Fig. 3.15 illustrate vortex cells in the ureter. A backflow at the inlet at time T was as the result of wall movement from expansion to its initial position. Recirculation can be seen at the proximal part of ureter at time 3T/4 as the result of wall expansion. In these figures some parts of the ureter are zoomed in and the velocity vectors are plotted.

Fig. 3.12. Urine velocity vectors at T/4. Four different regions of a, b, c and d were defined on the ureter and were zoomed in.
Fig. 3.13. Urine velocity vectors at T/2. Four different regions of a, b, c and d were defined on the ureter and were zoomed in.
Fig. 3.14. Urine velocity vectors at 3T/4. Four different regions of a, b, c and d were defined on the ureter and were zoomed in.
Fig. 3.15. Urine velocity vectors at T. Four different regions of a, b, c and d were defined on the ureter and were zoomed in.

In the above figures, the length of the vectors shows the relative urine velocity magnitude. Backflow and recirculation can be seen in different parts of the ureter at different times. The physical reason for this event is the effect of the inertia of the wall on the flow of urine. An important characteristic of peristaltic motion is that regions exist
where the streamlines are closed and the fluid recirculates, a phenomenon known as trapping which is a characteristic of pumping motion [62]. The streamlines at times $T/4$ and $3T/4$ are shown in Fig. 3.16 which are in good agreement with the reports on the trapping effect in peristaltic movement [62].

Fig. 3.16. Ureteral streamlines during peristaltic wave propagation (a) $T/4$ (b) $3T/4$.

3.5.3 Pressure Gradient Magnitudes along the Ureter Axis

As the flow is steady in the moving frame, one can characterize the pumping performance by means of the pressure rise over a characteristic axial length ($dp/dx$). The pressure gradient magnitudes along the ureter axis were calculated for different times of $T/4$, $T/2$, $3T/4$, and $T$ and averaged over five periods.

The results as shown in Fig. 3.17 (a, b, c, d), showed that the pressure gradient magnitude along the ureteral longitudinal direction on its symmetry line was the maximum around the contraction, and these peaks decreased as a result of the wave
dissemination in the longitudinal direction to the bladder. Higher pressures and much lower pressures along axis were the cause of these peaks in the plots (Fig. 3.17 a, c). The pressure gradient magnitude along axis at times T/2 and T did not have significant changes as there was no contraction or expansion on the wall.

There are some regions in the pressure gradient magnitude plots (Fig. 3.17 (a and c)) at time T/4 (around 0.1 m and 0.2 m) and 3T/4 (around 0.05 m and 0.15 m) in which there is transition in the direction of the urine flow. This transition causes the pressure gradient to decrease and by reaching to the contraction part of the wall, this value increases again.
Fig. 3.17. Pressure gradient magnitude along the ureter axis at (a) T/4, (b) T/2, (c) 3T/4, and (d) T.
3.5.4. Analysis of the Shear Stresses on the Wall

The Shear stresses on the wall were calculated for different times of T/4, T/2, 3T/4, and T. The Shear stress is proportional to the velocity gradient:

$$\tau = \mu \left( \frac{\partial V_r}{\partial z} + \frac{\partial V_z}{\partial r} \right)$$

(3.8)

where $V_r$ is the velocity in the r direction and $V_z$ is the velocity in the z direction.

Fig. 3.18 illustrates the wall shear stress at different times of peristalsis. As the velocity increases (as the result of contraction at time T/4) the wall shear stress increases as can be seen in Fig. 3.18 (a). Higher values of shear stress on the wall were detected at the recirculation vortex cells (Fig. 3.18 b, d).
Fig. 3.18. Wall shear stress during peristaltic movement at (a) T/4, (b) T/2, (c) 3T/4, (d) T.
3.5.5 Analysis of the Axial Velocity Profiles

The bolus length in the peristaltic motion was assumed to be 60 mm. Here 12 profiles were defined (5mm, 10mm, 15mm, 20mm, 25mm, 30mm, 35mm, 40mm, 45mm, 50mm, 55mm and 60mm). The axial velocities were plotted along the radius as shown in Fig. 3.19.

Backflow of the urine could be seen in the axial velocity profiles at different times of peristaltic (Fig. 3.19). Velocity values were higher after the contraction. The velocity changes from zero at the wall (because of the no slip condition) to a maximum at the ureter center. Local recirculation and wall movement causes the velocity profiles to be different from what they would be in a fully developed condition. Higher velocities at T/2 and T can be seen in the figures. Negative velocity (backflow) was detected at the inlet of the ureter at time T.
Fig. 3.19. Axial velocity profiles versus the distance from the ureteral axis on the twelve defined profiles at (a) T/4, (b) T/2, (c) 3T/4, and (d) T (from top to bottom).
3.5.6. Analysis of the Pressure Profiles

The pressures along the defined profiles were plotted as shown in Fig. 3.20 (a, b, c, d). Fig. 3.20.a shows increase in the pressure from the beginning of the bolus till the end. Low pressures were detected at times T/2 and T as the cause of high velocities in the ureter flow (Fig. 3.20.b,d). As the wall of the ureter expands, the pressure increases till the end of the bolus (Fig. 3.20.c).
Fig. 3.20. Ureteral pressure profiles versus the distance from the ureteral axis at the twelve defined profiles at (a) T/4, (b) T/2, (c) 3T/4, (d) T.
3.6 Analysis of Different Sizes of a Stone type in the Ureter

Kidney stones (calculi) are jagged mineral deposits that form in the kidney and drop into the collecting system. Stones often get stuck and block the flow of urine and cause severe pain and blood in the urine. The kidney stones form in different sizes and shapes in the urinary system (Fig. 3.21).

Fig. 3.21. Different sizes of kidney stones (calculi) [80].

In this section, the peristaltic movement will be analyzed with different sizes of cylindrical shape stones in the proximal part of the ureter. Rectangular stones were chosen as the common shape of stones would have corners and have a shape near rectangle [83]. The rectangular stone which is a cylinder shape stone in two dimension axisymmetric geometry was modeled for the two different sizes and solved numerically using the ANSYS FLUENT software as shown in Fig. 3.22.
Fig. 3.22. Geometry of two different sizes of cylinder stone. Stone of size 1x1mm (top) and stone size 2x2 mm (bottom).

The stones were assumed to be cylindrical and their distance from the inlet was set to be 30 mm. Two different sizes, 1x1 mm and 2x2 mm stones, were placed in the ureter and the model was solved numerically. These sizes of stones represent a 25% and 50% blockage in the ureteral wall. The results of the different blockages were compared to the ureter without stone and the effect of the size of the stone on the dynamics of the ureter was analyzed.

3.6.1 Analysis of the Pressure Contours and Velocity Vectors

The ureter model was solved initially for 1200 iterations in steady state and without any movement on its walls. The pressure contours and the velocity vectors are shown in Fig. 3.23 and Fig. 3.24. Higher pressures and lower velocities were seen for the bigger stone (50% blockage) in comparison to other two cases. The velocity profiles proximal and on the stone were plotted in Fig. 3.24 (b).
Fig. 3.23. Pressure contours of the steady state solved ureter model. From top to bottom are the no stone ureter, 25% blockage and 50% blockage.
Fig. 3.24. Velocity vectors of the steady state solved ureter model. (a) From top to bottom are the no stone ureter, 25% blockage and 50% blockage.

The average velocities were reported to be higher on top and bottom of the stone compare to the average velocities downstream and upstream the ureter (Fig. 3.24). The velocity profiles on top and bottom of the stone, proximal, and distal to the stone were reported to be parabolic (fully developed laminar flow). The pressure contours were plotted for the three cases of the ureter with no stone, the ureter with stone of size 1x1 (25% blockage) mm and the ureter with stone of size 2x2 (50% blockage) mm at different times of peristaltic movement. Fig. 3.25 illustrates the pressure contours at time T/4 of the peristaltic movement in the three different cases. As can be seen from the figure, the 50% blockage case caused a higher pressure in the ureter. The velocity vectors at time T/4 were shown in Fig. 3.26. Higher velocities were detected in ureter with no stone and the 25% blockage case. Recirculation can be seen distal (right side) to the
bigger stone. The 50% blockage case is causing back flow at the inlet as the cause of wall movement. Higher pressures correspond to lower velocities as shown in Fig. 3.25 and Fig. 3.26.

![Pressure contours at T/4](image)

Fig. 3.25. Pressure contours at T/4 (a) ureter with no stone, (b) ureter with stone 1x1mm, (c) ureter with stone 2x2 mm.
Fig. 3.26. Velocity vectors during peristaltic movement at T/4 (a) ureter with no stone, (b) ureter with stone 1x1mm and (c) ureter with stone 2x2 mm.
The pressure contours were plotted and compared at T/2 in Fig. 3.27. At this time of peristalsis, there is no contraction or expansion on the ureter wall, therefore the blockage is not high enough to cause drastic pressure differences in the ureter. The velocity vectors were plotted at time T/2 and as shown, the velocity of the urine, distal to the stone of size 1x1 mm is higher than the stone 2x2 mm (Fig. 3.28).

Fig. 3.27. Pressure contours at T/2 (a) ureter with no stone, (b) ureter with stone 1x1 mm, (c) ureter with stone 2x2 mm.
Fig. 3.28. Velocity vectors during peristaltic movement at T/2 (a) ureter with no stone, (b) ureter with stone 1x1mm and (c) ureter with stone 2x2 mm.
Fig. 3.29 illustrates the pressure contours at time $3T/4$ of the peristaltic movement. Higher pressures were detected after the contraction in the mid ureter in all cases. The velocity vectors were also plotted in Fig. 3.30 for the three different cases. Higher velocities were detected in the mid ureter for the 50% blockage case. Recirculation can be seen in the proximal ureter.

![Fig. 3.29. Pressure contours at 3T/4 (a) ureter with no stone, (b) ureter with stone 1x1mm, (c) ureter with stone 2x2 mm.](image)

Fig. 3.29. Pressure contours at 3T/4 (a) ureter with no stone, (b) ureter with stone 1x1mm, (c) ureter with stone 2x2 mm.
Fig. 3.30. Velocity vectors during peristaltic movement at 3T/4 (a) ureter with no stone, (b) ureter with stone 1x1mm and (c) ureter with stone 2x2 mm.
The pressure contours were plotted at time T as shown in Fig. 3.31. Higher pressures were detected at the inlet of the 50% blockage case. The velocity vectors of the three cases were plotted in Fig. 3.32. The 25% blockage showed higher velocities upstream the stone. Backflow was detected at the inlet of the ureter.

Fig. 3.31. Pressure contours at T (a) ureter with no stone, (b) ureter with stone 1x1mm, (c) ureter with stone 2x2 mm.
Fig. 3.32. Velocity vectors during peristaltic movement at T (a) ureter with no stone, (b) ureter with stone 1x1mm and (c) ureter with stone 2x2 mm.
3.6.2 Pressure Gradient Magnitudes along the Ureter Axis

The pressure gradient magnitude along axis was plotted and analyzed for the ureter in different situations. To analyze the effect of the blockage percentages at the beginning of the peristaltic movement, three different cases were solved. Here, a stone of size 2.4x2.4 mm which represents a blockage of 60% was added to the simulation. Fig. 3.33 shows the pressure gradient magnitudes at the beginning (t = 1s) of the peristaltic movement. Higher pressure gradients were found for the 25% blockage case proximal to the ureter. At the distal part of the ureter, the 60% blockage case has a huge pressure drop and this amount decreases in 50% and 25% blockage cases. A high peak of pressure gradient can be seen following the pressure drop that the value is highest in the 60% blockage case (Fig. 3.33 (b)).
Fig. 3.33. Pressure gradient magnitude at the beginning (t=1s) of the peristalsis. The ureter with no stone is plotted in dark blue, 25% blockage case in red, 50% blockage case in purple and the 60% blockage case in light blue. (a) pressure gradient along the axis (b) pressure gradient from 20 – 40 mm which the stones are placed.
The pressure gradient magnitudes at T/4, T/2, 3T/4 and T were plotted along axis for the no stone ureter, the 50% and 25% blockages (Fig. 3.34). At time T/4 there is a huge pressure drop distal to stone. As the fluid is almost blocked by the bigger stone the pressure gradient proximal to the 50% blockage case does not have a peak as can be seen in the 25% blockage case (Fig. 3.34.a). Higher pressure gradients were detected at time T/2 for the 50% blockage case proximal to the ureter and this value was lower than 25% blockage case in the distal part of the stone (Fig. 3.34.b). At the wall expansion time in the peristalsis, higher pressure gradients were seen proximal and distal the stone in the 25% blockage case. The pressure gradients were slightly higher in 50% blockage at time T in the peristaltic movement.
Fig. 3.34. Pressure gradient magnitudes (Pa/m) along ureter axis (blue curve: ureter with no stone, red curve: 25% blockage, green curve: 50% blockage) at (a) T/4, (b) T/2, (c) 3T/4, (d) T.
3.6.3 Analysis of the Shear Stresses on the Wall

To analyze the effect of the different sizes of the stone on the wall, shear stresses of four different cases of 1) the ureter with no stone, 2) the ureter with 25% blockage, 3) the ureter with 50% blockage and 4) the ureter with 60% blockage were plotted along the ureteral wall. Fig. 3.35 illustrates the wall shear stress at the beginning of the peristaltic movement. Table 3.1 shows the values of these peaks in the wall shear stress. As it can be seen from the table the shear stresses on the wall significantly increase when the blockage is 50% or higher.

![Wall shear stress for the three different status of ureter at the beginning of peristaltic.](image)

Fig. 3.35. Wall shear stress for the three different status of ureter at the beginning of peristaltic. (dark blue: the ureter with no stone, red: 25% blockage, purple: 50% blockage and green 65% blockage).
Table. 3.2. Wall shear stress peak values at the beginning of the peristalsis for different stone sizes.

<table>
<thead>
<tr>
<th>No stone ureter case</th>
<th>25% Blockage</th>
<th>50% Blockage</th>
<th>60% Blockage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wall shear stress [Pa]</td>
<td>0.0310</td>
<td>0.0646</td>
<td>0.3110</td>
</tr>
<tr>
<td>x1</td>
<td>x2.09</td>
<td>x10.06</td>
<td>x20.97</td>
</tr>
</tbody>
</table>

The wall shear stresses were plotted for the no stone ureter, 25% and 50% blockage cases at times T/4, T/2, 3T/4 and T as shown in Fig. 3.36. The shear stress on the wall in the 50% blockage is higher than 25% and no stone case at time T/4. The recirculation makes this high wall shear stress. This difference decreases at T/2, however the 50% blockage has still higher values in comparison to the 25% blockage. At times 3T/4 and T the effect of the stones are negligible on the wall shear stress as shown in Fig. 3.36.c and d.
Fig. 3.36. Wall shear stress (Pa) for the three cases (blue curve: ureter with no stone, red curve: 25% blockage, green curve: 50% blockage) at (a) T/4, (b) T/2, (c) 3T/4 and (d) T.
3.6.4 Analysis of the Axial Velocity Profiles

In the next step the axial velocities were plotted to analyze the backflow at different times in the different cases. Fig. 3.37 illustrates the axial velocities for ureter with and without obstruction. Lower velocities were found at T/4 in the 50% blockage case. Negative velocity values at the inlet of the ureter in 50% blockage case corresponded to the backflow as the result of the wall compression (Fig. 3.37.a). The velocity profiles near the wall of the ureter have a negative peak as the result of recirculation in those regions. Higher velocities were detected at time T/2 and T which the wall has no deformation (Fig. 3.37.b and d).
Fig. 3.37. Ureteral axial velocity profiles during peristaltic for the three different cases (blue curve: ureter with no stone, red curve: 25% blockage, green curve: 50% blockage) at (a) T/4, (b) T/2, (c) 3T/4 and (d) T.
3.6.5 Analysis of the Pressure Profiles

Fig. 3.38 show the pressure profiles at different times and for the different cases during peristaltic movement. Fig. 3.38.a shows much lower pressures in the 50% blockage case proximal to the stone and much higher pressures distal to the stone. The pressures of the 25% blockage did not show much difference to the no stone ureter case. In Fig. 3.38.b higher values of pressure were recorded for the 50% blockage in the proximal and distal parts of the stone. At the time of wall expansion, the 50% pressure values were slightly higher than other cases (Fig. 3.38.c). The pressure values in the distal part of the stone were recorded to be lower in the 50% blockage case at time T as shown in Fig. 3.38.d.
Fig. 3.38. Ureteral pressure profiles during peristaltic wave propagation at (a) T/4, (b) T/2, (c) 3T/4, (d) T. (blue curve: ureter with no stone, red curve: 25% blockage, green curve: 50% blockage).
3.7 Analysis of Different Types of Stone in the Ureter

The kidney stones are formed in different shapes (types) as well as different sizes (Fig. 3.39). Each shape might have different effect on the dynamics of the ureter. These effects will be discussed in this section.

Fig. 3.39. Different types of kidney stones [111].

The two dimensional axisymmetric ureteral model was created and meshed in the ANSYS FLUENT software as shown in Fig. 3.40. Three most common shapes of cylindrical, spherical and conical stones with same characterization length ($\frac{A(\text{area})}{P(\text{Perimeter})} = 0.7\text{mm}$) were placed in the proximal part of the ureter inlet (Fig. 3.40).
3.7.1 Analysis of the Pressure Contours and Velocity Vectors

The ureter model was first solved with a convergence iteration tolerance of $10^{-6}$ in the steady state with no boundary movement. The pressure contours and the velocity vectors were plotted in Fig. 3.41 and Fig. 3.42. As can be seen the conical stone has the highest pressures around the stone and the spherical stone has the lowest between the stone types. The spherical stone showed the highest velocities, after the no stone ureter case, between the stone types and the lowest velocities were reported for the conical stone as the result of the corners and shapes of the stones.
Fig. 3.41. Pressure contours of different shapes of stones in the ureter and the ureter with no stone in the steady state simulation.
Fig. 3.42. Velocity vectors of different shapes of stones in the ureter and the ureter with no stone in the steady state simulation.

The pressure contours were plotted for the three cases of the ureter with cylinder, circle and triangle stones at different times of peristaltic movement. Fig. 3.43 illustrates the pressures at time $T/4$ of the peristaltic in the three different cases. As can be seen from Fig. 3.43, the conical stone caused the highest pressure in the following bolus and the circle had lowest pressures between stone shapes. Fig. 3.44 shows the velocity vectors.
of the blockages at T/4. The velocity was seen to be the highest distal to the circle stone. As the conical stone is almost completely blocking the fluid, the velocity is the lowest distal to the stone in this case. It can be seen that the fluid has a reverse direction in the conical and cylindrical stones as they are blocking the flow stream. The spherical stone showed the highest velocities distal to the stone.

Fig. 3.43. Pressure contours at T/4 (a) the ureter with cylindrical stone, (b) the ureter with spherical stone, (c) the ureter with conical stone.
Fig. 3.44. Velocity vectors during peristaltic movement at T/4 (a) the ureter with cylindrical stone, (b) the ureter with spherical stone, (c) the ureter with conical stone.
The pressure contours were plotted and compared at T/2 in Fig. 3.45. Lowest and highest pressures were found to be in the ureter with conical and spherical stones, respectively. The velocity vectors were plotted at time T/2 and as shown in Fig. 3.46. The velocity vectors were detected to be highest in the proximal and lowest in the distal part of the conical stone.

Fig. 3.45. Pressure contours at T/2 (a) the ureter with cylindrical stone, (b) the ureter with spherical stone, (c) the ureter with conical stone.
Fig. 3.46. Velocity vectors during peristaltic movement at T/2 (a) the ureter with cylindrical stone, (b) the ureter with spherical stone, (c) the ureter with conical stone.
Fig. 3.47 illustrates the pressure contours at time $3T/4$ of the peristaltic movement for the three different types of the stones. The pressures were seen to be high following the contraction of the ureter wall and the highest pressures were recorded for the spherical stone. The velocity vectors were also plotted in Fig. 3.48 and showed higher values in the conical stone case.

Fig. 3.47. Pressure contours at $3T/4$ (a) the ureter with cylindrical stone, (b) the ureter with spherical stone, (c) the ureter with conical stone.
Fig. 3.48. Velocity vectors during peristaltic movement at 3T/4 (a) the ureter with cylindrical stone, (b) the ureter with spherical stone, (c) the ureter with conical stone.
Finally the pressure contours at time T were plotted and higher values were detected in the spherical stone case (Fig. 3.49). Backflow can be seen in all cases in the velocity vector plots (Fig. 3.50) and the highest velocities were seen in the conical stone case (slightly different from other cases).

Fig. 3.49. Pressure contours at T (a) the ureter with cylindrical stone, (b) the ureter with spherical stone, (c) the ureter with conical stone.
Fig. 3.50. Velocity vectors during peristaltic movement at T (a) the ureter with cylindrical stone, (b) the ureter with spherical stone, (c) the ureter with conical stone.
3.7.2 Analysis of the Pressure Gradient Magnitudes

To analyze the effect of different types of stones on the ureter, the pressure gradient magnitudes along the axis were plotted for the different cases at the beginning of the wall compression in the peristalsis (Fig. 3.51). As can be seen from the figure, pressure magnitude proximal to the ureter is the highest for the spherical stone (not blocking the flow) and the curve is different from the cylindrical and conical stone because of the shape of the stone. High pressure drop and pressure peak were seen distal to the cylindrical and conical stone (Fig. 3.51.b).
Fig. 3.51. Pressure gradient magnitude at the beginning of the peristalsis. Pressures of ureter with no stone are plotted in blue, cylindrical stone in red, spherical stone in green and conical stone in pink. (a) pressure gradients along the axis (b) pressure gradients from 20 – 40 mm which the stones are placed.
The pressure gradient magnitudes were plotted along axis at T/4, T/2, 3T/4 and T (Fig.3.52). Fig. 3.52.a illustrates the pressure gradients at time T/4 in the wall compression. The pressures proximal to the cylindrical stone showed a huge pressure drop distal to this stone type with the conical stone having the lowest pressure gradients. The spherical stone reported the highest pressure gradient around the stone as the result of the wall compression. At time T/2 when the wall is not under deformation, the cylindrical stones reported the highest pressure gradient values proximal to the stones and the spherical stone showed the highest pressure drops distal to the stones. When the wall is expanding high pressure gradient drop in the conical stone (in the distal part of the stone) were followed by high pressure gradient peak for the spherical stone case (Fig. 3.52.c). The pressure gradients were slightly different at time T of peristaltic movement with a higher value reported for the spherical stone case (Fig. 3.52.d).
Fig. 3.52. Pressure gradient magnitudes along ureter axis (the ureter with no stone is plotted in dark blue, cylindrical stone in red, spherical stone in green and the conical stone in pink) (a) T/4, (b) T/2, (c) 3T/4, (d) T.
3.7.3 Analysis of the Shear Stress on the Wall

The wall shear stress was plotted at the beginning of the peristaltic movement for the different shapes of the stones (Fig. 3.53). As can be seen from the plot, the conical stone has the highest shear stress on the wall and then cylindrical stone. the spherical stones has the lowest shear stresses on the wall. Table 3.2 shows the peak values of these shear stresses on the wall.

Fig. 3.53. Wall shear stress at the beginning of the peristaltic movement for the different shapes of stones. (the ureter with no stone is plotted in dark blue, cylindrical stone in red, spherical stone in green and the conical stone in pink).
Table. 3.3. Wall shear stress peak values at the beginning of the peristalsis for different types of stone.

<table>
<thead>
<tr>
<th></th>
<th>No stone ureter case</th>
<th>Cylindrical stone</th>
<th>Spherical stone</th>
<th>Conical stone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wall shear stress [Pa]</td>
<td>0.0310</td>
<td>0.3121</td>
<td>0.0818</td>
<td>0.9230</td>
</tr>
<tr>
<td></td>
<td>x1</td>
<td>x10.09</td>
<td>x2.64</td>
<td>x29.87</td>
</tr>
</tbody>
</table>

The wall shear stress was plotted at times T/4, T/2, 3T/4 and T as shown in Fig. 3.54. The shear stress on the wall for the conical stone is the highest at time T/4. The cylindrical stone had almost half the stresses on the wall as the conical stone. The spherical stone did not have much effect the shear stresses on the wall (Fig. 3.54.a). This difference decreases at T/2 and at 3T/4 and T and it can be seen that the different types of stone have almost the same effect on the wall shear stress (Fig. 3.54.d).
Fig. 3.54. Wall shear stress for the different cases (the ureter with no stone is plotted in dark blue, cylindrical stone in red, spherical stone in green and the conical stone in pink) at (a) T/4, (b) T/2, (c) 3T/4 and (d) T.
3.7.4 Analysis of the Axial Velocity profiles

In the next step the axial velocities were plotted to analyze the backflow at different times in the different cases. Fig. 3.55 illustrates the axial velocities for ureter with and without obstruction. Highest velocities were detected at time T/4 for the spherical stone and the lowest were shown in the conical stone. The negative velocity values at the inlet of the conical and cylindrical stones describe the backflow velocities in these cases. Higher velocities were reported at T/2 and T in all cases.
Fig. 3.55. Ureteral axial velocity profiles during peristaltic for the four different cases (the ureter with no stone is plotted in dark blue, cylindrical stone in red, spherical stone in green and the conical stone in pink) at (a) T/4, (b) T/2, (c) 3T/4 and (d) T.
3.7.5 Analysis of the Pressure Profiles

Fig. 3.56 (a, b, c, d) show the pressure profiles for different times and the different cases during peristaltic movement. At the compression of the wall lowest values were detected for first the conical and then for the cylindrical stones in the proximal part of the stone, as the result of almost complete blockage of the flow. These values increased significantly distal to the stones place. At times of T/2 and T with no deformation on the wall, the spherical stones had the highest pressures and the cylindrical had the lowest values between stone shapes. It can be seen from Fig. 3.54.c that the pressures were almost the same proximal to the stone and higher for the conical stone in the distal part.
Fig. 3.56. Ureteral pressure profiles during peristaltic wave (the ureter with no stone is plotted in dark blue, cylindrical stone in red, spherical stone in green and the conical stone in pink) at (a) T/4, (b) T/2, (c) 3T/4, (d) T.
3.8 Conclusion

The peristaltic movement in the ureter transports fluid from the kidneys to the bladder. One of the most common diseases in the urinary system is the kidney stone formations in the ureters or kidneys. After detecting the stone, the urologist retracts the stones from the urinary system by ureteroscopy procedure. However, there might be no need for that stone to be retracted and the patient can be sent home for more follow up. The effect of different sizes and shapes of the stones on the ureter dynamics were studied in this chapter. The peristaltic movement in the ureter without stones was studied and the results were in good agreement with previous studies. Different sizes of stones showed a significant increase in the wall shear stress values. An increase in the blockage to 60% increased the stresses on the wall by almost 20 times. Different shapes of the stones were placed in the ureter and were studied.
CHAPTER IV
PERFORATION AND AVULSION FORCE MEASUREMENTS

4.1 Introduction

Kidney stones are a common disease in urinary system. Ureteroscopy is an effective treatment for this disease in which the surgeon retracts the stone by using a basket like device. This procedure might lead to serious complications such as perforation and avulsion. These complications are usually a result of excessive force to the retraction device. Providing safe and dangerous feedback of the forces for the residents/surgeons may help reduce these complications. In this study the avulsion and perforation forces were measured and a training device was built and tested.

4.2 Urinary Tract Diseases and Disorders

The purpose of the urinary system is to remove wastes from the body, regulate blood volume, blood pressure and pH, and control levels of electrolytes and metabolites. The kidneys produce urine by filtering wastes and extra water from blood. The kidneys pass urine through the ureter and fill the bladder. When the bladder is full, urine is passed through the urethra to eliminate the waste. The urinary system is vulnerable to a variety of infections and other problems such as blockages and injuries. Estimates indicate that diseases of the kidney and urinary tract account for approximately 830,000 deaths and 18,467,000 disability-adjusted life years annually. This ranks kidney diseases 12th among causes of death (1.4 percent of all deaths) and 17th among causes of disability [63].
Generally, urinary diseases progress to an end-stage renal disease (ESRD) and treatments include renal replacement therapy (RRT), hemodialysis, peritoneal dialysis, or transplantation [64]. Kidney diseases leading to ESRD has many causes, the prevalence varies by region, ethnicity, gender, and age.

4.2.1 Genetic Diseases

Advances in molecular biology and gene sequencing technology have increased the awareness of inherited kidney diseases. The characterization of inherited kidney diseases has improved, and novel mutations leading to selective renal defects have been recently described [64]. Some of the inherited diseases can lead to ESRD, however both inherited diseases and mutations account for only a small percentage of all people with ESRD.

4.2.2 Infections, Stones, and Obstructive Uropathy

Infections of the urinary tract are common worldwide and can be categorized as either uncomplicated or complicated. Uncomplicated infections include bladder infections, such as cystitis, which are seen almost exclusively in young women [65]. Among sexually active women, the occurrence of cystitis is 0.5 episodes per person annually, and recurrence develops in 27 to 44 percent of cases. Males are less vulnerable to uncomplicated infections of the bladder or the kidney. Complications in men are reported with an incidence of five to eight episodes per 10,000 men annually [65]. Even though uncomplicated urinary tract infections are considered benign, they have significant medical and financial implications which are estimated to be approximately US $1.6 billion per year [66]. As for acute urinary tract infections, hospitalization results in almost 1 million of such infections per year in the United States in which bladder catheterization is the most prominent cause [66].
Kidney stones are more common in industrial countries affecting 1 person in every 11 in the United States alone and the rate is increasing each year [67]. Factors such as age, gender, location and ethnic groups are major indicators of prevalence [68, 69].

4.2.3 Benign Prostatic Hypertrophy

Benign prostatic hypertrophy is a common cause of lower urinary tract symptoms and can lead to obstructive renal failure and ESRD. By the age of 80, 80% of men have benign prostatic hypertrophy. The actual incidence of benign prostatic hypertrophy is difficult to assess due to the lack of epidemiological data [74].

4.2.4 Acute Renal Failure

Acute renal failure refers to a sudden, and usually temporary, loss of kidney function that may be so severe that renal replacement therapy (RRT) is required. Even though acute renal failure can be a reversible condition, it carries a high mortality rate [69].

Acute renal failure is usually attributed to severe dehydration and rapid release of muscle cell contents, including potassium [70]. At this stage, kidney function shuts down unless body fluid and blood pressure are restored and frequent hemodialysis is available [71, 72].

4.2.5 Diabetes

Diabetes is one of the most common reasons leading to diseases of the urinary system. It is suggested that inherited factors play a major role in people's susceptibility to diabetic renal complications [73]. A family history of hypertension is also shown to be associated with an increased risk of diabetic nephropathy. When specific markers of risk are detected, high-risk individuals can be identified early and preventive measures can be
taken to reduce the risk of obtaining proteinuria and kidney dysfunction. The appearance of small amounts of protein in the urine is one of the earliest sign of diabetic nephropathy.

4.3 Kidney Stone Disease (Urolithiasis)

Kidney stones (calculi) are accumulated mineral deposits that form in the kidney and drop into the collecting system [75]. Stones often get stuck and block the flow of urine. This results in severe pain and blood in the urine (Fig. 4.1).

Fig. 4.1. A formed stone in the ureter [86].

Kidney stones are composed of inorganic and organic crystals combined with proteins. There are several varieties of kidney stones (see Fig. 4.2). Calcareous stones are the most common kidney stones, accounting for more than 80% of the stones. Other
common types of stones include uric acid, cystine, struvite and ammonium acid stones [76].

Kidney stones affect up to 5% of the population, with a lifetime risk of passing a kidney stone of about 8-10% [77]. Increased rate of the occurrence of kidney stones in the industrialized world is usually associated with race or ethnicity and the region of residence [78]. A seasonal variation is also seen, with high urinary calcium oxalate saturation in men during summer and in women during early winter [79]. The peak age in men is 30 years, women have a bimodal age distribution, with peaks at 35 and 55 years. Once a kidney stone forms, the probability that a second stone will form within five to seven years is approximately 50%. Despite recent advances in the surgical techniques and equipment available for the management of urinary stone, the occurrence of this condition continues to increase in the North American population. Associated costs are estimated to exceed 5.3 billion US dollars each year [77].
4.4 Treatment Strategies in the Urolithiasis

The diagnosis of a kidney stone can be made by observing the symptoms alone. The urologist will likely confirm the presence of stone by checking blood for kidney function (creatinine), check the urine for blood, and order at CT scan or X-ray to see how big and where the stone is. Once the diagnosis is made, a decision on whether to treat the stone or let it pass will be made based on the stone size, location and the level of pain.

4.4.1 Medical Treatments

Medical or a conservative treatment may be decided depending on nature of the blocking, i.e. if the stone is not blocking the kidney, and pain is minimal. The most important medicines are water and time. This treatment strategy with ultrasound follow-up is an appealing and effective approach for ureteral stones with a diameter of $\leq 7$ mm. Ureteral stones of less than 4 mm in diameter have a chance of over 70% to pass naturally [82].

4.4.2 Surgical Treatments

Most stones with a diameter more than 8 mm will ultimately require intervention [83]. Some of the common surgical treatments are presented in this study.

4.4.2.1 Extracorporeal Shock Wave Lithotripsy (ESWL)

ESWL has been established as a major therapeutic and minimally invasive choice for the treatment of renal stones the last twenty years [85]. The stone is visualized on X-ray and shocked up to 3000 times over about a 30-minute session (Fig. 4.3). This approach is ideal for calcium stones up to 2 cm. With increased expertise it has been shown that ESWL is safe and effective [86]. The fact that ESWL is a minimal invasive procedure that may be applied without local, regional, or general anesthesia has made it an attractive
treatment of ureteral stones. However, stone free rates after a single treatment session still remains higher with ureteroscopy [87].

![Extracorporeal Shock Wave Lithotripsy (ESWL)](image)

**Fig. 4.3. Extracorporeal Shock Wave Lithotripsy (ESWL) [84].**

4.4.2.2 Ureteroscopy

Ureteroscopy involves retrograde visualization of the urinary system using a rigid, semi-rigid, or flexible ureteroscope (Fig. 4.4). The ureteroscope has a working channel that allows the introduction of a variety of instruments for stone fragmentation and removal [88]. For smaller distal stones the grasper or the forceps is better since it allows better control in manipulation within the ureter. The ureteroscopic removal of the stone with a basket is a quick approach with minimal morbidity [89]. This approach is more suitable for small distal ureteral stones and many variable type of baskets (such as nitinol tipples basket) have been developed to enable the urologist to remove the stone [28].
Fig. 4.4. Ureteroscopy procedure. A basket will be used to retract the stone [87].

Laser lithotripsy is a reliable method of fragmenting bigger stones into smaller ones and it is carried out through all types of ureteroscopes [91]. Different varieties of lithotripters include ultrasonic lithotripsy, electro hydraulic lithotripsy, ballistic lithotripsy, pneumatic lithotripsy, and laser lithotripsy.

4.4.2.3 Percutaneous Nephrolithotomy (PCNL)

PCNL is an invasive method which involves creating an opening into the renal collecting system through which nephroscopy can be performed. The nephroscope has a working channel through which an intracorporeal lithotripsy device (lithotrite or laser) can be introduced (Fig. 4.5). Stone fragments are removed using suction, graspers, or basket extraction. The technique enables stones to be retrieved and the patient does not have to pass any fragments, as is common with shock wave lithotripsy and ureteroscopy. Although percutaneous nephrolithotomy is thought to be more invasive than other
treatments, it has been demonstrated that it is safe and efficient, particularly when stones are large, multiple, or complex [92].

![Image](image.png)

Fig. 4.5. Percutaneous Nephrolithotomy (PCNL) procedure [93].

4.5 Complications of the Ureteroscopy

Ureteroscopy with stone extraction has gained a noticeable role in the management of urolithiasis (formation of stones in urinary system) [94]. The overall ureteroscopy complication rate is 7%-12% [95]. When feasible, basketing is considered to be the most rapid method of removing a ureteral stone [96]. Much of the efficacy is conditioned on the quality of the disposable stone baskets, which have improved stone extraction techniques [97, 98]. Nonetheless, stone basketing has the potential to cause ureteral injury. Avulsion and perforation of the ureteral wall are considered as most common complications of this treatment. In a study it was shown that in a 15-year single center experience of ureteroscopic management of lower ureteric calculi a ureteric perforation had a rate of 0.5% to 3.3% and ureteric avulsion a rate of 0.1% to 1.3% [110]. Hart in 1967 and Hodgein 1973, both after difficult manipulation of a ureteral stone with Dormia basket, reported the first cases of ureteral avulsion [99, 100]. Most of the complications that were involved with stone basketing are minor and only require close observation or
minimal intervention. Complications are considered major if operative intervention is required [101]. Major complications may have severe and lasting consequences [102].

4.5.1 Ureteral Avulsion (Major Complication)

Avulsion of the ureter is probably the most catastrophic of injuries caused by stone basketing [103]. The injury is typically recognized immediately because the stone is often removed along with a segment of ureter (see Fig. 4.6). The greatest risk factor for ureteral avulsion appears to be attempts to remove a stone that is too large to be retrieved in one piece with excessive force. In addition, basketing a stone in the upper third of the ureter increases the risk because the proximal ureter has less muscle support and contains a thinner lining of mucosal cells than the distal ureter [104].

Extraction of impacted stones can also cause ureteral avulsion [105]. Ureteral mucosa that doubles on itself must be immediately recognized and reduced before stone extraction. If this segment is unknowingly trapped within a basket, ureteral avulsion can easily occur [106].
4.5.2 Ureteral Perforation (Minor Complication)

Perforation and urinary extravasation may occur during stone basketing. Butler et al. reported data on four cases of ureteric perforation caused by the Dormia basket among 2273 ureteroscopies [107]. Schuster et al. reviewed 322 ureteroscopies and reported eight ureteral perforations that occurred while extracting stones impacted in the collecting system wall [108]. The risk is increased by manipulation of impacted or large stones, forceful manipulation especially with stainless steel baskets [109]. When a perforation occurs, the procedure should be terminated. Efforts to continue manipulation are self-defeating because visibility usually deteriorates rapidly as a result of bleeding or collapse of the ureter (Fig. 4.7) [110].
4.6 Prevention of Ureteroscopic Complications

Prevention is the best way to avoid serious complications. By training the surgeons/urology residents with the safe and unsafe extraction forces, the complication might reduce. In a recent study, 11 human ureters from patients who were undergoing nephrectomy for either kidney tumors or non-functioning kidney were harvested. The specimens were then cut into multiple oriented tissue strips for tensile testing. Strips were
stretched to failure in a tensile testing machine. The tensile strength was reported to be lower in the proximal parts of the ureter [113]. Pedro and colleagues conducted a study to examine the avulsion force in a pig model as well as perforation forces in human ureters. They harvested six porcine ureters and placed a stone through a small renal pelvis incision at the ureteropelvic junction. The stone was then trapped using a basket and was pulled down the ureter to find the avulsion force. They measured the average force for avulsion to be almost 10 N. The perforation forces were measured to be almost 7.5 N in porcine and 6 N in human ureter [112].

4.7 Materials and Methods

In this section, the safe and injury forces were estimated by eleven clinicians in 1) a bench top test and in 2) an *ex-vivo* porcine ureter test. There are different ways to measure forces, but depending on the context of the application, some force sensing technologies prove more ideal than others. The most well-known device used to measure force amongst researchers and engineers is the load cell [114]. Eleven clinicians participated in the test, two experienced attending surgeons and 9 post graduate urology residents of various levels. Two fifth year, one fourth year, two third year, two second year, and two first year post graduate year (PGY) residents were amongst the clinicians. The sites involved in these tests were Southern Illinois University, School of Medicine, Division of Urology, St. John’s Medical Hospital, and Memorial Medical Center, Springfield, IL.

4.7.1 Bench Top Test

A miniature, low force load cell (OMEGA® LCL-010 Series thin beam) with maximum load tolerance of 2.2 kg was used for the force measurements. To be able to measure the tension forces, the sensor was fixed on a mounting kit as shown in Fig. 4.8.
Fig. 4.8. Low force load cell (OMEGA® LCL-010 Series thin beam) [147].

The calibration of the load cell was performed by fixing it to a platform on an optic table and suspending various calibrated weights from the system. Due to the low output voltage range of the sensor, an instrumentation amplifier was used to increase the range (see Fig. 4.9). The amplified voltage was fed to the DATAQ data acquisition system DI-710.

Fig. 4.9. Calibration setup of the sensor on the optic table.
Fig. 4.10 illustrates the block diagram of the calibration and data acquisition system. The force was applied to the load cell. Finally the output voltage was displayed on a WINDAQ waveform browser for further analysis.

Fig. 4.10. Block diagram of the calibration and data acquisition system.

In the bench top test set up a basket handle was attached to the sensor to facilitate the test. Clinicians were asked to pull the handle downwards to the extent that they felt it was absolutely safe for the ureter and then release it back (Fig. 4.11). They were then asked to pull the handle to the extent that they felt they would have gone beyond their safety zone (perforation) and again release the handle. Finally they were asked to pull the handle to the extent that they definitely felt they would have caused avulsion and then release the handle back to its initial position. Each of the three tests was run three times for distal and proximal parts of the ureter and the results were recorded. The clinicians did not have a visual output (display or screen) for monitoring their applied forces.
4.7.2. Ex-vivo Porcine Ureter Test

An *ex-vivo* model utilizing a porcine kidney with an intact ureter was designed. Small stones of sizes of 3.0 and 4.0 mm were used to simulate ureteral stones and a stricture was made on the mid ureter. The porcine kidney was then fixed on a platform.

![Stricture](image1)

Fig. 4.12. *Ex-vivo* porcine kidney with an intact ureter. A stricture was made and the stone was placed proximal to the stricture.

A 3 French kidney basket was then advanced proximal to the stricture. The clinicians detected the stone by utilizing the ureteroscope and then they grasped the stone with the
basket. The external end of the basket was attached to the load cell (OMEGA® LCL-010 Series thin beam) and the load cell was fixed on a small platform (Fig. 4.13). The load cell was then connected to the data acquisition system (DI-710) and the data was recorded and displayed on a WINDAQ waveform browser.

![Fig. 4.13. Withdrawal system with load cell attached to the external end of the basket.](image)

In the next step the clinicians were asked to hold the handle securely and then pull the withdrawal system (as a retraction procedure) to the extent they felt it is absolutely safe for the ureter, and then release the withdrawal system. They were then asked to pull the withdrawal system back to the extent that they felt they had gone beyond their safety zone (perforation) and again release it. Each test was run three times for the distal and proximal parts of the ureter and the output was recorded for further analysis (Fig. 4.14).
Fig. 4.14 (a). Withdrawal system and ureteroscope, Basket is advanced through an opening on the ureteroscope.
Fig. 4.15 (b). Withdrawal system and ureteroscope, Stone was detected and trapped inside the basket and the withdrawal system was pulled back (b).
4.8 Force Measurement Results

The load cell OMEGA® LCL was calibrated and the calibration curve was plotted and used for further analysis. The curve illustrates the relation between the output voltage of the load cell and the forces (Fig. 4.15).

![Calibration curve of the load cell OMEGA® LCL.](image)

Bench top tests and *ex-vivo* porcine tests were run and the results were analyzed in the WINDAQ and MATLAB commercial software platforms. The P values were calculated with student t-test statistical method (P values less than 0.05 were considered statistically significant).

4.8.1 Bench Top Test Results

In the bench top tests, the clinicians applied the retraction forces on the load cell and the test was repeated three times for each of the proximal and distal cases. Fig. 4.16 shows the output force of a clinician (one of the two attending clinicians with over 25 years of experience) when operating in the proximal part of the ureter.
Fig. 4.16. Output force of surgeon 3 in proximal ureter (bench top test). Each run is assigned with a color. The safe, Cautious (perforation), and dangerous (avulsion) regions are shown in the figure.

Three runs were conducted and each run was assigned a color. The safe, cautious (perforation) and, dangerous (avulsion) regions are shown in Fig. 4.16 with arrows. The Maximal Average Forces (MAF) for each clinician in the proximal and distal ureter in each region were calculated and plotted. The total MAF of safe forces was $4.59 \pm 1.25$ Newton (N) in the distal and $4.19 \pm 1.07$N in the proximal parts of the ureter ($P = 0.27 > 0.05$). Fig. 4.17 illustrates the MAF of each clinician in the proximal and the distal ureter.
Fig. 4.17. Maximal Average Forces in safe region.

MAF value in the cautious region were measured to be 7.84 ± 2.49 N in the distal, and 6.63 ± 2.23 N in the proximal (P = 0.18) parts of the ureter (Fig. 4.18).

Fig. 4.18. Maximal Average Forces in cautious (perforation) region.

Finally, the MAF in the dangerous region was 10.78 ± 2.49 N in the distal and 9.69 ± 1.35 N in the proximal part of the ureter (P = 0.16). Fig. 4.19 shows the MAF values plotted for each surgeon in the proximal and the distal ureter.
The results showed that for each clinician the applied forces in the distal ureter were higher than in the proximal part of the ureter. By observing the results of each clinician in the green (safe), yellow (cautious) and red (dangerous) region (Fig. 4.20), one can see low variations in the results for the control group (the two attendings). The variations increase when one gets to the less experienced clinicians (first years of residency). It is also observed that some of the residents (PGY3, PGY2, PGY1) applied either much higher or much lower forces during test.
Based on these findings, three groups were defined for the clinicians, the control group (G1) that included the two attendings, the second group (G2) which included the fifth and fourth Post Graduate Year (PGY4, PGY5) residents and G3 that included the PGY1, PGY2 and PGY3. The standard deviation of the applied forces in these three groups was calculated. The variation in all three tests were significantly higher in G3 (P = 0.02) and it decreases when it gets to the control group. Higher variations were noted in the red region (Fig. 4.21). The average forces of perforation and avulsion, in the control group, were measured to be $6.00 \pm 0.62$ N and $9.28 \pm 0.83$ N respectively.
Fig. 4.21. Standard deviation of G1, G2 and, G3 in green, yellow and red regions.

4.8.2 Ex-vivo Porcine Ureter Test Results

In this test setup the applied forces in the safe and cautious regions were measured and the output of the load cell was plotted and analyzed. Fig. 4.22 illustrates the three runs of a clinician in the proximal part of the ureter. The safe and cautious regions are shown with arrows in the figure.

Fig. 4.22. Output force for surgeon 3 in proximal ureter (porcine test).
The parameters that were calculated and analyzed in this test are given below:

- **MAF (Maximal Average Forces)**
- **Maximum Time** ($T_m$): the time from 5% of the maximum force to the peak of the curve. This parameter indicates the operation time
- **Rise Time** ($T_r$): the time to reach 65% of the maximum forces. This parameter describes the speed of operation
- **Work**: the amount of work (or effort) by the clinician given by the area under each curve.

### 4.8.2.1 Maximal Average Force (MAF) Results

The MAF in the green region were $4.88 \pm 1.67$ N in the distal and $3.80 \pm 1.25$ N in the proximal parts of the ureter. There was no significant difference ($P = 0.08$) between these two values however the applied forces in distal were higher than in the proximal parts (Fig. 4.23).

![Bar chart showing MAF Distal and MAF Proximal forces](chart.png)

**Fig. 4.23. Maximal Average Forces in safe region.**
The MAF values in the yellow region (Fig. 4.24) were 8.34 ± 2.55 N and 6.81 ± 1.86 N in distal and proximal parts of the ureter respectively (P = 0.28).

Fig. 4.24. Maximal Average Forces in cautious region.

The difference between the MAF values in the proximal and the distal parts were higher in PGY1 and PGY2 groups. Fig. 4.25 illustrates the average of the proximal and distal values of the clinicians in the green and yellow regions. The green bars show the MAF values in the safe region and the yellow bars are the MAFs measured in the cautious region.
Fig. 4.25. Maximal Average Forces in safe and cautious regions.

The groupings were mentioned before, and this further validated the groupings. The control group (G1), G2 (PGY5s and PGY4) and, G3 that included the first, second and third year residents (PGY1, PGY2, PGY3). The variation between the applied forces in each group is plotted in Fig. 4.26. As shown here, the variation in G3 is significantly higher than the control group. The variation in the yellow region in G3 was higher in yellow region than in the green region.
4.8.2.2 Maximum Time ($T_m$) and Rise Time ($T_r$) Results

The $T_m$ values in the distal and proximal parts of the ureter were not significantly different in the green region ($P = 0.09 > 0.05$), however, these values were significantly different in the yellow region ($P = 0.01$). The $T_m$ value was noted to be significantly higher in the yellow region than in the green region ($P = 0.006$) as shown in Fig. 4.27.
These results indicate that the clinicians spend more time in the proximal part of the ureter than in distal part of the ureter. The $T_r$ values had high variation in G3 (4.50 ± 1.47s) and G2 (3.12 ± 0.76s) in comparison to the control group (2.11 ± 0.46s). There was not a significant difference between the control group and G2 ($P = 0.07$) however the $T_m$ values in G3 were significantly different from the control group ($P = 0.01$).

The $T_r$ values in the distal and the proximal ureter were not significantly different in the green region ($P = 0.07 > 0.05$), however, these values were found to be significantly different in the yellow region ($P = 0.03$). Although the $T_r$ values were higher in the yellow region (1.85 ± 0.50s) than in the green region (1.70 ± 0.28s), they were not significantly different from each other ($P = 0.4$) (see Fig. 4.28).
Fig. 4.28. Average T(rise) values in green and yellow regions.

The average values of $T_m$ and $T_r$ are presented in Table 4.1.

Table 4.1. The maximum time and rise time results in the ex-vivo porcine ureter test.

<table>
<thead>
<tr>
<th>Test region</th>
<th>$T_m$ in distal ureter (s)</th>
<th>$T_m$ in proximal ureter (s)</th>
<th>$T_r$ in distal ureter (s)</th>
<th>$T_r$ in proximal ureter (s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Green Region (Mean ± SD)</td>
<td>3.5 ± 0.73</td>
<td>4.03 ± 0.65</td>
<td>1.38 ± 0.33</td>
<td>2.03 ± 0.42</td>
</tr>
<tr>
<td>Yellow Region (Mean ± SD)</td>
<td>4.65 ± 0.90</td>
<td>5.42 ± 1.38</td>
<td>0.39 ± 0.50</td>
<td>2.12 ± 0.59</td>
</tr>
</tbody>
</table>

* Significant at P value < 0.05 by student t-test.

4.8.2.3 Work Results

The area under the curves of each test was calculated and analyzed (Fig. 4.29). The average work done by clinicians in the green region (11.21 ± 4.12 J) was significantly different from the yellow region (13.73 ± 4.61 J, $P = 0.02$). The average work was higher in the proximal part than in the distal part in both the green and the yellow regions. The work was significantly different in the yellow region from the distal
(12.47 ± 4.88 J) to the proximal part of the ureter (15.00 ± 4.60 J, P = 0.004). There was a constant variation in the work done by the control group, however, this value increased in G2 and even more so for the G3 (these groups had higher operation times and MAF values).

Fig. 4.29. Average of works done in green (safe) and yellow (cautious) regions.

4.8.3. Bench top Test MAF values vs. Ex-vivo Test MAF values

The MAF values in the safe and cautious regions for bench top test and the ex-vivo porcine test are shown in Fig. 4.30 and 4.31. The result are similar (P = 0.54) and consistent with each other, however, in most cases the MAF values in porcine test are lower than the values in bench top load cell force test. The forces were also compared in the green region and they were not significantly different (P = 0.48).
Fig. 4.30. Maximal average forces in safe region for load cell test and *ex-vivo* test.

Fig. 4.31. Maximal average forces in cautious region for load cell test and *ex-vivo* test.
4.8.4 Discussion on the Measured Forces

Ureteroscopy and basket extraction is the most common method for removing ureteral stones [86]. Ureteral perforation, mucosal injury, ureteral rupture and, ureteral avulsion are complications of this procedure [87]. These complications may lead to increased operating room time, cost and in some cases may have severe and lasting consequences. Excessive force in retrieval of the stones that are too large to be removed in one piece is the greatest risk factor for such complications [101-103]. Ureteroscopic training devices help develop endourologic skills, however, they lack force feedback on how much force can be safe to avoid ureteral complications. This is one of the first studies to address the safe, cautious and, dangerous extraction forces in proximal and distal parts of the ureter with two different methods used, i.e. bench top and porcine ureter tests.

A study found in the literature measured the perforation forces to be \((7.50 \pm 1.14)\) N in pig ureter [112]. They also measured the average force for avulsion to be \(10.00 \pm 1.86\) N. The results reported in this research were consistent with the forces reported in the literature. However, the forces need to avulse the human ureter would be less than in a porcine ureter. In this study the clinicians were asked to run the tests and apply forces as much as they apply on a human ureter. The maximal average perforation forces were \(7.13 \pm 2.36\) N in bench top tests and \(7.07 \pm 2.20\) N in the porcine test model \((P = 0.54)\). The maximal average avulsion forces were measured to be \(9.12 \pm 3.01\) N in the bench top tests, and as mentioned before are in excellent agreement with [112].

It is noted that in both tests, the differences in proximal and distal MAF values were not significant, but in all cases the proximal forces were lower than the distal forces.
and this may imply that the ureter is more vulnerable in its proximal area than in its distal area. In a recent study the literature on ureteral avulsion was reviewed and it was shown that most of the injuries were taking place in the proximal parts of ureter [114]. The high variation between the applied forces in G3 and G2 compared to the control group G1, indicates that there may be an opportunity to create specialized training programs for the residents using devices with force feedback. The measured MAF values were either lower or higher than the control group. The forces in the porcine test with visual feedback (the ureteroscope display) were less than the bench top tests which indicates the role of visual display in the extraction of the stone.

Additionally, the operation time was noted to be higher in the proximal tests than in the distal test and also this parameter was noted to be higher in the yellow region when compared to the green region. This result indicates that the clinicians may be acting more cautiously in the more sensitive parts of the ureter (proximal). The speed of extraction was calculated and the results show that the clinicians spend more time (smaller $T_r$) in getting to their maximum force values in the yellow region and especially in the proximal part of the ureter. There was a high variation in the time parameters of G3 and G2 in comparison to the control group (G1). The clinicians average work output illustrates that there is more caution in the manipulation of the basket in the yellow region than in the green region. Also more work was done in the proximal ureter than in the distal part of the ureter to avoid any injury to the ureteral wall. An interesting finding in this study is the comparison between the measured parameters in the control group and the second (G2) and third group (G3) which indicate the need for specialized training of the residents on extraction forces.
4.9 Training Device Design

A training device was built based on the measured forces, to switch on a yellow and a red light when the extraction forces during basketing were in the unsafe (perforation and avulsion) region. Building this device took two steps: 1) preparing the retraction handle and attaching it to a force sensor, 2) programming and designing a circuit based on the measured MAF values from the tests in section 4.8.

4.9.1 Retraction Basket Preparation

Here, a 3F stainless steel kidney basket was utilized and the external wire was attached to a connector and then to a force sensor (OMEGA® LCL-010 Series thin beam) with load tolerance of 2.2 kg (sees Fig. 4.32). The load cell was fixed to a platform.

![Kidney basket attached to force sensor and platform](image)

Fig. 4.32. A kidney basket attached to the force sensor and the platform.

4.9.2 Circuit Preparation

The output of the load cell was fed to an instrumentation amplifier. Instrumentation amplifiers (in-amps) are precision gain blocks that have a differential input and an output that may be differential, or single-ended with respect to a reference terminal. These devices amplify the difference between two input signal voltages (here, the output of the force sensor) while rejecting any signals that are common to both inputs. The in-amps are widely used in many industrial, measurement, data acquisition, and
medical applications where dc precision and gain accuracy must be maintained within a noisy environment, and where large common-mode signals (usually at the ac power line frequency) are present. The amplifier used here is an LT1101 that is a precise micropower single supply instrument (Fig. 4.33). The inverting and non-inverting outputs of the sensor (green and white wires) were connect to pin number 3 and 6 (a gain of 100 was used).

![Fig. 4.33. Schematic of LT1101 instrumentational amplifier. The outputs of the load cell were connected to pins 3 and 6.](image)

The maximum average value of unsafe forces were measured to be 7.07 ± 2.20 N. Based on the force values and by utilizing the load cell calibration curve, the safe and unsafe voltages were calculated and used to design the training device. The output of this amplifier was then connected to another amplifier (LM324) that was used as a voltage comparator (Fig. 4.34). The resistors of the circuit were calculated based on the safe and unsafe voltages and three LEDs, green, yellow and red, were connected to the output of this circuit. The green LED light was designed to go on while the applied forces were in safe region, the yellow LED was on at the time of perforation (cautious) forces and
finally the red LED was on when the extraction forces increased to avulsion (dangerous) forces (Fig. 4.34 (b)).

Fig. 4.34. (a) Schematic of LT1101 amplifier (b) Circuit design for the different range of applied forces.
4.9.3 Training Device Bench Top Test

Testing was performed by fixing a model of the ureter constructed from polyurethane tubing (internal diameter of 4mm) on the optic table. A stricture was created on the tube and a metal bead 2.8mm in diameter, simulating the stone, was placed proximal to the stricture in the tube. The output of the load cell was connected to a DATAQ data acquisition system (DI-710) and the output voltages were recorded and displayed on a WINDAQ waveform browser for further analysis. The wires of the prepared basket trapped the stone and the entire system was withdrawn from the ureter model by first sweeping the stone down to the stricture and then increasing the force step-by-step up to the dangerous forces. The voltages were recorded while the green, yellow and red LED went on (Fig. 4.35). By utilizing the calibration curve, the forces were calculated and showed to be in perfect agreement with previous measured forces.
Fig. 4.35. (a) The green LED is on in safe applied forces. (b) The yellow LED went on when the applied forces exceed to perforation (cautious) force region (C) The red LED went on with forces exceeding into avulsion region forces.
4.10 Conclusion

A crucial contributing factor to a successful surgery is sensory feedback. Complications of ureteroscopy usually involve the attempt to remove a large stone with extra forces using a kidney basket [101-103]. To reduce these complications, the urologist should manage the forces applied during stone extraction. This study addressed the need for force extraction awareness and training. The measured force values could be used to design "smart devices" that could aid in reducing the complication rate and hence lead to fewer complications. Improved training of the urology residents on the extraction forces can only lead to improved patient safety as the residents become practicing clinicians. It should be noted that the tests were run with the assumption of a healthy ureter. Ureteral abnormalities such as inflammation, urinary tract infections, stone configuration and basket type can change the measured parameters.
CHAPTER V
DESIGN OF A SMART DEVICE

5.1 Introduction

Stone retrieval devices are important accessory instruments for endourology. With increased use of kidney stone baskets, preventing excessive forces during stone extraction becomes important. A force measurement device was designed in this study that provides an instantaneous visual measurement of the applied forces during stone extraction. Based on the forces measured in the previous chapter, regions of safe and unsafe were defined on the device. A bench-top test was performed using the device. The proposed device will provide instantaneous force measurements imposed on the ureter during stone extraction, and thereby, aid in reducing the risk of complications by highlighting the safe and potentially unsafe extraction forces. Additionally, this “smart device” can be used in physician training sessions. The force feedback sensor can give the trainees an intuitive sense of the safe and unsafe extraction forces.

5.2 Instrumentation in the Ureteroscopy

Urolithiasis (formation of stone) affects 5-15% of the population worldwide [115]. The options for management of the ureteral stones include conservative approaches such as active monitoring, minimally invasive procedures such as shock wave lithotripsy (SWL) and ureteroscopy, and less often, laparoscopic ureterolithotomy. In stone disease, ureteroscopy has been favored for the treatment of ureteral calculi because of the ease with which stones can be accessed with a ureteroscope. Improved optics, flexible
ureteroscopes, miniaturization of instrumentation, and digital technology have made access to the ureter and the collecting system easier and more reliable [116, 117]. Other instruments that are used to retract the stone in the ureteroscopy method include stone migration devices, kidney baskets and forceps. Each of these instruments is described in more detail in this chapter.

5.2.1 Stone Migration Devices

Stone migration or retropulsion, the movement of kidney stone fragments towards the upper ureter or kidney, as a result of ureteroscopic lithotripsy (laser therapy) is one of the challenges that the surgeon usually face during surgery. Stone migration may lead to increased operative times due to the need to capture retropulsed fragments, and increased costs when the urologist is required to switch from the semirigid to the flexible ureteroscope to find a retropulsed fragment [118-120]. To this end, there are several commercially available devices which have been designed to prevent stone retropulsion [6]. Currently available devices include the Stone Conical ® (Boston Scientific, Natick, MA), NTrap® (Cook Medical, Bloomington, IN), and Accordion® (Percsys, Palo Alto, CA) which are devices positioned in the ureter alongside the stone and with retropulsion “elements” which are positioned distal to the stone to prevent the migration of fragments (Fig. 5.1).
Fig. 5.1. Accordion (Percsys) stone trapping device (a) device passes the stone, (b) it controls the movement of stones and widens ureter for enhanced visualization of stone (c) it prevents the fragmented stones from migration [121].

5.2.2 Stone Forceps

Stone forceps (or “graspers”), like baskets, are stone extraction devices that can be used ureteroscopically [122]. There are approximately 12 commercially available forceps manufactured by five companies. Forceps consist of a handle, a sheath overlying a flexible shaft (sheath 2.4–5.0 F), and a forceps or grasping structure at the distal end. They come in a range of lengths, from 40 to 120 cm, to be used in a flexible or semirigid ureteroscope. They can be distinguished from a basket in that the wires do not merge at a point. Instead, there is an open space that can be used to engage a stone. The grasping widths range from 8 to 20 mm. The forceps most commonly consist of three hooked prongs and are made of stainless steel, rather than nitinol, for sufficient closing or grasping strength (Fig. 5.2). The Boston Scientific Graspit has a unique design, with 2 nitinol loops that are serrated for additional grip. Stone forceps can be used for nearly the same indications as stone baskets. They can be used for stone extraction or manipulation and for the removal of foreign bodies. However, they are not used to mobilize a stone for
facilitation of laser lithotripsy [123]. Their grasping strength, in specific circumstances, may be greater than with that of a stone basket.

![Graspit forceps (Boston Scientific), constructed of serrated nitinol](image)

Fig.5.2. Graspit forceps (Boston Scientific), constructed of serrated nitinol [124].

5.2.3 Stone Baskets

Early in the history of endourology, treatment of upper tract stones was accomplished by blind basketing of small lower ureteral stones followed by manual extraction. With the development of intraluminal ureteroscopes, the baskets were engaged under fluoroscopic guidance and direct vision. When the flexible ureteroscope was introduced in the early 1980s, flexible working instruments were developed with the goals of maintaining maximal scope deflection and irrigant flow, and optimizing the performance of the instruments. The earliest stone baskets were of the Dormia design (Fig. 5.3). This designed consisted of a helical structure that facilitated engagement of the stone and subsequent withdrawal [125]. The Dormia baskets were constructed with three or four wires, with or without a tip that could be passed beyond the stone. The problems with these baskets included trauma to the collecting system from a rigid tip extending beyond the cage, particularly if the stone was in the proximal part. Also, the long distance between the scope and the stone made engagement of the stone difficult [126].
Fig. 5.3. Dormia helical stone baskets (Boston Scientific, Natick, MA, USA) [124].

The introduction of the nitinol tipless basket marks the transition to the modern era of endourology [127]. The N-Circle was the first nitinol basket introduced (Cook Urological) (Fig. 5.4). Nitinol is a combination of nickel and titanium, and the flexibility of the material allowed full deflection of nephroscopes and later flexible ureteroscopes.

Fig. 5.4. NCircle (Cook Urological, 1.5 F) the earliest tipless nitinol basket [151].

There are many different stone basket types available for use today and they have common elements. At the distal end, there are 3–16 wires forming a basket cage (most commonly four), composed of either stainless steel or nitinol (nickel/titanium). There are a variety of basket cage configurations, including spherical, helical, paired wire, or tipless. Baskets are typically available in two lengths: shorter for use through a semirigid ureteroscope (65–90 cm) and longer for flexible ureteroscopes (115–120 cm). At the proximal end of the basket is a handle that opens or closes the basket, some have locking
or basket articulating mechanisms. When the basket is closed, the basket wires retract into the sheath, and the basket appears to shorten. All stone baskets are for use in a single patient, but multiple stone extractions can be performed with a single device, so basket durability is of utmost importance.

5.2.3.1 Complications of Basketing

Despite improvements in endoscopes and their working instruments, complications still occur. Knowledge of device limitations and potential complications is essential for the surgeons. Ureteral avulsion and perforation are among the most feared complications of ureteroscopy, and stone extraction devices are often involved [128]. Ureteral perforation occurs when a hole is created across all layers of the ureteral wall. Contemporary series report the incidence of ureteral perforation to be approximately 2% or less, with the incidence of major perforations requiring further surgical repair to be approximately 0.1–0.6% [129-132]. Avulsion occurs when the ureter circumferentially tears apart resulting in total discontinuity of the ureter (Fig. 5.5). Immediate operative intervention to rectify the avulsion is usually the rule if recognized intraoperatively. Reconstruction of the avulsed ureter can be quite challenging and may ultimately lead to loss of the affected kidney [145, 146].
The most common cause of avulsion and perforation is attempted basket extraction of stones or stone fragments too large to safely pass down the ureter with extra forces (Fig. 5.5). Other risk factors include stone basketing in the proximal ureter, retrieval of impacted stones, ureteral anatomic anomalies, and diseased ureters [133-135].
5.3 Design of the "Smart Device"

A force sensor with three defined force regions of safe, cautious, and dangerous was designed and the prototype was built and tested. In general, force could be measured either by a force transducer or a spring.

5.3.1 Force Measurement Methods

In recent years, sensors and specially force measurement sensors in medicine are becoming a growing need to realize further effective treatments and quantitative assessments [136, 137]. For example, quantitative safety assessment can be realized by introducing such force sensors by monitoring the interaction force on the conventional medical devices such as surgical knife or forceps [139].

5.3.1.1 Load Cell Force Measurement

A load cell is a sensor or a transducer that converts an applied load or force into an electronic signal. This electronic signal can be a voltage change, current change or frequency change depending on the type of load cell and circuitry used. Load cells can be made using resistive, capacitive, inductive or other techniques [140]. Most commonly available load cells are based on the principle of change of resistance (piezo-resistive) in response to an applied load. Load cells are traditionally built using resistive bonded foil strain gauges (Fig. 5.6). Strain gauges are essentially resistors built using standard semiconductor etching techniques and are bonded to a metallic member such as a cantilever beam or diaphragm.
Fig. 5.6. Load cells, (a) Strain gauge under load, (b) Button style compression load cells [138].

Usually at least four strain gauges are configured in a Wheatstone Bridge configuration with four separate resistors connected as shown in Fig. 5.7. When the metallic member to which the strain gauges are attached, is stressed by the application of a force, the resulting strain leads to a change in resistance in the resistors [141]. This change in resistance results in a change in output voltage. These load cells are precise in force measurement but they are also costly.
5.3.1.2 Spring Force Measurement

This force measurement method works by Hooke's Law \( F(N) = K(rate) \times \Delta x(m) \) which states that the force needed to extend a spring is proportional to the distance that spring is extended from its rest position. Therefore the scale markings on the spring balance are equally spaced. In the design of the device, this method had been used as it is inexpensive and simple.

5.3.2 Proposed Device Description

The proposed device includes a hollow tube with a slot on the left side (see Figures 5.8). The external wire of a kidney basket (e.g. a Cook® Medical basket) was connected to a spring with specific rate and maximum load tolerance. The other end of the spring was hooked on a screw by a swivel onto the right end part of the handle. This hollow tube was attached to the basket by a two sided screw (drawings in Appendix C).
Calibration of the spring was performed by suspending calibrated masses and measuring the extended length of the spring as shown in Fig. 5.9. A pointer was used to help read the scale on the ruler and the scale was viewed at eye level to avoid parallax error. The measurements were repeated and plotted for further analysis.

Three regions of green (safe), yellow (caution) and, red (avulsion or danger) were assigned on the slot of the prototype as shown in Fig. 5.10 (b). These regions were
defined by the perforation and avulsion forces reported in the previous chapter. The safe region illustrates the range in which the applied forces on the ureter will not make any injuries and as measured will be less than $7.07 \pm 2.20$ N. This amount of force is assigned to a specific extension of the spring as measured in the calibration section. Once the indicator of the handle enters the yellow region, there will be a risk of perforation but still avulsion will not occur. This would be an indicator for a surgeon to be more cautious. The perforation forces were reported to be between $7.07 \pm 2.20$ N and $9.12 \pm 3.01$ N. The red region indicates the avulsion forces that are more than $9.12$ N, and would be an indicator to the surgeon to reduce the applied force. It must be made clear here that the device is an aid to a surgeon and not designed to work for all cases. The surgeon, at the end, is still responsible for the safety of the patients.
Fig. 5.10. Proposed sensor handle (a) Cook NCircle kidney basket [151], (b) prototype attached to Cook® Medical basket.

5.4 Prototype Bench Top Test

To test the prototype the forces applied by the user should be measured. The most well-known device used to measure force amongst researchers and engineers is the load cell [28]. Here an OMEGA® LCL-010 Series thin beam load cell with maximum load tolerance of 20N is used. To calibrate the sensor, weights were suspended from it and the
output voltages were recorded (Fig. 5.11) using a data-acquisition system. Due to low output voltage range of the sensor, an instrumentation amplifier was used to increase the output range. The DATAQ-DI710 data acquisition system records and displays (WINDAQ waveform browser) the output voltage of the sensor.

Bench top testing was performed by preparing a model of the ureter constructed from polyurethane tubing with an internal diameter of 4mm as shown in Fig. 5.12. A stricture was created on the tube and a metal bead (2.8mm in diameter) simulating the stone was placed proximal to the stricture in the tube.
The prototype was attached to the Cook® Medical kidney stone basket from one side and to the OMEGA® LCL-010 Series thin beam load cell from the other side (Fig. 5.13). The wires of the basket trapped the stone and, the entire system was withdrawn from the ureter model by first sweeping the stone down to the stricture and then increasing the force step-by-step up to the perforation and avulsion forces. In this step the output voltages of the pullback test (green, yellow and, red regions) were recorded and based on the calibration curve the forces were measured and compared to the results reported previously.
5.5 Prototype Test Results

The spring was calibrated before being utilized. The mass and average extension curve was plotted and used to define the different force regions on the handle of the sensor as shown in Fig. 5.14.

![Spring calibration curve](image)

**Fig. 5.14. Spring calibration curve.**

The OMEGA® LCL-010 Series thin beam load cell was calibrated by suspending masses from the sensor and recording the output voltage as shown in Fig. 5.15.

![Force sensor calibration curve](image)

**Fig. 5.15. Force sensor calibration curve.**
The bench top test was performed by attaching the prototype to the OMEGA ® LCL-010 Series thin beam load cell and withdrawing the whole system from a polyurethane model of ureter from a stricture. The first region of voltage was recorded by the movement of the indicator on the prototype in the safe (green) region. This procedure was run five times and the output figures were plotted (Fig. 5.16). Next the cautious voltages were recorded while the indicator entered the yellow region up to red region (Fig. 5.17) and finally, the voltages of the indicator in the red region were recorded and the figures were plotted as shown in Fig. 5.18.

Fig. 5.16. Output force results of the bench-top test in safe region (green).
Fig. 5.17. Output force results of the bench-top test in cautious (yellow).
Fig. 5.18. Output force results of the bench-top test in dangerous (red).

Fig. 5.19 illustrates the pullback forces of the prototype during one run. The peaks indicate the maximum forces in green, yellow and red region respectively. The forces related to these voltage ranges were defined by the calibration chart and compared to the results from previous chapter.
Fig. 5.19. Recorded force regions in the bench-top testing.

Table 5.1. The average maximum values of each region.

<table>
<thead>
<tr>
<th>Region</th>
<th>Run 1 max Voltage (v)</th>
<th>Run2 max Voltage (v)</th>
<th>Run3 max Voltage (v)</th>
<th>Run4 max Voltage (v)</th>
<th>Run5 max Voltage (v)</th>
<th>max Force (N)</th>
<th>max Average Voltage (v)</th>
<th>max Average of Forces (N)</th>
<th>max Forces reported in [112]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Green (safe)</td>
<td>0.33</td>
<td>5.24</td>
<td>0.314</td>
<td>5.14</td>
<td>0.329</td>
<td>5.38</td>
<td>0.335</td>
<td>5.48</td>
<td>0.339</td>
</tr>
<tr>
<td>Yellow (cautious)</td>
<td>0.64</td>
<td>10.99</td>
<td>0.632</td>
<td>10.31</td>
<td>0.715</td>
<td>11.66</td>
<td>0.673</td>
<td>10.99</td>
<td>0.638</td>
</tr>
<tr>
<td>Red (dangerous)</td>
<td>1.13</td>
<td>18.48</td>
<td>1.02</td>
<td>16.77</td>
<td>1.04</td>
<td>17.05</td>
<td>1.04</td>
<td>17.03</td>
<td>1.08</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Not reported</td>
</tr>
</tbody>
</table>
5.6 New Design of the Device

The prototype was redesigned in a way which there would be no need to attach it to the current kidney baskets in the market. Fig. 5.20 illustrates the new design of the device. The front part of the device includes a slot for the wire open/close controller and the rear part is designed to place the spring and a slot which the indicator would be placed.

![Fig. 5.20. New design of the "smart device".](image)

5.7 Conclusion

A wide variety of medical device applications utilizes force sensors. Providing a feedback of the applied forces is a critical factor to a successful surgery. Avulsion and perforation of the ureter are serious complications of ureteroscopy that involve attempts to remove a large stone with extra forces by a kidney basket. To prevent the complications during basketing, a smart device was designed to sense the forces during basketing. Safe, cautious and, danger zones were defined on the sensor handle and the device was
calibrated and tested. The feedback forces provided by the sensor will lead to fewer complications during basketing, save time, and aid in reducing the procedure cost. In addition to this, the proposed prototype can also improve the physician’s skills of basketing during training.
CHAPTER VI
CONCLUSION AND FUTURE WORK

This Chapter gives a summary for the research work presented in this dissertation and highlights its main contributions. Moreover, some of the extensions to the work done in this dissertation are explained.

6.1 Summary

In this dissertation, different modalities in kidney stone disease (urolithiasis) treatment have been proposed. The main objectives of the dissertation are to increase the stone free rate with less complications during ureteroscopy and to analyze the effect of different shapes and sizes of calculi on the urinary system.

The ureter was modeled based on reported morphometric data of urinary system and by utilizing the ANSYS FLUENT software [17]. To study the effect of size of a stone (the mount of the ureter blockage) on the urine flow and the ureter wall, different sizes of cylindrical stones were placed in the ureter model. The results showed that by an increase in the ureter blockage from 25% to 60%, the stresses on the wall will increase significantly. The effect of different shapes (cylindrical, spherical and conical) of stones with same characterization length was studied on the urine flow and the ureter wall. It was concluded that the compression and expansion of the wall as well as the size of the stone play an important role in the dynamics of the ureter. Similar to other engineering
models that simulate a system as intricate as a living organism, several simplifications were made in the simulation. These simplifications were mainly in (1) geometry; in reality, the ureteral collapsed lumen is stellate in form [25], (2) rate of peristalsis; the contraction wave velocity may vary during peristalsis through the ureter due to the controlling function of a pacemaker in the renal pelvis [4], and (3) the shapes of the stones. It should be noted that due to computational restrictions, the physiological conditions of ureter undergoing higher luminal pressure level (20 – 40 mmHg) were not considered. Although by applying pressure loadings to the ureteral inlet and outlet, one can assume approximately the true constant level of pressure in the ureter to be around 1 mmHg [6].

The avulsion and perforation forces were measured in two different test set ups. In the bench top test the clinicians were asked to apply forces on the sensor to the extent they felt they are in safe, cautious and dangerous region of operation forces. In an ex-vivo test setup, porcine ureters were prepared and the clinicians were asked to grasp the stone by the basket and retract the withdrawal system (the kidney basket attached to a force sensor) by two different force ranges of safe and cautious. Different parameters such as operation time, speed of operation and the work done by the surgeons were analyzed as well as the maximal average forces for each surgeon and each test. These measured forces were compared and then used to build a training system. This training system switches a green LED light on when the applied forces are of no risk to the ureter, a yellow LED on when the applied forces have the risk of perforation of the ureter and finally a red LED on when the imposed forces are a risk for avulsing the ureteral wall.
The system was tested on a benchtop test setup and the forces were measured and compared to the reported perforation and avulsion forces in literature.

A "smart device" was designed based on the measured safe and injury forces reported in Chapter V. This prototype can provide instantaneous force measurements imposed on the ureter during stone extraction. This might aid in reducing the risk of complications by highlighting the safe and hazardous forces. A prototype was built and bench top tests were performed. The results were consistent with the measured forces in Chapter IV and also in a great agreement with previous work done by researchers. By using this prototype the surgeon will have a visual feedback of the applied forces during basketing on ureter wall and this will increase the safety and effectiveness of endourological procedures. Finally, it is worth noting that the proposed force sensor can also be used in embolic protection devices (EPDs). These devices prevent or reduce plaque debris from reaching the distal bed of the coronary arteries. Using excessive force in retrieving this device might cause injuries to the walls of arteries.

6.2 Future Work

There are different shapes and geometries of kidney stones which form inside the urinary system. In this project three different shapes were analyzed, however, these stones could be modeled as a star shape or elliptic or others. The limitation of this study was that the wall deformations in the ureter are caused by the wall stimulation as well as fluid forces, and therefore need to be studied through fluid-structure interaction. Also further studies on the ureteral peristaltic could be better understood through a 3-D ureter model analysis.
The forces required to avulse or perforate the ureter are higher in the porcine ureter than in the human ureter. The injury forces, especially the avulsion forces have not been studied well in the human ureter. Other factors, which are likely to play a role and were not evaluated in the study, are impacted stones that result in local inflammatory processes, strictures, urinary tract infections, previous ureteroscopies, and type of equipment. No accounting for these factors, as well as sex, age, and other demographics parameters, was performed, but this is a preliminary study that was not designed to overcome these issues.

The built prototype could be redesigned based on the porcine ureter injury forces and be tested on porcine ureters to evaluate its performance. Studies on the avulsion forces on the human ureter are needed as to use this device on the human ureter. The “smart device” then can be used as a training device or in the surgery rooms during stone extraction procedures.
BIBLIOGRAPHY


APPENDICES
APPENDIX A
FORCE SENSOR

When small load measurements are required, the OMEGA ® LCL Series thin beam load cells are exceptionally well suited. The LCL Series is designed to measure many different parameters found in medical instrumentation, home appliances, process control, robotics, automotive and many other high volume applications. A specially developed integrated strain gage includes all balancing, compensating and conductive elements and is laminated to the beam to provide excellent stability and reliability. Here an LCL-005 model was used that it has a load capacity of 2.27 kg.

Fig. A.1. OMEGA ® LCL Series thin beam load cells.

Careful design considerations must be taken into account when mounting OMEGA’s LCL Series thin-beam load cells. The sensor’s performance depends on the
mechanical interface. All thin-beam load cells require mounting clamps to create a “double bend” during loading, as shown in Fig. A.2.

![Schematic of load cell mounting kit.](image)

Fig. A.2. Schematic of load cell mounting kit.

This illustration is exaggerated to show the clamp’s effectiveness in producing opposing moments that create the double bend. Fig. A.3 illustrates the sizes and design of the mounting kit. Blocks A and B were attached as shown in Fig. A.2.
The excitation voltage was supplied from the data acquisition voltage source port. There are four different colored wires connected to the load cell. Black and red wires are the -EXC and +EXC ports respectively. The positive and negative output signals are wires in green and white respectively. An electrical output is generated as the double bend causes tension and compression on the sensor strain gage. The output of the load cell was connected to an amplifier (LT1101). Fig. A.4 illustrates a schematic of the LT1101 amplifier. This amplifier is a single supply amplifier and has different ranges of gains. A gain of 100 was used in this project.
Fig. A.4. LT1101 amplifier schematic.

The connection of the amplifier to a sensor is shown in Fig. A.5.

Fig. A.5. Connection of the wires of the load cell to the LT1101 amplifier.

The output (port 8) of the amplifier was connected to the data acquisition system.
The grounds of the sensor and the amplifier were connected to the ground port of the data acquisition system.
The DATAQ Instruments DI-710 series is a family of instruments for general purpose and stand-alone datalogger and data acquisition applications (Fig. B.1). The device should first be installed on a computer.

**USB Device Installation:**

1. All DATAQ Instruments USB devices should be disconnected from the Computer.
2. The DATAQ Instruments CD should be inserted to the computer drive. The installation software should start automatically. If it does not, it should be started manually by double-clicking the Setup application (setup.exe) located on the root of the DATAQ Instruments CD.
3. In the “What do you want to do?” window, the “Install WINDAQ Software” should be selected and then click OK.

4. In the “Installing Software” window, the “Install Software for DI-148, DI-158, DI-710, DI-715B, and DI-718B(x) instruments” option should be selected.

5. In the “WINDAQ Installation” dialog box, the “Install Software” option and should be selected to continue. If it is wished to view the hardware documentation the appropriate radio button should be selected. Documentation will be saved to the hard drive during installation.

6. In the “Welcome!” box, the OK should be clicked to continue.

7. If License agreement is accepted, the registration information (name and company) should be entered in the appropriate text boxes when prompted.

8. When prompted, following that, the installation directory should be specified. It is recommended that the default location should be used. If DI-148, DI-158, DI-710, DI-715B, or DI-718B instrument were installed, the installation directory should be set to the same folder.

9. The “Select an Interface” box should be selected.

10. The USB device or cable should not be connected to the PC until installation is complete. If the device is currently connected, it should be disconnect it before continuing with this installation.

11. When prompted to select a Program Manager Group, a destination (or group window) in the Start Menu for WINDAQ software icons should be specified. It is recommended that the default is accepted.
12. User access should be set a priori in the “Installation Option” dialog box. After WINDAQ Software installs, a prompt to install WINDAQ/XL Trial Version and Advanced CODAS Analysis software will appear. If it is wished to install either software, the Yes option should be clicked. The screen prompts should be followed to complete the installation.

13. Once the software installation is complete a “Successful Installation” box will appear.

The device(s) now should be plug into the PC and power should be applied (if required). There is no need to re-install this software when installing more DI-710 USB devices to PC (Fig. B.2).

![Different ways to transfer SD data files.](image)

Fig. B.2. Different ways to transfer SD data files.
In this research experiment, the positive channel was connected to the output of the amplifier to read the output of sensor. The ground port was connected to the ground port of the sensor (Fig. B.4). The first +5V port was used to power up the force sensor and the second was used as a voltage supply for the amplifier. The output of DI-710 was connected by the USB cable to the computer.
In the next step WINDAQ software was used. This software acquires displays, and records waveform data. The steps to use this software are as follows:

Step 1. Enabling Channels for Acquisition

The channels are configured for acquisition only in SET-UP mode. It is not permitted to add, delete, or configure channels in RECORD mode. To ADC channel configuration can be activated by clicking on Channels (Fig. B.5) in the Edit Menu or on the Channels: field in the status bar. This displays the Channel Selection grid (Fig. B.6). The channel selection grid displays the current status of all channels and enables and disables the channels. In the illustration above, the boxes formed by the top row of the grid represent the internal channels available on the hardware device (the numbers above the top row of boxes refer to the channel numbers).

![Channel bar](image)

Fig. B.5. Channel bar.
A check mark in the channel box indicates an enabled channel. The channel box should be clicked on to enable/disable a channel and place/remove a check mark in/from its channel box.

**Step 2. Viewing Enabled Channels**

The default number of channels displayed varies by instrument. The Format Screen in the View menu should be selected to change the current display. In the format box, the desired display format should be clicked. Format Screen allows for overlapped and non-overlapped waveform displays. An overlapped format (Fig.B.7) allows the user to closely examine the relationship between two waveforms. A non-overlapped format (Fig.B.8) allows the user to isolate each waveform’s transition to within a defined area.
In this research project, as one channel was used to read the output of the sensor, one channel was displayed on the view page.

Fig. B.7. Non-overlapped display.

Fig. B.8. Overlapped display.
Step 3. Specifying a Sample Rate

The total sample throughput rate is the rate that the instrument acquires samples for all channels combined. The Sample Rate must be specified before recording; default varies. This change can be done through edit menu (Fig. B.9).

![Sample Rate](image)

Fig. B.9. Specifying a sample rate.

The total sample throughput rate is the rate that the instrument acquires samples for all channels combined.

Step 4. Specifying Gain and Measurement Range

A gain factor (varies by instrument) should be chosen to get the best possible measurement resolution for your signals (Fig. B.10). A gain of 1 (unity) provides the widest measurement range possible on any given instrument.
Step 5. Recording Waveforms to Disk

The Record function on the File menu initiates recording to disk. To begin waveform recording: 1. The Record option in the File menu (or F4) should be selected. This displays the Open File dialog box (Fig. B.11). A file name to create a new file or open an existing file to append to it should be specified. To create a new file, a maximum file size must be specified. To get the desired results, experiments with different file sizes, sample rates, and recording time should be carried out.

2. The desired file size should be entered, otherwise, the default should be accepted.
3. The Enter key should be pressed to close the dialog box and begin recording to disk. WINDAQ enters RECORD mode and simultaneously digitizes, displays on the monitor, and streams analog channel data to disk. The Status: field in the bottom annotation line indicates RECORD (Fig. B.12).

![Fig. B.12. Recording mode in WINDAQ display.](image)

The Stop option on the File menu (or Control + F4) should be pressed to pause recording. This suspends data storage to disk, but the real time display remains active. The Status: field in the bottom annotation line indicates STBY. The “Storage:” field of the status bar displays the amount of file space consumed as a percentage of total file space consumed. Recording may be started or stopped as many times as desired. When the target data file has filled, data acquisition to disk will cease, the “Storage:” field of the status bar will display “100% used” and the Status: field of the status bar will display FILE FULL (Fig. B.12). The recorded data can be opened in Excel software.
Fig. B.13. Full memory usage mode in data recording.
APPENDIX C
PROTOTYPE DRAWINGS

The drawings of the different parts of the kidney basket prototype are sown in this section. Fig. C.1 illustrates the handle design. There is an opening on the tube that the indicator was placed. Fig. C.2. shows the connector screw between the baskets and the designed prototype. Fig. C.3 and C.4 were placed at the rear part of the handle to hold the spring to the wires of the basket.
Fig. C.1. The handle of the prototype.
Fig. C.2. The connector screw between the handle and the basket.
Fig. C.3. Spring and swivel holder.
Fig. C.4. Screw to fix the spring to the rear part of handle.
APPENDIX D
USER DEFINE FUNCTION CODE

The User defined Function used in moving the wall boundaries of ureter in the ANSYS FLUENT simulations is as bellow:

```c
#include "udf.h"
#define  v      0.02
#define  lambda   0.12
#define  Pi      3.1415

DEFINE_GRID_MOTION(wall, domain, dt, time, dtime)
{
    Thread *tf = DT_THREAD (dt);
    face_t f;
    Node *node_p;
    real  x, y, ym, yf, L, k, w, fr, a; /*All of this variables are defined as real, not integer */
    int n;

    SET_DEFORMING_THREAD_FLAG (THREAD_T0 (tf));

    a =  0.0015;
    L = 0.3; /* This is entered as a real number */
    fr =  2.5 * v / L;
    w = 2.0 * Pi*fr;
    k = 2.0 * Pi / lambda;

    begin_f_loop (f, tf)
    {
        f_node_loop (f, tf, n)
        {
            node_p = F_NODE (f, tf, n);
            if (NODE_POS_NEED_UPDATE (node_p))
                {
                    NODE_POS_UPDATED (node_p);
                }
        }
    }
```
\[ x = \text{NODE}_X(\text{node}_p); \]
\[ y = 0.004 - a^* \sin(w^*\text{time})\sin(k^*x)); \]
/*constant value is 0.004 to match the geometry*/

\[ \text{NODE}_Y(\text{node}_p) = y; \]
}
}
end_f_loop(f, tf);
}
******/
/*
*/
/* End of the UDF. */
/*
*/
******/

The code used to average the parameters in five period of simulation run in the MATLAB software is as bellow:

clc
clear all
close all
filename = 'C:\Users\zn3\Desktop\PressureGradientMagnitudes.xlsx';

A = xlsread(filename, 4);
a = size(A);
a = a(1);
for i = 1:a
    x(i) = A(i, 1);
end
for i = 1:a
    y1(i) = A(i, 2);
end
for i = 1:a
    y2(i) = A(i, 3);
end
for i = 1:a
    y3(i) = A(i, 4);
end

for i = 1:a
    y4(i) = A(i, 5);
end

for i = 1:a
    y5(i) = A(i, 6);
end

c3 = 1;
c2 = 0;
c1 = 1;
c = 0;
r = 0;
y_a = 0;
y_b = 0;
c_counter = 0;
for i = 1:a
    r = x(i)
c1
    if r < c1
        c2 = c2 + 1;
y_b = y_b + (y_1(i) + y_2(i) + y_3(i) + y_4(i) + y_5(i)) / 5;
    end
    if r >= c1
        c_counter(c3) = c2;
y_a(c3) = y_b / c2
        c3 = c3 + 1;
y_b = (y_1(i) + y_2(i) + y_3(i) + y_4(i) + y_5(i)) / 5;
c1 = c1 + 1;
c2 = 1;
    end
end
APPENDIX E

FORCE MEASUREMENT PROTOCOLS

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January 14, 2015

Protocol Guide for Tests

A) Instructions on the load cell bench top tests (Proximal and Distal):

1) Pull the wire downwards (as shown in the figure) to the extent that you feel it is absolutely safe for the ureter, and slowly release it back (Fig. E.1).

2) Please go all the way back to zero force.

3) Next, please pull the wire downwards (as shown in the figure) to the extent that you feel you have gone beyond your safety factor, but not quite reached the avulsion stage in your mind, and then slowly release it back.

4) Again, please go all the way back to zero force.

5) Next, please pull the wire downwards (as shown in the figure) to the extent that you definitely feel that you will cause avulsion, and then slowly release it back.

6) Again, please go all the way back to zero force.
Fig. E.1. Load cell bench top test protocol.

B) Instructions on the Pig Ureter (PU) test (Proximal and Distal)

7) Please grasp the stone using the basket handle, as you would do normally in such procedures, and then holding the handle securely, please pull the device (attached to the handle) to the left (as shown in the figure) to the extent that you feel it is absolutely safe for the ureter, and slowly release it back (Fig. E.2).

8) Please go all the way back to zero force.

9) Next, please grasp the stone using the basket handle, as you would do normally in such procedures, and then holding the handle securely, please pull the device (attached to
the handle) to the left (as shown in the figure) to the extent that you feel you have gone beyond your safety factor, but not quite reached the avulsion stage in your mind, and then slowly release it back.

10) Again, please go all the way back to zero force.

11) Next, please grasp the stone using the basket handle, as you would do normally in such procedures, and then holding the handle securely, please pull the device (attached to the handle) to the left (as shown in the figure) to the extent that you definitely feel that you will cause avulsion, and then slowly release it back.

12) Again, please go all the way back to zero force.

![Ex-vivo porcine force measurement test.](image)

**Fig. E.2.** *Ex-vivo* porcine force measurement test.
APPENDIX F
FLOW OF FLUID OVER CYLINDER IN ANSYS FLUENT

The purpose of this appendix is to illustrate the setup and solution of an unsteady flow past a circular cylinder and to study the vortex shedding process [152]. This tutorial was used as validation of the CFD ureter model and the flow over the cylinder stones. The geometry suggests a steady and symmetric flow pattern. For lower value of Reynolds number, the flow is steady and symmetric. Any disturbance introduced at the inlet gets damped by the viscous forces. As the Reynolds number is increased, the disturbance at the upstream flow cannot be damped. This leads to a very important periodic phenomenon downstream of the cylinder, known as `vortex shedding'. A cylinder of unit diameter (Figure 1) was considered. The computational domain consists of an up-stream of 11.5 times the diameter to downstream of 20 times the diameter of the cylinder and 12.5 times the diameter on each cross-stream direction. The Reynolds number of the flow, based on the cylinder diameter, was 150. The lift coefficient as a function of time was calculated in this problem.
The geometry was prepared in the ANSYS software and meshed as shown in Fig. F.2. The boundary layer was resolved around the cylinder. A submap mesh was used in the block containing the cylinder.

This is an unsteady problem in a symmetric geometry. In experiments, uncontrollable disturbances in the inlet flow cause the start of the vortex shedding.
Similarly, in the computational model, the numerical error accumulates and the vortex shedding starts. The materials were set in the software (density of 150 and viscosity of 1). In the next step the boundary conditions were set (velocity for the inlet 1 m/s). The PISO (Pressure Implicit with Splitting of Operator) scheme was set for the Pressure-Velocity Coupling. The PISO allows the use of higher time step size without affecting the stability of the solution. Hence it is the recommended pressure-velocity coupling for solving transient applications. The Second Order Upwind scheme was chosen for the momentum discretization method. The Time Step Size was chosen to be 0.2s. The Strouhal number for flow past cylinder is roughly 0.2. In order to capture the shedding correctly, at least 20 to 25 time steps was chosen in one shedding cycle.

\[
Sr = \frac{f \times D}{U}
\]  

(F.1)

The In this case D=U=1 and therefore the frequency (f) would become 0.2 Hz. And the period would be calculated to be 5 seconds (time step size 0.2s). The number of iterations was set to be 600 (30 iterations per time). The drag forces were set to be reports and also the lift coefficients (Fig. F.3)
Fig. F.3 shows a clear sinusoidal pattern, which is a sign of a sustained vortex shedding process. All the other flow variables also show the asymmetry in the solution. This plot can be used to compute the correct value of Strouhal number. The problem is non-dimensionalized (i.e., $D = U = 1$) and $Sr = f = 1/(\text{shedding cycle time}) = 1/6.52 = 0.153$. The results matches fairly well with the value (0.183) as reported in the literature [156]. The pressure contours were plotted (Fig. F.4). The contour shows a clear asymmetric pattern in the flow. The local pressure minima are the center of the vortices.
The contours of vorticity were plotted. The figure shows clear vortex shedding process (Fig. F.5).

The instantaneous streamline was displayed to see the incipient and shed vortex clearly (Fig. F.6). The contour shows the incipient vortex at the top end and shed vortex
at the bottom end in the wake of the cylinder. Zoom in to get a better view of the shedding process.

![Contours of streamline function.](image)

This simulation demonstrated a classical problem of flow past the cylinder. Different methods like monitor plots and animations were used to track the vortex shedding phenomenon. Additional aspects like choosing time step, using PISO for transient simulation and calculating the Strouhal number were also covered.