Optimization of WSU
Total Ankle Replacement Systems

A thesis submitted in partial fulfillment of the
requirements for the degree of
Master of Science

By

Bradley Jay Elliott
B.S., Wright State University, 2010

2012
Wright State University

Tarun Goswami, D.Sc.
Thesis Director

David B. Reynolds, Ph.D.
Assistant Chair, Department of Biomedical, Industrial, & Human Factors Engineering

Committee on Final Examination

Tarun Goswami, D.Sc.

David B. Reynolds, Ph.D.

Richard T. Laughlin, M.D.

Mary E. Fendley, Ph.D.

Andrew T. Hsu, Ph.D.
Dean, Graduate School
ABSTRACT


Total ankle arthroplasty (TAR) is performed in order to reduce the pain and loss of ambulation in patients with various forms of arthritis and trauma. Although replacement devices fail by a number of mechanisms, wear in the polyethylene liner constitutes one of the dominating failure modes. This leads to instability and loosening of the implant. Mechanisms that contribute to wear in the liners are high contact and subsurface stresses that break down the material over time. Therefore, it is important to understand the gait that generates these stresses. Methods to characterize and decrease wear in Ohio TARs have been performed in this research. This research utilizes finite element analysis of WSU patented total ankle replacement models. From the FEA results, mathematical models of contact conditions and wear mechanics were developed. These models were used to determine the best methods for wear characterization and reduction. Furthermore, optimization models were developed based on geometry of the implants. These equations optimize geometry, thus congruency and anatomical simulations for total ankle implants.
# TABLE OF CONTENTS

## I. INTRODUCTION

## II. BACKGROUND

A. ANKLE JOINT ANATOMY  
B. GAIT  
C. ANKLE BIOMECHANICS  
D. ANKLE JOINT TRAUMA AND DISEASE  
E. EVOLUTION OF TOTAL ANKLE REPLACEMENT MODELS

## III. LITERATURE REVIEW

A. TAR EFFICACY  
   1. AGILITY  
   2. STAR  
   3. BP (BUECHEL-PAPPAS)  
   4. HINTEGRA  
   5. OTHERS  
   6. REVISION MODES  
B. STRESS AND PRESSURE IN TAR UHMWPE BEARINGS  
   1. FEA OF CONTACT AND SUBSURFACE STRESSES  
   2. EXPERIMENTALLY DETERMINED CONTACT STRESSES  
   3. TAR ALIGNMENT AND CONTACT STRESSES  
C. UHMWPE IN TARS  
   1. PROPERTIES  
   2. WEAR RATE
D. MATHEMATICAL CHARACTERIZATION 42
   1. HERTZIAN CONTACT 42
   2. ARCHARD’S WEAR LAW 43

IV. MATERIAL AND METHODS 44
   A. GAIT FORCES 44
   B. FINITE ELEMENT MODELING 48
      1. VISCOELASTIC PARAMETERS 60
   C. MATHEMATICAL WEAR MODELING 64
      1. MAXIMUM CONTACT PRESSURE WITH HERTZIAN CONTACT 64
      2. ARCHARD’S LAW AND FRETTING WEAR 66
   D. STRESS OPTIMIZATION 67

V. RESULTS 68
   A. FINITE ELEMENT ANALYSIS 68
   B. MATHEMATICAL WEAR MODELING 85

VI. STRESS OPTIMIZATION 88
   1. AVERAGE SURFACE STRESS 88
   2. MAXIMUM SURFACE STRESS 92
   3. MAXIMUM CROSS SECTIONAL STRESS 95
   4. AVERAGE CROSS SECTIONAL STRESS 100
   5. STRESS DEPTH 105
   6. FINAL OPTIMIZATION PARAMETERS 109

VII. DISCUSSION 111
   A. FINITE ELEMENT ANALYSIS 111
   B. MATHEMATICAL ANALYSIS OF STRESS AND WEAR RATE 116
   C. OPTIMIZATION OF WSU TARS 117
LIST OF FIGURES

1. Bones and Joints of Ankle Complex .................................................. 5
2. Motions of the Ankle Joints ................................................................. 6
3. Ankle Joint Stresses During Stance Phase of Gait .............................. 11
4. Comparison of the Tensile Strength of Hip and Ankle Cartilage With Respect to Age .......................... 12
5. Fracture of the Fibular Malleolus ....................................................... 14
6. Ankle Joint Fused With Fixation Screws .......................................... 15
7. First generation unconstrained TAR (left); First generation contrained TAR (right) .................. 17
8. Examples of Fixed Bearing TAR (Left - Agility by Depuy Inc.) and mobile bearing TAR (Right – STAR by Small Bones Innovations Inc.) .......................... 18
9. Agility Total Ankle Replacement ...................................................... 21
10. Scandinavian Total Ankle Replacement .......................................... 22
11. BP Total Ankle Replacement ......................................................... 23
12. HINTEGRA Total Ankle Replacement ........................................... 25
13. Graph of Failure Mechanisms ......................................................... 27
14. Contact pressures for each gait position (Agility – top, Mobility – bottom) ........................................... 31
15. Contact stresses in Agility TAR ....................................................... 33
16. Contact stresses at various points during the gait cycle .................... 35
17. Subsurface stresses in various TKR liners ........................................ 36
18. Creep Strain and Relaxation vs. Time ............................................. 39
19. Mathematically determined ankle joint force waveform by Seireg and Arvikar .......................... 45
20. Axial force waveform ................................................................. 45
21. Axial load with respect to percentage of gait at 866.4 N bodyweight ........ 46
22. Actual axial force waveform overlayed with approximate axial gait waveform

23. Implant Design M1 Solid Model

24. Implant Design M2 Solid Model

25. Implant Design M3 Solid Model

26. Implant Design N1 Solid Model

27. Implant Design N2 Solid Model

28. Implant Design N3 Solid Model

29. Implant Design N4 Solid Model

30. M1 articulating surface area, $A_S$

31. M1 force application area, $A_F$

32. M1 condylar arcs (radius of curvature and angle of curvature, $\theta_C$)

33. M1 condylar arc length

34. M1 condyle mid-articulating length

35. Condylar thickness, $T_C$, and cross-sectional area, $A_C$

36. Example of boundary conditions for Model M2

37. 125 kGy Crosslinked UHMWPE Creep Strain at 50° C

38. Normalized Shear Compliance for UHMWPE Data

39. Experimentally Determined UHMWPE Creep vs. Predicted Creep

40. Maximum Mises Stress Model: M1 Material: Ti6Al4V

41. Maximum Mises Stress Model: M1 Material: CoCr

42. Maximum Mises Stress Model: M1 Material: Stainless Steel

43. Maximum Mises Stress Model: M2 Material: Ti6Al4V

44. Maximum Mises Stress Model: M2 Material: CoCr

45. Maximum Mises Stress Model: M2 Material: Stainless Steel

46. Maximum Mises Stress Model: M3 Material: Ti6Al4V

47. Maximum Mises Stress Model: M3 Material: CoCr

48. Maximum Mises Stress Model: M3 Material: Stainless Steel
49. Maximum Mises Stress Model: N1 Material: Ti6Al4V
50. Maximum Mises Stress Model: N1 Material: CoCr
51. Maximum Mises Stress Model: N1 Material: Stainless Steel
52. Maximum Mises Stress Model: N2 Material: Ti6Al4V
53. Maximum Mises Stress Model: N2 Material: CoCr
54. Maximum Mises Stress Model: N2 Material: Stainless Steel
55. Maximum Mises Stress Model: N3 Material: Ti6Al4V
56. Maximum Mises Stress Model: N3 Material: CoCr
57. Maximum Mises Stress Model: N3 Material: Stainless Steel
58. Maximum Mises Stress Model: N4 Material: Ti6Al4V
59. Maximum Mises Stress Model: N4 Material: CoCr
60. Maximum Mises Stress Model: N4 Material: Stainless Steel
61. Model M1 Mises Stresses Through Gait Cycle
62. Model M2 Mises Stresses Through Gait Cycle
63. Model M3 Mises Stresses Through Gait Cycle
64. Model N1 Mises Stresses Through Gait Cycle
65. Model N2 Mises Stresses Through Gait Cycle
66. Model N3 Mises Stresses Through Gait Cycle
67. Model N4 Mises Stresses Through Gait Cycle
68. Average cross-sectional stresses through the width of the liners
69. Maximum cross-sectional stresses through the width of the liners
70. Contact Pressure at Maximum Point
71. Comparison of Contact Pressure for 2nd Generation Ohio TARs
72. Maximum Predicted Contact Pressure
73. Actual vs. Predicted Average Surface Mises Stress
74. Average Mises Stress vs. Articulating Surface Area
75. Average Surface Mises Stress vs. Condylar Angle of Curvature
76. Average Surface Mises Stress vs. Force Application Area
77. Actual Maximum Stress vs. Predicted Maximum Surface Stress

78. Maximum Surface Stress vs. Condylar Angle of Curvature

79. Maximum Surface Stress vs. Force Application Area

80. Actual Maximum Cross-Sectional Stress vs. Predicted Maximum Cross-Sectional Stress

81. Maximum Cross-Sectional Stress vs. Condylar Angle of Curvature

82. Maximum Cross-Sectional Stress vs. Articulating Surface Area

83. Maximum Cross-Sectional Stress vs. Force Application Area

84. Maximum Cross-Sectional Stress vs. Condyle Thickness

85. Actual Average Cross-Sectional Stress vs. Predicted Average Cross-Sectional Stress

86. Average Cross-Sectional Stress vs. Condyle Thickness

87. Average Cross-Sectional Stress vs. Cross-Sectional Area

88. Average Cross-Sectional Stress vs. Force Application Area

89. Average Cross-Sectional Stress vs. Condylar Angle of Curvature

90. Actual Stress Depth vs. Predicted Stress Depth

91. Stress Depth vs. Force Application Area

92. Stress Depth vs. Articulating Surface Area

93. Stress Depth vs. Condylar Angle of Curvature

94. Stress Depth vs. Force Application Area

95. Maximum Surface Stress Comparison

96. Average Surface Stress Comparison

97. Maximum Cross-Sectional Stress Comparison

98. Average Cross-Sectional Mises Stress Comparison

99. Depth of Maximum Stress Comparison

100. Model M1 Mesh

101. Model M2 Mesh

102. Model M3 Mesh
103. Model N1 Mesh
104. Model N2 Mesh
105. Model N3 Mesh
106. Model N4 Mesh

108. Maximum Cross-Sectional Mises Stress Model: M1 Material: CoCr
110. Maximum Cross-Sectional Mises Stress Model: M2 Material: Ti6Al4V
111. Maximum Cross-Sectional Mises Stress Model: M2 Material: CoCr
112. Maximum Cross-Sectional Mises Stress Model: M2 Material: Stainless Steel
114. Maximum Cross-Sectional Mises Stress Model: M3 Material: CoCr
117. Maximum Cross-Sectional Mises Stress Model: N1 Material: CoCr
118. Maximum Cross-Sectional Mises Stress Model: N1 Material: Stainless Steel
119. Maximum Cross-Sectional Mises Stress Model: N2 Material: Ti6Al4V
120. Maximum Cross-Sectional Mises Stress Model: N2 Material: CoCr
121. Maximum Cross-Sectional Mises Stress Model: N2 Material: Stainless Steel
123. Maximum Cross-Sectional Mises Stress Model: N3 Material: CoCr
125. Maximum Cross-Sectional Mises Stress Model: N4 Material: Ti6Al4V
126. Maximum Cross-Sectional Mises Stress Model: N4 Material: CoCr
127. Maximum Cross-Sectional Mises Stress Model: N4 Material: Stainless Steel
LIST OF TABLES

1. Events of the Gait Cycle 7
2. Cancellous Bone Mechanical Properties 9
3. Cortical Bone Mechanical Properties 10
4. Yield Properties of Cortical Bone 10
5. Demographic of Ankle Joint Arthritis 13
6. Long-term Survival Rates: 1st Generation TARs 17
7. Timeline of Total Ankle Replacements 19
8. 2nd Generation Total Ankle Implants 20
9. Synopsis of Implant Efficacy by Type 27
10. In Vivo Wear Rates in Mobile Bearing TARs 41
11. Polynomial Coefficients for Mathematically Determined Gait Waveform 48
12. Geometric Characteristics of TAR Models 56
13. TAR Materials & Properties 56
14. Model Component Element and Node Counts 59
15. Variable Values for Wear Rate Model 66
16. FEA Determined Mises Stresses and Stress Depths 68
17. Contact Pressure Comparison 86
18. Average Contact Pressure Across Entire Gait Cycle 87
19. Yearly Predicted Wear Rates 87
20. Optimized Geometric Parameters and Related Stress Profile 110
I. INTRODUCTION

Cases of arthritis in the ankle joint are far less prevalent than those seen in other joints, such as the hip and knee. In fact, fewer than 7.5% of all patients suffer from some form of ankle arthritis [1]. Still, degenerative conditions such as post-traumatic arthritis (PTA), rheumatoid arthritis (RA), and osteoarthritis (OA) can lead to pain, decreased range of motion in the gait, and general disability [2].

Building on the early successes of total knee replacements (TKRs) and total hip replacements (THRs), total ankle replacements (TARs) were developed in the early 1970’s in order to be a better alternative to ankle arthrodesis for conditions such as PTA and OA. However, where THRs and TKRs had relatively low revision rates even early on, TARs were marred by failures almost from their very inception. Cases of instability, excessive polyethylene wear, and malunion between the bone and implant in first generation models raised questions to the viability of TARs. As a result, arthrodesis or fusion is considered the golden standard for treating ankle joint disorders. It wasn’t until the early 1990’s that a newfound interest for TARs caused researchers to again look toward ways of improving the devices. Stability, increased range of motion (ROM), improved wear characteristics for the polyethylene components, and improved union techniques were all concerns for the next wave of TARs.
Even with vast improvements made to TARs in the past two decades, revision rates continue to be higher than those seen in THRs and TKRs. This is in large part due to the drastically different biomechanical factors affecting the ankle joint, such as the small contact area between the talus and the tibia [66]. This small contact area, along with higher joint reaction forces compared to other joints [41], leads to very high contact stresses in TARs. Coupled with the relatively low yield point and wear resistance of ultra-high molecular weight polyethylene (UHMWPE), these stresses contribute greatly to failures in the TAR liners [129].

Wear in the UHMWPE liners is one of the leading causes of failure causing revision in TARs. One study found that as much as 54% of TAR revision surgeries may be directly or indirectly caused by wear of UHMWPE liners [3]. This is because UHMWPE wear not only contributes to instability in the joint as the surface decays, but it also produces UHMWPE debris that causes osteolysis and aseptic loosening between the bone and the implant [136]. Therefore, it’s important to determine the types and causes of UHMWPE wear in TARs and develop new methodologies for their prevention.

The objective of this research is to better understand the roles that contact stress and pressure play in the wear characteristics of TARs. Finite element analysis (FEA) was performed on seven WSU patented TARs to determine the effect of TAR geometries and resulting contact stresses in each liner. Force loading conditions through the entire ankle gait cycle were applied to the models in order to determine at what moment peak stresses developed in the liners. Viscoelastic parameters from the literature were used with the FEA. FEA was conducted for each of the seven models to determine the acceptability of their materials; CoCr, stainless steel, and Ti6Al4V as talar and tibial components.
A model of the axial loading profile was developed based on data from literature and was coupled with Hertzian contact mechanics to develop a new characteristic model for the maximum contact pressure in TARs. This was then used alongside Archard’s law of wear between two bodies to derive a new wear rate equation that takes into account the maximum contact pressure between the two components, as well as the geometry of the implant.

Finally, several optimization models were developed through linear interpolation from FEA stress data. These models consider geometric characteristics of the TARs and allow for determinations of maximum and average surface stress, maximum and average cross-sectional stress, and stress depth in order to better design future TARs to minimize these factors.

This research was designed with the ultimate goal of being able to characterize and predict the amount of wear in any given TAR and to develop new models based on this research.
II. BACKGROUND

II A. Ankle Joint Anatomy

There are a total of six bones in the ankle joint complex. The two bones of the lower leg, the tibia and the fibula, work together for load bearing and stability of the ankle. The tibia is the primary load-bearing bone of the lower leg and the fibula is responsible for stability of the true ankle joint, called the talocrural joint. Next, the talus is the major articulating bone of the ankle, with interactions between the tibia, the fibula, the calcaneus, and the navicular. The calcaneus below the talus is responsible for posterior stability of the foot and ankle. Finally, the navicular and cuboid articulate with the talus and the calcaneus to provide mid-foot stability.

The ankle is an intricate joint because it is actually a complex comprised of three primary joints that all function in tandem to accomplish normal anatomical motion. The ankle joint complex is made up of the talocrural joint, the midtarsal joint, and the subtalar joint [4]. The talocrural joint is comprised of the talus, the tibia, and the fibula [4]. In this joint the talar dome articulates between the lateral malleolus of the fibula and the medial malleolus of the tibia and acts as a hinge joint. Together, the tibial and fibular malleoli form the tibiofibular articulation. The multiaxial articulation between the talus and the calcaneus make up the subtalar joint. Finally the midtarsal joint, also called the transverse tarsal joint, is a complex comprised of the talonavicular and the calcaneocuboid joints. The talonavicular joint, formed by the interaction between the talus and the navicular, acts as another multiaxial joint, while the calcaneocuboid joint,
which is made up from the articulation between the calcaneus and the cuboid, acts like a biaxial saddle joint [4]. Figure 1 illustrates the bones of the foot as well as its joints.

![Bones of the Foot](image_url)

**Figure 1:** Bones and Joints of Ankle Complex [5]

The large ROM that the ankle joint is capable of articulating through also leads to its increased complexity when compared to other musculoskeletal joints. The ankle joint is responsible for plantarflexion and dorsiflexion (PD) of the foot, as well as inversion and eversion (IE) and abduction and adduction (BD). Furthermore, all these axial movements combine into a fourth triaxial set of motions called pronation and supination (PS). Each sub-joint of the ankle complex articulates with a combination of these
motions and together they make up the overall ROM of the joint. The talocrural joint is primarily responsible for DP, allowing for seventy degrees of rotation during passive articulation and fifteen degrees of DP during the stance phase of a normal walking gait cycle [6]. Coupled with DP, the talocrural joint is also responsible for approximately five degrees of BD [7]. This is largely due to the shape of the talar dome, which can be approximated as conical in nature. Because the medial radius of curvature of the talar dome is slightly smaller than that of the lateral radius, the axis of rotation becomes shifted slightly into the frontal plane [8]. Therefore, the overall motion created by the talocrural joint is said to be either dorsiflexion-abduction or plantarflexion-adduction.

The subtalar and midtarsal joints combine to be the primary source of IE in the ankle [7], with the subtalar joint being responsible for roughly eight degrees of DP, eight degrees of PS, and eleven degrees of IE [9]. These joints are the primary adaptive articulators in the ankle, allowing for motion to be adjusted for uneven surfaces [10]. Figure 2 shows the magnitude of DP and IE in the ankle joint over the course of the stance phase of the gait cycle.

Figure 2: Motions of the Ankle Joints [11]
II B. Gait

During normal walking, the joints of the ankle articulate with respect to the foot’s motion. The gait cycle refers to the entire course of one walking step, from heel strike of one foot to the heel strike of the other foot [11]. The gait cycle can be broken up into two main phases, the swing phase and the stance phase [44]. The swing phase refers to the act of lifting the foot and swinging the leg while the stance phase refers to the time when the foot is planted on the ground (Fig. 2).

Table 1: Events of the Gait Cycle

<table>
<thead>
<tr>
<th>Event</th>
<th>% Gait Cycle</th>
<th>Period</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foot Strike</td>
<td>0</td>
<td>Initial double limb support</td>
<td>Stance (62%)</td>
</tr>
<tr>
<td>Opposite Foot-off</td>
<td>12</td>
<td></td>
<td>Single limb support</td>
</tr>
<tr>
<td>Opposite Foot Strike</td>
<td>50</td>
<td></td>
<td>Second double limb support</td>
</tr>
<tr>
<td>Foot-off</td>
<td>62</td>
<td></td>
<td>Initial swing</td>
</tr>
<tr>
<td>Foot Clearance</td>
<td>75</td>
<td></td>
<td>Mid swing</td>
</tr>
<tr>
<td>Tibia Vertical</td>
<td>85</td>
<td></td>
<td>Terminal swing</td>
</tr>
<tr>
<td>Second Foot Strike</td>
<td>100</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Adapted from Rose and Gamble [44]
Table 1 shows the events of the gait cycle, beginning with the point of heel strike, called the foot strike, and ending with the second foot strike. It also shows how the different events correlate to each phase. The stance phase of the gait cycle is of much more significance when observing the ankle joint complex than the swing phase because the joint is only loaded during this phase of the cycle.

During the stance phase, the talocrural joint articulates with approximately twenty five degrees of DP; with about fifteen degrees of that being plantarflexion and ten degrees being dorsiflexion [11]. The ankle joint is in a state of plantarflexion during the footstrike event, as the heel contacts with the ground. The angle of plantarflexion in the talocrural joint decreases through the footstrike event until the foot is flat on the ground and the joint is considered to be in a neutral position. During the same course of events, the subtalar and midtarsal joints evert. Next, the ankle joint shifts from being neutral to being increasingly more dorsiflexed, as weight is shifted toward the front of the foot. This occurs at approximately 40% of the gait cycle. Dorsiflexion of the talocrural joint continues increasing until the opposite foot strike. At that point, dorsiflexion begins to sharply decrease toward a neutral joint position and then the foot plantarflexes directly prior to foot-off [44]. Also, the subtalar and midtarsal joints invert, such that the joint becomes rigid during foot-off [45].

II C. Ankle Biomechanics

The bones of the ankle complex are comprised of cortical and cancellous bone tissue. Cortical bone is often described as dense and compacted, while cancellous bone is more spongy and porous. However, even while their structures are different, cortical and
Cancellous bone tissues are biologically the same [12]. A theory presented by Wolff, known as now as Wolff’s law postulates that cortical bone is the compressed state of cancellous bone in response to high stresses experienced during loading [13]. This theory is largely disputed by researchers, though [10]. Because of their differing structures, cortical bone and cancellous bone have very different material properties from each other. According to a study by Rho [14], cancellous bone in the tibia was found to have a significantly higher average elastic modulus than that of cortical bone. Tables 2-4 tabulate the mechanical and yield properties of cortical and cancellous bone. The tables show that cortical bone has a much higher yield and ultimate strain when compared to cancellous bone but is less elastic in comparison.

<table>
<thead>
<tr>
<th>Reference</th>
<th>Bone</th>
<th>( \varepsilon_y ) (%)</th>
<th>( \varepsilon_u ) (%)</th>
<th>E (MPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Compression</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Keavenly[15]</strong></td>
<td>Bovine Tibia</td>
<td>1.08</td>
<td>1.86</td>
<td>2380</td>
</tr>
<tr>
<td><strong>Morgan[16]</strong></td>
<td>Human Tibia</td>
<td>0.73</td>
<td>N/A</td>
<td>1091</td>
</tr>
<tr>
<td><strong>Morgan[16]</strong></td>
<td>Great. Trochanter</td>
<td>0.70</td>
<td>N/A</td>
<td>622</td>
</tr>
<tr>
<td><strong>Morgan[16]</strong></td>
<td>Human Vertebra</td>
<td>0.77</td>
<td>N/A</td>
<td>344</td>
</tr>
<tr>
<td><strong>Morgan[16]</strong></td>
<td>Femoral Neck</td>
<td>0.83</td>
<td>N/A</td>
<td>3230</td>
</tr>
<tr>
<td><strong>Fyhrie [17]</strong></td>
<td>Human Vertebra</td>
<td>0.67</td>
<td>1.5</td>
<td>500</td>
</tr>
<tr>
<td><strong>Kopperdahl [18]</strong></td>
<td>Human Vertebra</td>
<td>0.81</td>
<td>1.45</td>
<td>219</td>
</tr>
<tr>
<td><strong>Linde [19]</strong></td>
<td>Knee</td>
<td>N/A</td>
<td>2.0</td>
<td>408</td>
</tr>
<tr>
<td><strong>Tension</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Keavenly[15]</strong></td>
<td>Bovine Tibia</td>
<td>0.78</td>
<td>1.37</td>
<td>2630</td>
</tr>
<tr>
<td><strong>Morgan[16]</strong></td>
<td>Human Tibia</td>
<td>0.65</td>
<td>N/A</td>
<td>1068</td>
</tr>
<tr>
<td><strong>Morgan[16]</strong></td>
<td>Great. Trochanter</td>
<td>0.61</td>
<td>N/A</td>
<td>597</td>
</tr>
<tr>
<td><strong>Morgan[16]</strong></td>
<td>Human Vertebra</td>
<td>0.70</td>
<td>N/A</td>
<td>349</td>
</tr>
<tr>
<td><strong>Kopperdahl [18]</strong></td>
<td>Human Vertebra</td>
<td>0.78</td>
<td>1.59</td>
<td>301</td>
</tr>
<tr>
<td><strong>Shear</strong></td>
<td></td>
<td></td>
<td>G (MPa)</td>
<td></td>
</tr>
<tr>
<td><strong>Ford [20]</strong></td>
<td>Bovina Tibia</td>
<td>1.35</td>
<td>4.24</td>
<td>349</td>
</tr>
</tbody>
</table>

* Adapted from Galik [10]
Table 3: Cortical Bone Mechanical Properties

<table>
<thead>
<tr>
<th>Reference</th>
<th>Estimated E (GPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Runkle and Pugh [21]</td>
<td>8.69 ± 3.17 (dry)</td>
</tr>
<tr>
<td>Townsend et al. [22]</td>
<td>11.38 (wet)</td>
</tr>
<tr>
<td>Williams and Lewis [23]</td>
<td>1.30</td>
</tr>
<tr>
<td>Ashman and Rho [24]</td>
<td>12.7 ± 2.0 (wet)</td>
</tr>
<tr>
<td>Ryan and Williams [25]</td>
<td>0.76 ± 0.39</td>
</tr>
<tr>
<td>Hodgkinson et al. [26]</td>
<td>15 (estimated)</td>
</tr>
<tr>
<td>Kuhn et al. [27]</td>
<td>3.81 (wet)</td>
</tr>
<tr>
<td>Mente and Lewis [28]</td>
<td>7.8 ± 5.4 (wet)</td>
</tr>
<tr>
<td>Choi et al. [29]</td>
<td>5.35 ± 1.36 (wet)</td>
</tr>
<tr>
<td>Rho et al. [30]</td>
<td>10.4 ± 3.5 (dry)</td>
</tr>
<tr>
<td>Rho et al. [31]</td>
<td>14.8 ±1.4 (wet)</td>
</tr>
<tr>
<td></td>
<td>19.6 ± 3.5 (dry)</td>
</tr>
<tr>
<td></td>
<td>15.0 ± 3.0 (dry)</td>
</tr>
</tbody>
</table>

* Adapted from Rho et al. [12]

Table 4: Yield Properties of Cortical Bone

<table>
<thead>
<tr>
<th>Reference</th>
<th>Bone</th>
<th>( \varepsilon_y ) (%)</th>
<th>( \varepsilon_u ) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tibia</td>
<td>6.9 (compression)</td>
<td>11.6 (compression)</td>
</tr>
<tr>
<td>Mosekilde [33]</td>
<td>Vertebrae</td>
<td>N/A</td>
<td>7.4 (compression)</td>
</tr>
<tr>
<td>Hansson [34]</td>
<td>Vertebrae</td>
<td>6.0 (compression)</td>
<td>7.4 (compression)</td>
</tr>
<tr>
<td>Turner [35]</td>
<td>Bovine Distal Femur</td>
<td>1.24 (compression)</td>
<td>N/A</td>
</tr>
<tr>
<td>Kopperdahl [18]</td>
<td>Bovine Distal Femur</td>
<td>0.81 (compression)</td>
<td>1.45 (compression)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.78</td>
<td>1.59</td>
</tr>
<tr>
<td>Rohl [36]</td>
<td>Vertebrae</td>
<td>N/A</td>
<td>1.55 (tension)</td>
</tr>
<tr>
<td>Keavenly [15]</td>
<td>Bovine Proximal Tibia</td>
<td>0.78 (tension)</td>
<td>1.37 (tension)</td>
</tr>
</tbody>
</table>

* Adapted from Kopperdahl [18]

The articulating surfaces of the bones in the ankle joint are lined by a cartilage membrane that is meant to decrease friction during movement. Furthermore, the joint is a synovial one, meant to further decrease friction and reduce wear of the joint’s articulating surfaces. Morrison reported that the coefficient of friction in a normal synovial joint ranges from 0.002-0.04 [37]. The cartilage that lines the ankle joint is only about 1.6 mm
thick and is significantly thinner than cartilage in the knee, which is approximately 6-8 mm [38]. Along those same lines, the articulating surface area between the tibia and the talus is only roughly 440 mm$^2$ [38]. This is much smaller than the contact area on the articulating surface of the knee, which is approximately 1150 mm$^2$ [39].

Loads acting on the ankle joint are much larger than those acting on the hip and knee. While the knee and hip experience maximum loads that are roughly three to four times a person’s body weight (BW), respectively, the ankle joint can see as much as six times BW during a normal walking gait cycle [41]. These high forces, coupled with the small contact area of tibiotalar joint leads to contact pressures ranging from 9 MPa to 13 MPa according to Anderson et al. [43] and Kimizuka, et al [42]. Compared to the average pressure found in the knee, 3 to 4 MPa, the ankle is under much more stress compared to other joints [40]. Figure 3 shows simulated stresses acting on the ankle joint during the stance phase of the gait cycle.

![Figure 3: Ankle Joint Stresses During Stance Phase of Gait](image_url)
II D. Ankle Joint Trauma and Disease

One would imagine that such high contact pressures on the ankle joint would lead to a high incidence of primary arthritis caused by wear of the articulating surfaces. However, this is surprisingly not the case. Saltzman, et al. found that only 48 out of 639 arthritis cases during a one year period were of the ankle joint [1]. According to Buckwalter and Saltzman, the discrepancy between arthritis in the ankle joint versus the hip and knee joints has a great deal to do with the how resilient ankle cartilage is compared to that in other joints [46]. They postulate that ankle cartilage retains its tensile and fractural properties in response to aging, and thus osteoarthritis is not as prevalent in the ankle joint. This theory compares favorably to another study done by Kempson, showing that while the tensile strength of hip cartilage decreased from 33 MPa to 16 MPa from age 7 to age 60, the tensile strength of ankle cartilage only decreased from 24 MPa to 20 MPa over similar time period [51]. Figure 4 illustrates how the tensile strength of ankle cartilage generally decreases with age at a much slower rate than it does in hip and knee joints.

![Figure 4: Comparison of the Tensile Strength of Hip and Ankle Cartilage With Respect to Age [52]](image-url)
Even though ankle arthritis occurs less often than arthritis in other joints, it typically occurs in younger patients and is more likely to be caused by some secondary factor, such as traumatic injury [1].

Table 5: Demographic of Ankle Joint Arthritis[3]

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Mean Age (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RA</td>
<td>216</td>
<td>57 (13)</td>
</tr>
<tr>
<td>OA</td>
<td>119</td>
<td>61 (11)</td>
</tr>
<tr>
<td>PtA</td>
<td>175</td>
<td>56 (12)</td>
</tr>
<tr>
<td>Other</td>
<td>21</td>
<td>58(13)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>531</strong></td>
<td><strong>58 (13)</strong></td>
</tr>
</tbody>
</table>

Table 5 shows the demographic of ankle arthritis in 531 people who received total ankle replacements in Sweden between 1993 and 2005. Out of these cases, 33% were seen for ankle arthritis caused by some traumatic incident such as a fracture. This is only second to those patients with rheumatoid arthritis, coming in at just under 41% of those studied. However, the total percentage of post-traumatic arthritis sufferers reported by Henrickson, et al. [3] was much less than that reported by Saltzman, et al., [1] who found that as much as 70% of all arthritis is caused by some form of trauma to the ankle joint.

Injuries that may lead to post-traumatic arthritis of the ankle joint include fractures of the tibial plafond and talus, as well to the malleoli. Damage of the talar dome condyles is also a possible cause of arthritis [47]. Figure 5 shows fracturing to the fibular malleolus in an ankle joint.
According to Lindsjo, malleolar fracture contributes to arthritis in 14% of cases [49]. Furthermore, fracture of the tibial plafond has a high rate of arthritic occurrence due to the high probability of cartilage damage [48]. In fact, according to a study conducted by Marsh et al., severity of the cartilage injury is directly related to the severity of ankle joint arthritis [50].

Treatments for ankle joint arthritis range from non-operative methods such as orthotics, anti-inflammatories, and modifications to the patient’s footwear to cortisosteroid injections at the joint [47]. However, these methods are rarely a lasting solution to the problem. Eventually, ankle joint arthrodesis or total ankle arthroplasty may be considered as a more invasive option to limiting pain and disability due to ankle arthritis. Ankle arthrodesis consists of removing the articulating cartilage and fusing the
joint by way of some fixation method like screws and plates [10] as illustrated in Figure 6. This procedure is done in order to relieve pain and correct deformities of the ankle joint. However, it has the added side effect of greatly diminishing the ROM in the joint, particularly decreasing DP and PS in the talocrural joint [52]. In response to the decreased ROM, the subtalar and midtarsal joints compensate [53]. The result of this overcompensation is increased stress on the subtalar and midtarsal joints, which leads to increased articular surface wear and more arthritis [54]. While ankle arthrodesis has often been described as “the golden standard” for treating ankle arthritis [56], there are several associated complications such as the previously discussed overcompensation and drastically decreased ROM, as well as pseudoarthrosis and infection [55]. For these reasons, alternatives that would allow most ROM to be kept and still diminish pain and disability, such as total ankle arthroplasties, have widely been sought by researchers.

Figure 6: Ankle Joint Fused With Fixation Screws [47]
II E. Evolution of Total Ankle Replacement Models

In light of the successes researchers had with total hip and total knee implants, the logical next step was to develop a total ankle implant that would provide the ROM that arthrodesis didn’t, while also providing stability and integrity [57]. The first total ankle devices were designed and implanted by Lord in the early 1970’s [58]. Lord used inverted total hip implants for these surgeries [56]. These first implants were largely two component, cemented designs and were either constrained or unconstrained [56]. Versions of constrained can unconstrained implants are illustrated in Figure 7. Constraint refers to the implant’s ability to resist displacement and rotation when a force acts upon it [130]. Unconstrained implants, which generally had incongruent (geometrically dissimilar) tibial and talar components, allowed for much greater ROM but were largely unstable and had poor wear characteristics due to the small point loads they were under. Constrained designs, however, had a more congruent shape that was more spheroid of cylindrical. These designs sacrificed ROM for stability and more even loading conditions [59]. As a result, constrained implants showed promise early on but were abandoned due to their tendency to loosen at the bone-implant interface because of the high torsional stresses caused by the increased constraint [56]. Unfortunately, researchers found very little long-term success for early ankle implants, with survival rates ranging from 65% to as low as 10% over the course of ten years [56]. Table 6 shows the long-term survival rates of several early total ankle implants, as compiled by Jackson and Singh.
Table 6: Long-term Survival Rates: 1st Generation TARs

<table>
<thead>
<tr>
<th>Prosthesis</th>
<th>Author &amp; Year</th>
<th>Number</th>
<th>Av. Follow-up Time (years)</th>
<th>Survival Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mayo (Constrained)</td>
<td>Kitaoka (1994) [60]</td>
<td>204</td>
<td>5</td>
<td>79</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>10</td>
<td>65</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>15</td>
<td>61</td>
</tr>
<tr>
<td>ICLH (Constrained)</td>
<td>Bolton-Maggs (1985) [61]</td>
<td>62</td>
<td>5.5</td>
<td>47</td>
</tr>
<tr>
<td>TPR (Constrained)</td>
<td>Jenson (1992) [62]</td>
<td>23</td>
<td>4.9</td>
<td>48</td>
</tr>
<tr>
<td>Conaxial (Constrained)</td>
<td>Wynn and Wilde (1992) [63]</td>
<td>30</td>
<td>2</td>
<td>73</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>5</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Newton (Unconstrained)</td>
<td>Newton (1982) [64]</td>
<td>50</td>
<td>3.4</td>
<td>78</td>
</tr>
<tr>
<td>Smith (Unconstrained)</td>
<td>Dini (1980) [65]</td>
<td>21</td>
<td>2.3</td>
<td>93</td>
</tr>
</tbody>
</table>

*Adapted from Jackson & Singh [56]

Figure 7: First generation unconstrained TAR (left); First generation constrained TAR (right) [7]
Due to very little overall success with first generation TARs, researchers typically recommended joint arthrodesis because of its proven viability [66]. This line of thought continued for several years. However, with the second generation of TARs researchers believed that they could design an implant that would better mimic the ankle joint’s anatomy, kinematics, ligament stability, and alignment [47]. Based on these ideas and with a much greater consideration for the role of the bearing surface, two types of second generation TAR were developed; mobile and fixed bearing devices. Fixed bearing devices have their meniscal bearings fixed to the tibial component such that they act as a single unit. Typically, these implants have an articulating groove that is wider than talar component, which allows for slight IE of the ankle joint without it being entirely unconstrained. Also, the talar component is wider on its anterior side to increase stability during dorsiflexion [66]. Some of the TARs that fit into this category are Agility (Figure 8 – left), INBONE, Eclipse, SALTO Talaris, and ESKA [66].

**Figure 8:** Examples of Fixed Bearing TAR (Left - Agility by Depuy Inc.) [68] and mobile bearing TAR (Right - S.T.A.R. by Small Bones Innovations Inc.) [69]
Mobile bearing devices, however, do not have fixed meniscal bearings. They typically have flat, unconstrained upper surfaces that allow for IE. The lower surface of the bearing is concentric with the talar component to promote DP [66]. Some examples of mobile bearing TARs include STAR (Figure 8 – right), Mobility, AES, Hintegra, and LCS [7]. Table 7 provides a brief history of TARs from their inception to the present.

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Year</th>
<th>Event</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1970’s</td>
<td>1970</td>
<td>Lord implants the first TAR from a modified total hip implant [58]</td>
<td>Unconstrained</td>
</tr>
<tr>
<td></td>
<td>1972</td>
<td>Smith TAR first used [59]</td>
<td>Unconstrained</td>
</tr>
<tr>
<td></td>
<td>1972</td>
<td>Imperial College of London Hospital (ICLH) TAR first used [67]</td>
<td>Constrained</td>
</tr>
<tr>
<td></td>
<td>1973</td>
<td>8 St. Georg TARs implanted before abandonment [67]</td>
<td>Semiconstrained</td>
</tr>
<tr>
<td></td>
<td>1973</td>
<td>Newton TAR is first used [59]</td>
<td>Unconstrained</td>
</tr>
<tr>
<td></td>
<td>1974</td>
<td>Conaxial first used [59]</td>
<td>Constrained</td>
</tr>
<tr>
<td></td>
<td>1974</td>
<td>New Jersey TAR first implanted [67]</td>
<td>Constrained</td>
</tr>
<tr>
<td></td>
<td>1975</td>
<td>Irvine TAR introduced [59]</td>
<td>Unconstrained</td>
</tr>
<tr>
<td></td>
<td>1976</td>
<td>Thompson-Richard (TPR) prosthesis is first implanted [59]</td>
<td>Unconstrained</td>
</tr>
<tr>
<td></td>
<td>1976</td>
<td>First generation Mayo implant introduced [59]</td>
<td>Unconstrained</td>
</tr>
<tr>
<td></td>
<td>1978</td>
<td>Polyethylene bearing is added to New Jersey TAR – becomes LCS implant (Low Contact Stress) [67]</td>
<td>Unconstrained</td>
</tr>
<tr>
<td>1980’s</td>
<td>1981</td>
<td>Two-component STAR device first used [67]</td>
<td>Unconstrained</td>
</tr>
<tr>
<td></td>
<td>1984</td>
<td>Bath-Wessex TAR first implanted [59]</td>
<td>Unconstrained</td>
</tr>
<tr>
<td></td>
<td>1984</td>
<td>Agility TAR is introduced [59]</td>
<td>Semiconstrained</td>
</tr>
<tr>
<td></td>
<td>1986</td>
<td>STAR implant is introduced [59]</td>
<td>Unconstrained</td>
</tr>
<tr>
<td></td>
<td>1989</td>
<td>Second Generation Mayo TAR first used [59]</td>
<td>Semiconstrained</td>
</tr>
<tr>
<td></td>
<td>1989</td>
<td>BP (Buechel-Pappas) TAR is introduced [67]</td>
<td>Unconstrained</td>
</tr>
<tr>
<td>1990’s</td>
<td>1990</td>
<td>ESKA implant first used in Germany [67]</td>
<td>Unconstrained</td>
</tr>
<tr>
<td></td>
<td>1992</td>
<td>Agility TAR receives FDA approval [67]</td>
<td>Unconstrained</td>
</tr>
<tr>
<td></td>
<td>1997</td>
<td>SALTO mobile bearing device introduced in France [67]</td>
<td>Unconstrained</td>
</tr>
<tr>
<td>2000’s</td>
<td>2000</td>
<td>HINTEGRA TAR introduced [67]</td>
<td>Unconstrained</td>
</tr>
<tr>
<td></td>
<td>2002</td>
<td>Mobility TAR begins use in Europe/New Zealand/US [67]</td>
<td>Unconstrained</td>
</tr>
<tr>
<td></td>
<td>2003</td>
<td>BOX TAR introduced in Italy [67]</td>
<td>Unconstrained</td>
</tr>
<tr>
<td></td>
<td>2005</td>
<td>INBONE TAR begins use in US/New Zealand and receives FDA approval [135]</td>
<td>Unconstrained</td>
</tr>
<tr>
<td></td>
<td>2006</td>
<td>SALTO fixed bearing implant receives FDA approval and begins US use [135]</td>
<td>Unconstrained</td>
</tr>
<tr>
<td></td>
<td>2007</td>
<td>Eclipse implant receives FDA approval and begins use in the US [135]</td>
<td>Unconstrained</td>
</tr>
<tr>
<td></td>
<td>2009</td>
<td>STAR device becomes first FDA approved mobile bearing TAR [134]</td>
<td>Unconstrained</td>
</tr>
</tbody>
</table>
III. LITERATURE REVIEW

III. A. TAR Efficacy

In the United States there are only a handful of TARs that have been approved for clinical use by the FDA. These five implants are Agility, INBONE, Salto Talaris, Eclipse, and STAR [7]. Out of these, the STAR implant is the only one featuring a mobile bearing design and was only approved in 2009 [70]. However, there are several other designs being researched in parts of Europe and Japan. Several of these implants can be found in Table 8 with their dates of original use and regions of use.

<table>
<thead>
<tr>
<th>Implant</th>
<th>Region of Use</th>
<th>Date of Initial Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agility [71]</td>
<td>USA/ New Zealand/ Switzerland</td>
<td>1984</td>
</tr>
<tr>
<td>INBONE [72]</td>
<td>USA/ New Zealand</td>
<td>2005</td>
</tr>
<tr>
<td>SALTO Talaris [73]</td>
<td>USA</td>
<td>2006</td>
</tr>
<tr>
<td>Eclipse [74]</td>
<td>USA</td>
<td>2007</td>
</tr>
<tr>
<td>STAR [75]</td>
<td>USA/Europe</td>
<td>1981</td>
</tr>
<tr>
<td>Mobility [75]</td>
<td>Europe/New Zealand/USA</td>
<td>2002</td>
</tr>
<tr>
<td>BOX [76]</td>
<td>Italy</td>
<td>2003</td>
</tr>
<tr>
<td>HINTEGRA [77]</td>
<td>Switzerland/Scandanavia/ Canada/ South America</td>
<td>2000</td>
</tr>
<tr>
<td>BP [78]</td>
<td>USA/Europe</td>
<td>1989</td>
</tr>
</tbody>
</table>

*Adapted from Gougoulias et al. [67]
III A. 1. Agility

**Figure 9:** Agility Total Ankle Replacement [67]

In a study conducted by Spirt, et al., the average survival of 306 Agility TAR devices (Figure 9) over the course of five years was 80% [79]. They also found that the two primary causes of failure in the Agility devices were aseptic loosening of the talar component and infection.

These results are similar to those found by Hosman, et al., who found that after thirty two months, nine Agility TARs failed out of a total of 117 patients [80]. These findings also corroborate those by Spirt, et al. in that the main failure modes were again either aseptic loosening of either the tibial or talar component or infection [79].

In another study of 132 Agility TARs, it was found that fourteen (11%) of the devices failed. Knecht, et al. found that out of the fourteen failed implants, four patients suffered from aseptic loosening of the device, two devices were removed because their tibial components fractured, and five devices were revised secondary to compaction.

21
Furthermore, one device was removed due to infection while another was revised due to misalignment of the talar component. The last patient was lost before follow-up of their revision surgery [71].

III A. 2. STAR

Figure 10: Scandinavian Total Ankle Replacement [67]

A study of 200 STAR implants (Figure 10) was conducted by Wood and Deakin to determine the complications associated with the device. They found that out of the 200 arthroplasties performed using the 200 STAR implants fourteen failed (7%) and required either a new prosthesis or an ankle arthrodesis. Out of the fourteen cases, one implant failed due to deep infection, two were revised due to fracture of the medial malleolus, and two were removed because of cavitation in the bone around the implant. Another six implants failed due to aseptic loosening and migration of either component and three more devices were removed and the ankle fused because of pain [82].

In another study of the long-term results of eighty six STAR devices implanted from 1998 to 2000, Mann et al. found that eleven (14%) of the eighty six implants
required some form of revision or removal. The reasons for secondary surgery include two cases of aseptic loosening, two cases of osteolysis at the bone-implant interface, one instance of fracture of the polyethylene insert, one occurrence where the talar component was loose, subsidence in three patients, and medial malleolar fracture in two patients [81].

Hosman, et al.’s study of New Zealand National Joint Registry found that out of forty five STAR devices implanted over six years, only three had failed (7%). The reasons for failure were for loosening of the talar component in one case, loosening of the tibial component in another case, and pain in the third case [80].

III A. 3. BP (Buechel-Pappas)

![Figure 11: BP Total Ankle Replacement](image)

According to Henricson, et al. out of 531 TARs implanted from 1993 to 2005 in Sweden, ninety two of those were uncemented BP implants (Figure 11). Out of those ninety two patients with the implanted devices, a total of sixteen had at least one revision surgery. The reasons for revision are as follows: one for aseptic loosening, one due to
technical error, eight because of instability, one as a result of infection, three because of intractable pain, one due to PE wear, and one as a result of painful varus. Another point of interest here is that none of the revision surgeries were due to fracture according to this study [3].

In a six year study by Wood et al., 100 patients were implanted with BP devices. The researchers found that twelve of the devices failed as early as the first three years of implantation. Out of the twelve patients with failed implants, five suffered from aseptic loosening and subsequently underwent ankle arthrodesis. Four patients had recurrent deformities and one patient had a broken tibial implant that also required ankle fusion. Revisions of the initial implant were carried out for two patients, both with recurrent deformities [83].

Finally, in a study of thirty five patients with the BP implants Ali et al. found that only one of the devices failed (3%) after three years of implantation. The patient suffered from persistent pain from the time of implantation in 1999. Subsequently, a cemented tibial component was inserted in 2002. However, the pain persisted and the implant was removed in favor of fusion of the joint in 2003 [84].
III A. 4. HINTEGRA

Figure 12: HINTEGRA Total Ankle Replacement [67]

The HINTEGRA implant (Figure 12), in use since 2000, was implanted into a total of 122 ankles in the study conducted by its designers, Hintermann, et al. According to this study, there were a total of eight revisions over the course of three years. They found that out of those eight revisions, four were performed because of loosening of at least one of the components. One was revised due to dislocation of the polyethylene liner and the rest were performed for various other reasons not specified [77].

According to Henricson et al.’s 2007 study, they found that out of twenty nine HINTEGRA implants, four were revised (14 %). These revisions were performed for aseptic loosening (two cases), technical error (one case), and instability (one case) [3].
III A. 5. Others

Both the New Zealand and Swedish Arthroplasty Registers conducted short-term studies on the efficacy of Mobility TARs. Both studies found that no revisions had been conducted as of 2005 [3, 80]. Of interesting note is that the Mobility device is currently undergoing trials in the United States in order to obtain FDA approval [67].

According to Gougoulias et al., as of 2009 there were no results available for INBONE, Eclipse, or SALTO Talaris implants. However, all three implants have been used in the USA, with SALTO Talaris receiving FDA approval in 2006 [67].

III A. 6. Revision Modes

Table 9 gives a synopsis of all the devices discussed, as well as their causes for revision. Figure 13 details the overall causes for revision for all implants. The average failure rate for all implants based on this data is 9.5%. Also, it’s clear from Figure 13 that the majority of revisions occur because of component loosening, which may be the result of several different mechanisms, including malunion due to wear debris at the bone-joint interface.
Figure 13: Graph of Failure Mechanisms

<table>
<thead>
<tr>
<th>Implant Type</th>
<th>Author</th>
<th>N</th>
<th>Failures, N (%)</th>
<th>Revision Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agility</td>
<td>Spirt, et al.</td>
<td>306</td>
<td>33 (10.8)</td>
<td>22 Loosening</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5 Infection</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 Subsidence</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5 Unknown</td>
</tr>
<tr>
<td></td>
<td>Hosman, et al.</td>
<td>117</td>
<td>9 (8)</td>
<td>7 Loosening</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 Varus Malalignment</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 Infection</td>
</tr>
<tr>
<td></td>
<td>Knecht, et al.</td>
<td>132</td>
<td>14 (11)</td>
<td>4 Aseptic Loosening</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2 Tibial Component Fracture</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5 Compaction</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 Infection</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 Talar Component Misalignment</td>
</tr>
<tr>
<td>STAR</td>
<td>Mann, et al. [81]</td>
<td>BP</td>
<td>HINTEGRA</td>
<td></td>
</tr>
<tr>
<td>------------</td>
<td>-------------------</td>
<td>---------------</td>
<td>--------------</td>
<td></td>
</tr>
<tr>
<td>wood &amp; Deakin [82], 200, 14 (7)</td>
<td>1 infection</td>
<td>3 pain</td>
<td>1 pain</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 fracture of the medial malleolus</td>
<td>2 fracture of the medial malleolus</td>
<td>1 talar component loosening</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6 aseptic loosening</td>
<td>2 bone cavitation</td>
<td>1 component loosening</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 bone cavitation</td>
<td>2 osteolysis</td>
<td>polyethylene liner dislocation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 pain</td>
<td>3 subsidence</td>
<td>3 intractable pain</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 fracture of the polyethylene insert</td>
<td>3 tibial component loosening</td>
<td>1 PE wear</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 talar component was loose</td>
<td>1 technical error</td>
<td>1 painful varus</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 medial malleolar fracture</td>
<td>8 instability</td>
<td>5 aseptic loosening</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 osteolysis</td>
<td>3 intractable pain</td>
<td>6 recurrent deformities</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 aseptic loosening</td>
<td></td>
<td>1 broken tibial implant</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 pain</td>
<td></td>
<td>1 pain</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 talar component loosening</td>
<td></td>
<td>4 component loosening</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 tibial component loosening</td>
<td></td>
<td>1 polyethylene liner dislocation</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3 other</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2 aseptic loosening</td>
<td></td>
</tr>
</tbody>
</table>

**BP**

- **Henricson, et al. [3], 92, 16 (17)**
  - 1 aseptic loosening
  - 1 technical error
  - 8 instability
  - 3 intractable pain
  - 1 PE wear
  - 1 painful varus
  - 5 aseptic loosening

- **Wood et al. [83], 100, 12 (12)**
  - 6 recurrent deformities
  - 1 broken tibial implant

- **Ali et al. [84], 35, 1 (3)**
  - 1 pain

**HINTEGRA**

- **Hintermann, et al. [77], 122, 8 (7)**
  - 4 component loosening
  - 1 polyethylene liner dislocation
  - 3 other

- **Henricson et al. [3], 29, 4 (14)**
  - 2 aseptic loosening
<table>
<thead>
<tr>
<th>Mobility</th>
<th>Hosman, et al. [80]</th>
<th>29</th>
<th>0</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Henricson, et al. [3]</td>
<td>23</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>INBONE</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Eclipse</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>SALTO Talaris</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

III B. Stress and Pressure in TAR UHMWPE Bearings

Understanding why polyethylene bearings wear out is of upmost importance to researchers working to improve TARs. Many of the mechanisms of failure associated with TARs are either directly or indirectly determined by the amount of wear that occurs on the UHMWPE liners. Two of the determining factors for how long a bearing will last are how high peak stresses are and the number of cycles the liners are subjected to. Typically, the orthopaedic industry uses from one to three million cycles as one year worth of usage. UHWMPE yields at stresses over approximately 10.8 MPa and wear is much more likely to occur when sustained stresses are beyond that point [10]. It’s also important to understand some of the wear mechanisms and how they relate to different liner geometries.

Fretting wear is caused by the continuous contact of two bodies in cyclic motion. That is as the bodies move against each other over many cycles, the surface of the softer material is damaged. This type of wear also promotes further abrasive wear due to the wear particles formed and adhesive wear as the bodies fail to slip [85]. By Archard’s Law, it is proportional to the contact force and thus is also proportional to the contact stress.
Delamination wear is similar to fretting wear in that it has to do with the contact of two bodies sliding together. In this case, however, the surface of the softer material is removed or peeled away by the force of the other body acting on it [86]. Researchers believe that this type of wear may be caused by high subsurface stress concentrations in the delaminating body [87]. According to Suh, et al., it’s possible that cracks form below the surface of the material when subsurface stresses exceed yield, thus leading to delamination [87].

III B. 1. FEA of Contact and Subsurface Stresses

Several finite element (FE) studies have been conducted to determine the locations and magnitudes of stresses in UHMWPE TAR bearings. However, studies of contact stresses in TARs are still lacking compared to those performed for other total joint replacements such as the knee and hip.

In one study by Espinoza, et al., Agility and Mobility TARs were evaluated to determine the magnitude of contact pressures in the UHMWPE bearings during cases of misalignment of the components. The study was conducted using ANSYS FEA software for meshing and processing of the models. The Agility model consisted of roughly 80,000 hex elements while the Mobility model consisted of approximately 55,000 hex elements. Furthermore, the researchers modeled the tibial and talar components as both titanium (E=100 GPa, v=0.35) and CoCr (E=200 GPa, v=0.3) linear elastic materials, while the UHMWPE liners were modeled as elastic-plastic materials with elastic moduli of 1.05 GPa and yield strengths of 18 MPa. The models were configured into four different gait positions (heel-strike, midstance, heel-off, and toe-off) and were loaded
accordingly for a 80 kg body weight (heel-strike - 800 N, midstance – 2000 N, heel-off – 2800 N, toe-off – 800 N). The researchers also configured the device positions for various types of misalignment, including tibial component IE, talar component IE, and external rotation [88].

They found that average contact pressures during normal alignment exceeded 10 MPa and that average pressure distributions during heel-off were in excess of 18 MPa, far exceeding their 10 MPa yield stress criteria. They also found that while changing the alignment of the components increased the stress magnitude, it had little effect on its distribution. Furthermore, the researchers found that the Mobility mobile-bearing devices had average pressure magnitudes less than 10 MPa in normal alignment. However, contact pressure increased past 10 MPa on average when IE was greater than two degrees [88]. Figure 14 shows the contact pressures that the researchers found for both Agility and Mobility models.

**Figure 14:** Contact pressures for each gait position (Agility - top, Mobility - bottom) [88]
In an analysis of Agility TARs by Miller, et al., the shape of the talar component and bearing were studied using FEA to determine the role that talar component width plays in determining the magnitude and location of Mises stresses and contact pressures in TARs. Miller, et al. used ANSYS FEA software to assemble the Agility model with the lower portions of tibia and fibula models in order to construct an anatomically correct implant-bone interface. Meshing was also done using ANSYS software. In their study, titanium tibial and talar components (E=110 GPa, ν=0.33), as well as cancellous bone (E=280 MPa, ν=0.3) was modeled using ten-node linear-elastic tetrahedral elements, while the cortical bone shell (E=17.5 GPa, ν=0.3) was modeled using four-node linear-elastic quadrilateral elements. The UHMWPE mesh used eight-node nonlinear hexagonal elements with a yield strength of 11 MPa and Poisson’s ratio of 0.46. A bonded contact between the bones and components was established and simplified stainless steel screws (E=189.6 GPa, ν=0.3) were used for fusion of the tibia and fibula. The model had over 41,000 elements and 68,000 nodes. The researchers applied a maximum load of 3330 N, corresponding to five times a 660 N body weight and tested the model at various degrees of DP [89].

Their findings showed that for a standard talar component in a neutral joint position, the highest Mises stresses occurred at the edge and below the surface of the implant, approaching 20 MPa. However, they noted that the highest surface stresses were seen in the center of the liner and were just greater than 10 MPa. This is in contrast for the wider component, where they found maximum edge stresses and center stresses to be 16.3MPa and 9.3 MPa, respectively. Their peak contact pressure was found to be 38 MPa for the standard talar component and 26 MPa for the wider component. Overall,
they found that wider talar components lead to lower stresses and pressures in the polyethylene bearings [89]. Figure 15 illustrates the surface Mises stresses that Miller, et al. found in their study.

Figure 15: Contact stresses in Agility TAR [89]

Reggiani, et al.’s study of contact pressures on the UHMWPE bearing of BOX TARs is of note because it is the only one that takes into account both the entire stance phase of the gait cycle, as well as the contributions of the ankle ligaments during loading. The researchers used PAM-SAFE FEA software for meshing and processing. The tibial and talar components were modeled with four-node shell elements, with the tibial component comprised of 1566 elements, while the talar component had 1661 elements. The UHMWPE bearing was modeled as an elastic-plastic material with roughly 16,000
tetrahedral elements. The eight major ligaments of the ankle complex (tibiocalcaneal, calcaneofibular, anterior talofibular, posterior talofibular, tibionavicular, deep anterior tibiotalar, deep posterior tibiotalar, and superior tibiotalar) were modeled as two-node bar elements and attached according to anatomical placement. Two loading conditions were studied; passive flexion and the stance phase of gait. During passive flexion, DP was allowed along with antero-posterior and proximo-distal translation. During the stance phase stage of analysis, the joint was loaded with normal and shear forces, as well as torsional loads. These conditions corresponded to time dependent gait data that the researchers had reviewed [90].

They found that peak contact pressures on the tibial side of the liner were as high as 10.3 MPa and as high as 16.1 MPa on the talar side. The average pressures they found were 6.4 MPa and 10.3 MPa, respectively [90]. Figure 16 shows the contact pressure distributions in the TAR liner during various points of interest throughout the stance phase of gait.
Figure 16: Contact stresses at various points during the stance phase of gait [90]
Morra, et al. found that contact area plays a role in subsurface stresses in total knee replacements (TKRs). In that study, they performed FEA on four different TKRs, each with different contact areas. The researchers applied a 1950 N load to the devices at 0° flexion in order to simulate the maximum force occurring during the stance phase of gait in the knee [128].

They found that the device with the smallest contact area between the femoral component and the bearing had the largest occurrence of subsurface stress above their threshold value of 9 MPa [128]. Figure 17 shows subsurface stress distributions in the liners of various TKRs.

**Figure 17:** Subsurface stresses in various TKR liners [128]
III B. 2. Experimentally Determined Contact Stresses

In similar fashion to what was found for FEA models of stress in TARs, very few entries were found that studied the in vivo pressures found in TAR polyethylene liners. However, the few studies that have been conducted have similar findings to those that used FEA to determine the contact pressure.

In a study by McIff et al. in 2001, STAR implants were subjected to a 3650 N static axial load. They found that the maximum contact pressure on the upper surface of the UHMWPE liner was roughly 10 MPa. However, the lower surface saw stresses as high as 20 MPa on interior, exterior, and internal edges of the surface [91].

Nicholson et al. studied nine Agility implants in vivo. They were statically loaded in the axial direction with a 720 N force. The researchers found that the average contact pressure on the UHMWPE bearing was 5.6 MPa and the maximum pressure was 21 MPa [92].

III B. 3. TAR Alignment and Contact Stresses

Proper alignment of the components in TARs is necessary. Espinoza, et al. modeled misalignment of Agility and Mobility TARs in various clinically relevant configurations. These misalignment types included ±10° IE and 5° of rotation from the manufacturer’s recommended orientations. Furthermore, testing was conducted under various simulated loading conditions throughout the gait cycle (800 N – heel-strike, 2000 N – midstance, 2800 N – heel-off, 800 N – toe-off). The researchers found that the Mobility TARs were particularly sensitive to IE and were able to show that this misalignment increased the average stress in the liner from below 10 MPa to above its 10
MPa yield point. Furthermore, the stresses in the Mobility liner shifted toward the outer
dges of the liner as a result of IE. While the Agility TAR saw no such shift in stresses in
its liner, the average stress throughout the liner did increase as a result of IE. Rotational
misalignment showed little change in the stress magnitude and distribution in either
model. However, rotational misalignment of the Agility model did cause stresses to
orient into the transverse plane [88].

III C. UHMWPE in TARs

UHMWPE has been used in total joint replacements almost since their very
inception in 1962. Sir John Charnley was the first person to ever implant a total hip
replacement. In doing so, he was also the first person to use an UHMWPE component as
one of the articulating surfaces in a total joint replacement [93].

UHMWPE is an ethylene polymer with a molecular weight much higher than
other polyethylene materials. This high molecular weight gives it enhanced properties
when compared to other polyethylene polymers such as low density polyethylene (LDPE)
and high density polyethylene (HDPE). These enhanced properties include higher
resistance to wear and abrasion, as well as increased toughness [93]. In order to enhance
these properties even more, crosslinking is used to give the UHMWPE even better wear
resistance. Crosslinking involves subjecting the material to high radiations in order to
induce covalent bonding between the molecular chains [93]. However, the drawback to
this is that other properties decrease as a result of crosslinking, such as elastic modulus
and yield strength.
UHMWPE tends to fail due to wear over time. Fretting wear, abrasion, adhesion, and delamination all contribute to the removal of material, which then either causes more wear in the form of particles abrade the articulating surface or contributes to aseptic loosening through osteolysis [10].

III C. 1. Properties

UHMWPE is characterized as a linear viscoelastic material. That is, it exhibits viscous properties under constant loading conditions. If subjected to a constant load, the material tends to creep, meaning that it has a tendency to displace from its original shape over time. This is different than in linear elastic materials, where the load must be increased to induce a higher displacement and is time invariant. Linear creep strain tends to be logarithmic over time. During creep strain, stress relaxation also occurs and represents the decreasing stresses in the material as time goes on. Several studies have examined this behavior in UHMWPE and have found it to be logarithmically linear with relatively short loading times [94, 95]. An example of this behavior is shown in Figure 18.

![Creep Strain and Relaxation vs. Time](image)

**Figure 18:** Creep Strain and Relaxation vs. Time
The mechanical properties of UHMWPE depend on several different factors, such as its level of crosslinking, additives used during manufacture, resin type, and manufacture method [93]. In a comprehensive study of the properties of crosslinked UHMWPE, Lewis found that the yield strength varied widely, from 14.4 MPa [96] to as high as 50.4 MPa [97]. Of interesting note, however, is the fact that the highest yield strength came from a sample of material that was not crosslinked [98]. He also found that the elastic moduli ranged from 250 MPa [99] to 1219 MPa [100] and the failure strain ranged from 0 [101] to 953.8 % [97]. A few observations can be made about the range of failure strains presented here. There was no ultimate strain when the material was crosslinked with a maximum radiation dose of 500 Mrad. Furthermore, a very large failure strain was exhibited when the material was not crosslinked at all.

III C. 2. Wear Rate

Very few in vivo wear studies have been conducted for UHMWPE bearings specifically in TARs. Out of these, all analysis has centered on mobile bearing devices [70]. Table 10 gives a brief synopsis of these studies.

Bell, et al. utilized a 3100 N peak force and conducted their wear simulation for 5 million cycles on BP and Mobility TARs. Anterior/Posterior rotation was added for an additional million cycles, causing increased wear in the liners [102, 70].

Postak, et al. conducted wear analysis on STAR devices loaded at 3000 N peak force. During the simulation, the joint was articulated sinusoidally for 10 million cycles with ±15° of DP, ±2° rotation, and ±2.5 mm of displacement in order to simulate generalized motions of the ankle gait [103, 70].
Affatato, et al. conducted their wear testing on BOX TARs for 3 million cycles. They used similar loading conditions and kinematics as were used by Reggianni, et al [104, 70, 90].

<table>
<thead>
<tr>
<th>Author</th>
<th>Device</th>
<th>Wear Rate (mm$^3$/Mc)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bell et al. [102] (No AP)</td>
<td>BP</td>
<td>10.7 ± 11.8</td>
</tr>
<tr>
<td></td>
<td>Mobility</td>
<td>3.4 ± 10.0</td>
</tr>
<tr>
<td>Bell et al. [102] (w/ AP)</td>
<td>BP</td>
<td>16.4 ± 17.4</td>
</tr>
<tr>
<td></td>
<td>Mobility</td>
<td>10.4 ± 14.7</td>
</tr>
<tr>
<td>Postak et al. [103]</td>
<td>STAR</td>
<td>5.7 ± 2.1</td>
</tr>
<tr>
<td>Affatato et al. [104]</td>
<td>BOX</td>
<td>19.6 ± 12.8</td>
</tr>
</tbody>
</table>

*Adapted from Fryman [70]

If we assume that the average number of steps a person takes in one year is roughly two million [107], we can see that the volumetric wear rate per year in TARs ranges from 6.8 to 39.2 mm$^3$/year. These numbers fall into the range of wear rates compiled by Lewis [96]. He found that authors had specified wear rates ranging from 0 mm$^3$/Mc [105] to 20.7 mm$^3$/Mc [106]. Assuming again a rough estimate of two million cycles per year, we find that the range of wear rates is from 0 mm$^3$/year to 41.4 mm$^3$/year. In the case of no wear, the authors subjected the material to 20.2 Mrad of radiation for crosslinking and remelted it at 150° C [105]. The highest wear rate was found when the UHWMPE was crosslinked at 3.3 Mrad and was not remelted at all [106]. Both cases simulated wear in a hip joint simulator.

Wang, et al. found that wear rate in UHMWPE is heavily dependent on the mechanical properties of the material. They used a ring-on-flat wear machine to test whether materials with different material properties wear differently. The researchers...
found that their highest wear rate (4.421 mm³/Mc) occurred in a material with one of the lowest tensile yield and ultimate strengths [127].

III D. Mathematical Characterization

Contact and wear between two bodies has been mathematically characterized through Hertz Law of elastic contact and through Archard’s Law of wear.

III D. 1. Hertzian Contact

Hertzian contact between a spherical body and an infinite elastic half space assumes that both bodies are linear elastic and that there is no friction between the two [108]. This approximation allows one to assume a smaller possible contact area than a cylinder in contact with a half-space and thus allows for higher overall contact stresses between the two bodies [109]. Several studies have been performed that attempt to solve the Hertzian contact problem with respect to both spherical and cylindrical bodies [112, 113]. These methods use Hertz law to determine maximum contact pressure between two bodies. Subsequently, knowing contact pressure allows us to determine other contact stresses, such as the principle stresses and Mises stress [109].

Linear Viscoelastic contact between two bodies is similar to Hertzian contact except for the increased deformation that occurs because of the time dependent nature of the material. However, Oden and Lin [110] found that viscoelastic contact approaches Hertzian contact when displacements are sufficiently small. Furthermore, UHMWPE has been shown to exhibit linear elastic behavior up to its yield point and during non-constant loading conditions [111].
III D. 2. Archard’s Wear Law

Archard’s law of wear accounts for sliding velocity, contact force, and material properties of the wearing material in order to determine a volumetric wear rate for the material. Several studies have tried to predict the volumetric wear rate in total joint replacements by way of Archard’s law [114, 115].

Liu, et al. found that wear rates for total hip implants from 10 mm³/Mc - 50 mm³/Mc depending on the head diameter of the implant. These values (20 mm³/year to 100 mm³/year) exceed those found through in vivo research. However, it’s unknown what hip implant head diameters were used for the in vivo studies [114].

Kang, et al. used a similar Archard’s model to determine wear rates in the liners of total hip implants. They found lower values than were determined by Lui, et al., with wear rates ranging from 15 mm³/Mc to 25 mm³/Mc (30 mm³/year to 50 mm³/year). These values are closer to those values found through in vivo testing [116].
IV. MATERIALS & METHODS

All methods are derived from theoretical values, either obtained through finite element modeling or through the use of mathematical models previously discussed in the literature review.

IV. A. Gait Forces

In order to test the stress and wear in the total ankle bearings by way of FEA, a characteristic axial loading profile had to be determined. This research solely focused on the axial component of the force profile for simplification purposes. A characteristic gait waveform was developed utilizing data from Sereg and Arvikar’s study of joint reaction forces during walking [117]. In this study, the two researchers utilized mathematical modeling techniques to determine joint reaction forces as well as muscle load sharing. Figure 19 shows the loading patterns that they determined. The joint force in the Z-direction represents the axial force profile used for this research. This data has also been utilized by Reggiani, et al. in their modeling of ankle joint pressures during the stance phase of gait [90].
Figure 19: Mathematically determined ankle joint force waveform by Seireg and Arvikar [117]

Figure 20: Axial force waveform [117]
Figure 20 shows the gait waveform used for FEA analysis of the seven total ankle models. This data was specifically chosen because it was bodyweight independent and could be applied for people of varying weight conditions in the future. However, for the purposes of this research, a bodyweight was chosen that is characteristic of an average US male twenty years old or older. This bodyweight was 194.7 lb., which equates to 866.4 N [118]. Figure 21 shows the axial loading waveform in terms of the bodyweight in Newtons.

![Axial Gait at 866.4 N](image)

**Figure 21:** Axial load with respect to percentage of gait at 866.4 N bodyweight

This data was also used to generate a mathematical model of the axial gait waveform by way of curve fitting in MATLAB. This mathematical model was a ninth order polynomial, also used by K. M. Jackson [119]. The gait model was used in order to
develop models for determining maximum contact pressure in the UHMWPE bearing and subsequently determining the wear rate in those bearings. These models will be discussed in subsequent sections.

Figure 22: Actual axial force waveform overlayed with approximate axial gait waveform

Figure 22 shows the mathematically determined axial gait waveform and the actual axial force waveform collected from the literature, both plotted with respect to time. The time corresponds to a loading cycle of roughly one millisecond as defined by Reggiani, et al. The approximated and actual waveforms were statistically similar (P-value = 0.966). Table 11 shows the polynomial coefficients used for the approximated force waveform with respect to their polynomial order.
### Table 11: Polynomial Coefficients for Mathematically Determined Gait Waveform

<table>
<thead>
<tr>
<th>Order</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>-2.19e+31</td>
</tr>
<tr>
<td>8</td>
<td>9.66e+28</td>
</tr>
<tr>
<td>7</td>
<td>-1.72e+26</td>
</tr>
<tr>
<td>6</td>
<td>1.56e+24</td>
</tr>
<tr>
<td>5</td>
<td>-7.38e+19</td>
</tr>
<tr>
<td>4</td>
<td>1.53e+16</td>
</tr>
<tr>
<td>3</td>
<td>1.01e+13</td>
</tr>
<tr>
<td>2</td>
<td>-4.67e+8</td>
</tr>
<tr>
<td>1</td>
<td>5.59e+4</td>
</tr>
<tr>
<td>0</td>
<td>0.23</td>
</tr>
</tbody>
</table>

IV. B. Finite Element Modeling

First and second generation WSU TARs were analyzed. For reference purposes, they were designated as M and N generations, respectively. All seven models are patented by Wright State University and fall under the blanket moniker of Ohio TARs (Pub. No. US 2011/0035019 A1). Finite element modeling for all seven devices was performed using ABAQUS FEA software. As well, all analysis was performed based on the same methodology for every model. The only discrepancy involves the use of a global damping in order to perform analysis on some of the models without error. However, the smallest damping coefficient was used for each model such that errors did not occur during processing. Figures 23-29 show the different TAR designs analyzed.
Figure 23: Implant Design M1 Solid Model

Figure 24: Implant Design M2 Solid Model
Figure 25: Implant Design M3 Solid Model

Figure 26: Implant Design N1 Solid Model
Figure 27: Implant Design N2 Solid Model

Figure 28: Implant Design N3 Solid Model
Figure 29: Implant Design N4 Solid Model

Geometric characteristics of each implant can be found in Table 12. These traits include the UHMWPE bearing total articulating surface area (Figure 30), the force application area of the tibial components (Figure 31), the condylar angle of curvature and radius of curvature (Figure 32), the total contacting arc length of the condyles (Figure 33), the articulating surface width of the condyles (Figure 34), the condylar thickness (Figure 35), and the condylar cross-sectional area (Figure 35).
Figure 30: M1 articulating surface area, $A_S$ (highlighted in blue)

Figure 31: M1 force application area, $A_F$ (highlighted in blue)
Figure 32: M1 condylar arcs (radius of curvature and angle of curvature, $\theta_C$) (highlighted in blue)

Figure 33: M1 condylar arc length (circled)
Figure 34: M1 condyle mid-articulating length (circled)

Figure 35: Condylar thickness, $T_C$, and cross-sectional area, $A_C$ (highlighted in blue)
Table 12: Geometric Characteristics of TAR Models

<table>
<thead>
<tr>
<th>Geometric Characteristic</th>
<th>M1</th>
<th>M2</th>
<th>M3</th>
<th>N1</th>
<th>N2</th>
<th>N3</th>
<th>N4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liner Articulating Surface Area (mm²)</td>
<td>690.32</td>
<td>503.22</td>
<td>625.8</td>
<td>703.22</td>
<td>703.22</td>
<td>703.22</td>
<td>703.22</td>
</tr>
<tr>
<td>Condyle Angle of Curvature (°)</td>
<td>60.85</td>
<td>49.62</td>
<td>0</td>
<td>60.91</td>
<td>60.91</td>
<td>60.91</td>
<td>60.91</td>
</tr>
<tr>
<td>Condyle Radius of Curvature (mm)</td>
<td>27</td>
<td>22</td>
<td>27</td>
<td>27</td>
<td>27</td>
<td>27</td>
<td>27</td>
</tr>
<tr>
<td>Condyle Arc Length (mm)</td>
<td>23.73</td>
<td>20.54</td>
<td>23.3</td>
<td>23.33</td>
<td>23.33</td>
<td>23.33</td>
<td>23.33</td>
</tr>
<tr>
<td>Condyle Mid-Articulating Surface Width (mm)</td>
<td>2.36</td>
<td>3.356</td>
<td>27</td>
<td>2.3</td>
<td>2.3</td>
<td>2.3</td>
<td>2.3</td>
</tr>
<tr>
<td>Force Application Area (mm²)</td>
<td>812.9</td>
<td>746.45</td>
<td>1058.06</td>
<td>961.29</td>
<td>1148.38</td>
<td>1141.93</td>
<td>1032.26</td>
</tr>
</tbody>
</table>

Material properties were defined for the UHMWPE bearings according to the viscoelastic properties of the material that were compiled from the literature. These properties are discussed in detail in Section IV B.1.

Three different material property cases for the talar and tibial components were defined in ABAQUS. This was done in order to determine whether the material properties of the metallic components made a significant difference in terms of stresses and pressures in the PE bearings. These material properties can be found in Table 13 and were originally tabulated by Makola and Goswami [120].

Table 13: TAR Materials & Properties [120]

<table>
<thead>
<tr>
<th>Material</th>
<th>Young's Modulus, E (MPa)</th>
<th>ν</th>
<th>Coefficient of Friction, μ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cobalt-Chromium Alloy (CoCr)</td>
<td>250,000</td>
<td>0.29</td>
<td>0.15</td>
</tr>
<tr>
<td>Stainless Steel (SS)</td>
<td>200,000</td>
<td>0.3</td>
<td>0.12</td>
</tr>
<tr>
<td>Ti6Al4V</td>
<td>110,000</td>
<td>0.342</td>
<td>0.148</td>
</tr>
</tbody>
</table>
Surface-to-surface contact was defined between the tibial components and bearings as well as between the talar components and the bearings. Normal and tangential contact conditions were set for each surface-to-surface contact instance. The normal contact definition was “hard contact” for pressure overclosurer and the tangential contact was defined as penalty-based. Therefore, a different friction coefficient was defined for each material interacting with the UHMWPE liners. These friction coefficients can be found in Table 13. Because the bearing component was the penetrated surface, it was set as the slave surface, while the talar and tibial surfaces were set as the master surfaces because they were the penetrating surfaces.

Boundary conditions were established for each model such that the talar component was encasted, essentially allowing for no transitional or rotation degrees of freedom by that component. By encastring the talar component, the assumption is made that there is solid and stable fixation of the implant to the bone.

Pressure loading was defined on each tibial component individually based on geometry of the component, such that the loads were in the normal direction only. All pressures were defined as the initial force load (866.4 N) divided by the force application area. These areas can be found in Table 12. Furthermore, the gait waveform was defined in ABAQUS for each model according to the gait specifications found in Figure 21. This was done by assigning amplitude data to the initial normal pressure. This amplitude data essentially acts as a multiplier for the initial load throughout the entire step. Figure 36 gives an example of how the load and boundary conditions were established for model M2.
Figure 36: Example of boundary conditions for Model M2

A Visco step was used for analysis. This type of step allows for viscoelastic and elastic properties to be analyzed by ABAQUS. The total step time was set to be one, with a minimum increment size of $1E^{-9}$ and a maximum step size of $1E^{-2}$, or one percent per increment. This was done in order to achieve a relatively high resolution over the entire gait cycle. Furthermore, large strain theory was defined for this step.

The element type chosen for the mesh on each component was linear tetrahedral for simplification purposes. Each model’s parts were meshed individually such that the bearing had a more dense mesh compared to the talar and tibial components. This was done because the ABAQUS program recommends the use of a finer mesh on the slave component in a contact set. Convergence studies were conducted for each of the models to determine the optimum mesh density for analysis such that stress values did not vary by more than 5 percent. Table 14 gives the number of nodes and elements for each component for the seven models.
Once all of the initial parameters were set up, the models were ran individually. Post-processing was performed using the ABAQUS visualization toolset. Surface stress and pressure analysis was done by defining the contact surfaces of the liners in ABAQUS and exporting resultant data to be processed in the MATLAB software suite. The maximum values for Mises stresses and contact pressures in each model were determined. Average contact Mises stresses were also determined by averaging the stress across the entire surface at the point of maximum loading. This data was used to determine the average stress per unit area of each of the TAR liners.

Finally, sub-surface Mises stresses were obtained by performing an axial cut in each liner at the point of maximum sub-surface Mises stress. All stress values for the cross-section were obtained in all of the seven models and this data was used to obtain average cross-sectional Mises stresses as well as maximum sub-surface Mises stresses. Furthermore, the depth of maximum stress was found using the same cutting utility in Abaqus.
IV B. 1. Viscoelastic Parameters

Viscoelastic parameters were entered in ABAQUS according to creep strain data [121]. The data used from this study was for UHMWPE crosslinked at 125 kGy and subjected to a temperature of 50° C. This dataset was used because 50° C is a relatively close approximation of the 43.1° C maximum temperature Fialho found for the hip joint by way of FEA [122]. The data used is shown in Figure 37.

![UHMWPE Creep Strain](image_url)

**Figure 37:** 125 kGy Crosslinked UHMWPE Creep Strain at 50° C [121]

One method ABAQUS uses to determine the linear viscoelastic behavior of a material is to convert shear creep data to shear relaxation data and then to an exponential series known as Prony series. The shear relaxation Prony series is defined as:
In Eq. 1, \( \bar{\tau}_i^G \) and \( \bar{\sigma}_i^P \) are material properties.

In order to determine the Prony series for a material, ABAQUS requires that the data be converted to normalized shear compliance. Therefore, the original creep strain data was converted using the equations:

\[
E(t) = \frac{\sigma_0}{\varepsilon(t)} \quad \text{Eq. 2}
\]

In Eq. 2, \( E(t) \) is the time dependent elastic modulus of the material. \( \sigma_0 \) is the constant stress applied to the sample. In this case, that constant stress was 8 MPa. \( \varepsilon(t) \) is defined as the time dependent creep strain.

\[
G(t) = \frac{E(t)}{2(1+\nu)} \quad \text{Eq. 3}
\]

In Eq. 3, \( G(t) \) is the time dependent shear modulus of the material and \( \nu \) is Poisson’s ratio.

\[
J_S(t) = \frac{1}{G(t)} \quad \text{Eq. 4}
\]

Eq. 4 gives the shear compliance of the material, which is also time dependent.
In Eq. 5, $J_{SN}$ is the normalized shear compliance and $G_0$ is the long-term shear modulus of the material.

$$G_0 = \frac{E_0}{(1+\nu)}$$

Eq. 6

Finally, Eq. 6 gives the long-term shear modulus in terms of the long-term elastic modulus and Poisson’s ratio. The long-term shear modulus was found through experimentation to be 190.39 MPa, which gives a long-term elastic modulus of 556.31 MPa. Therefore, based on these parameters, a normalized shear compliance curve was found and can be seen in Figure 38.
Based on the normalized shear compliance curve and the long-term shear modulus, the ABAQUS software assigned a Prony series that is illustrated in Figure 39. The RMS error between the predicted vs. actual creep was 13.53%.

**Figure 38:** Normalized Shear Compliance for UHMWPE Data
IV C. Mathematical Wear Modeling

The mathematical determination of wear rate was performed using a two-step process. Namely, an approximate maximum contact pressure function was first determined and then this model was used in conjunction with Archard’s wear model in order to determine a wear rate based on implant geometry.

IV C. 1. Maximum Contact Pressure With Hertzian Contact

Hertzian contact was chosen to approximate the interaction between the talar component and the UHMWPE bearing because UHMWPE has been shown to exhibit linear elastic behavior up to its yield point and during non-constant loading conditions.

Figure 39: Experimentally Determined UHMWPE Creep vs. Predicted Creep
While Hertzian contact has not been defined for bodies in frictional contact, for simplification purposes friction was ignored for this mathematical model.

The Hertzian contact condition chosen to approximate the interaction between the talar component and the UHMWPE bearing was that of a spherical indenter penetrating an infinite elastic half-space. This particular geometric approximation was used in order to model the potential for small contact areas found in TARS. This is in contrast to the cylindrical contact approximation seen in other studies [10]. Cylindrical contact was thought to give a lower overall pressure value than would actually be found in the TARs.

Eq. 7

\[ p_0 = \frac{1}{\pi} \left( \frac{6FE^*}{R^3} \right)^{1/3} \]  

Eq. 7 is the maximum contact pressure, \( p_0 \), between the elastic half-space and the spherical indenter. \( F \) is the force of indentation, \( E^* \) is the effective elastic modulus between the two bodies, and \( R \) is the radius of curvature (Table 11) of the spherical indenter.

Solving for the indentation force yields Eq. 8:

Eq. 8

\[ F = \frac{\pi^3 p_0^3 R^2}{6 E^* R^2} \]

The effective elastic modulus is essentially the composite modulus between the two bodies. It is determined from the equation:

Eq. 9

\[ E^* = \frac{E_1 E_2}{E_2 (1-v_1) + E_1 (1-v_2)} \]
IV C. 2. Archard’s Law and Fretting Wear

Archard’s law accounts for the force of penetration, \( F \), as well as the distance of travel by the penetrating body, \( S \), in order to determine the wear volume. This is given by the equation:

\[
W = kFS \quad \text{Eq. 10}
\]

The variable \( k \) is called the wear coefficient. However, due to the time invariant nature of the model, the first order derivative of the sliding distance must be taken, which equates to a sliding velocity, \( V \), in order to determine the time variant wear rate.

\[
\dot{W} = kFV \quad \text{Eq. 11}
\]

Using Eq. 8 in conjunction with Eq. 11 produces a new wear rate equation that allows for indenter geometry and maximum contact pressure to be factors in its determination.

\[
\dot{W} = \frac{k \pi^2 p_0^3 R^2 V}{6E^2} \quad \text{Eq. 12}
\]

<table>
<thead>
<tr>
<th>Table 15: Variable Values for Wear Rate Model [123]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Coefficient</strong></td>
</tr>
<tr>
<td><strong>Value</strong></td>
</tr>
</tbody>
</table>
Table 15 shows the values of the variables used in order to determine wear rate. A sliding velocity of 35 mm/s was chosen. Fisher, et al. found that value is approximately the physiological sliding velocity of human joints [123]. Furthermore, Fisher et al. found that for that sliding velocity, the wear coefficient for UHMWPE polyethylene was $13.2 \times 10^{-12}$ mm$^3$/N·mm.

IV D. Stress Optimization

Based on the results of the finite element analysis of the seven TAR models, several optimization equations were determined. The statistical models were based on the relationships between the different geometric parameters and the resulting stresses. Statistical analysis for stress optimization was conducted using JMP 10 statistical software. Factorial analysis was performed, with stress as the dependent variable and the different geometric parameters as the model effects. For each stress value (maximum surface, average surface, maximum cross-sectional, average cross-sectional, stress depth), the model was constructed and insignificant effects were eliminated systematically until only effects significant to the model remained.

This analysis is discussed in more detail in Chapter VI.
V. RESULTS

V A. Finite Element Analysis

Table 16 shows the Mises stress values collected from the FEA of the seven TAR models, as well as for the three different metallic component materials tested. It also shows the maximum stress depths found in the twenty one trials.

<table>
<thead>
<tr>
<th>Table 16: FEA Determined Mises Stresses and Stress Depths</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Model</strong></td>
</tr>
<tr>
<td>Max Surface Stress (MPa)</td>
</tr>
<tr>
<td>Max Cross Sectional Stress (MPa) at Condyle</td>
</tr>
<tr>
<td>Average Mises Surface Stress (MPa)</td>
</tr>
<tr>
<td>CoCr</td>
</tr>
<tr>
<td>Average Mises Cross-Sectional Stress (MPa)</td>
</tr>
<tr>
<td>Max Mises Stress Depth (mm)</td>
</tr>
</tbody>
</table>
Figures 40-60 show the Mises stress magnitudes and distributions on the articulating surfaces of the mobile bearings. Figures 107-127 in the Appendix depict the cross-sectional stresses for each model.

**Figure 40:** Maximum Mises Stress Model: M1 Material: Ti6Al4V

**Figure 41:** Maximum Mises Stress Model: M1 Material: CoCr
Figure 42: Maximum Mises Stress Model: M1 Material: Stainless Steel

Figure 43: Maximum Mises Stress Model: M2 Material: Ti6Al4V
**Figure 44:** Maximum Mises Stress Model: M2 Material: CoCr

**Figure 45:** Maximum Mises Stress Model: M2 Material: Stainless Steel
Figure 46: Maximum Mises Stress Model: M3 Material: Ti6Al4V

Figure 47: Maximum Mises Stress Model: M3 Material: CoCr
**Figure 48**: Maximum Mises Stress Model: M3 Material: Stainless Steel

**Figure 49**: Maximum Mises Stress Model: N1 Material: Ti6Al4V
**Figure 50:** Maximum Mises Stress Model: N1 Material: CoCr

**Figure 51:** Maximum Mises Stress Model: N1 Material: Stainless Steel
Figure 52: Maximum Mises Stress Model: N2 Material: Ti6Al4V

Figure 53: Maximum Mises Stress Model: N2 Material: CoCr
Figure 54: Maximum Mises Stress Model: N2 Material: Stainless Steel

Figure 55: Maximum Mises Stress Model: N3 Material: Ti6Al4V
**Figure 56**: Maximum Mises Stress Model: N3 Material: CoCr

**Figure 57**: Maximum Mises Stress Model: N3 Material: Stainless Steel
Figure 58: Maximum Mises Stress Model: N4 Material: Ti6Al4V

Figure 59: Maximum Mises Stress Model: N4 Material: CoCr
Figure 60: Maximum Mises Stress Model: N4 Material: Stainless Steel

Figure 61: Model M1 Mises Stresses Through Gait Cycle
Figure 62: Model M2 Mises Stresses Through Gait Cycle

Figure 63: Model M3 Mises Stresses Through Gait Cycle
Figure 64: Model N1 Mises Stresses Through Gait Cycle

Figure 65: Model N2 Mises Stresses Through Gait Cycle
Figure 66: Model N3 Mises Stresses Through Gait Cycle

Figure 67: Model N4 Mises Stresses Through Gait Cycle
Figures 61-67 illustrate the progression of stress distributions through each UHMWPE bearing through 10% increments of the gait cycle.

**Figure 68:** Average cross-sectional stresses through the width of the liners

**Figure 69:** Maximum cross-sectional stresses through the width of the liners
Figure 68 and Figure 69 show the average and maximum cross-sectional stresses throughout the width of the TAR liners, respectively. The widths of each liner are represented as a percentage of their entire width, with zero and 100 representing the extreme edges.

**Figure 70:** Contact Pressure at Maximum Point

Figure 70 shows the contact pressure at the point in which the maximum occurs. Figure 71 compares contact pressures for just the second generation models. This is especially relevant because every one of the mobile bearings in the second generation models have the same geometry.
Figure 71: Comparison of Contact Pressure for 2nd Generation Ohio TARs

V B. Mathematical Wear Modeling

Using the theoretical gait profile that was developed, in conjunction with the Hertzian pressure equation, a characteristic pressure waveform was generated for a TAR with a condyle radius of 27 mm. This value was used because the majority of the bearings used had that condyle radius. Figure 72 illustrates this pressure waveform as a function of the gait time in seconds. Table 17 gives the difference between the maximum derived pressure and the average maximum pressure between all seven models, as well as the difference between the maximum derived contact pressure and the average maximum pressure between just the second generation implants.
Table 17: Contact Pressure Comparison

<table>
<thead>
<tr>
<th>Max Derived Contact Pressure (MPa)</th>
<th>82.39</th>
<th>--</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Average Contact Pressure – All Models (MPa)</td>
<td>75.2493</td>
<td>8.667% Difference</td>
</tr>
<tr>
<td>Max Average Contact Pressure – 2nd Generation Models (MPa)</td>
<td>77.883</td>
<td>5.47% Difference</td>
</tr>
</tbody>
</table>

The theoretical pressure equation produces an average contact pressure of 56.9 MPa. However, the highest FEA determined average contact pressure occurred in model M3 and was only 30.43 MPa. Table 18 shows the average contact pressure across the entire gait cycle for each model, as well as the average overall contact pressure for all of the models.
Yearly wear rates of the UHMWPE liners were tabulated using the maximum derived, maximum FEA-obtained, average derived, and average FEA-obtained contact pressures according to Equation 6. These values can be found in Table 19.

<table>
<thead>
<tr>
<th>Table 18: Average Contact Pressure Across Entire Gait Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model</td>
</tr>
<tr>
<td>-------</td>
</tr>
<tr>
<td>Average Contact Pressure [MPa]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 19: Yearly Predicted Wear Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum Derived Contact Pressure</td>
</tr>
<tr>
<td>Average Derived Contact Pressure – Entire Gait Cycle</td>
</tr>
<tr>
<td>Maximum FEA-Obtained Contact Pressure</td>
</tr>
<tr>
<td>Average FEA-Obtained Contact Pressure – Entire Gait Cycle</td>
</tr>
</tbody>
</table>
VI. STRESS OPTIMIZATION

VI A. Average Surface Mises Stresses

Figure 73 shows the fit of actual average surface stresses determined through FEA as a function of the predicted values obtained from the model. The P value for this fit was less than 0.0001 and the $R^2$ value for the fit was 0.97. Figures 74-76 show the fit between average surface stress and the geometric parameters used to develop the characteristic prediction model seen in Eq. 13. The variable $A_S$ is the contact surface area of the UHMWPE bearing, $\theta_C$ is the condylar angle of curvature, and $A_F$ is the force application area.

![Figure 73: Actual vs. Predicted Average Surface Mises Stress](image_url)
Figure 74: Average Mises Stress vs. Articulating Surface Area

Figure 74 illustrates the predicted inverse relationship between average stress in the liner and its articulating surface area. The analysis shows that as articulating surface area increases, the average stress across the entire surface of the bearing decreases, from roughly ten MPa with an articulating surface area of 575 mm$^2$ to approximately 4 MPa with the much larger surface area of 750 mm$^2$. The p-value is less than 0.0001.
Figure 75: Average Surface Mises Stress vs. Condylar Angle of Curvature

Figure 75 shows the predicted linear relationship between average surface stress and condylar angle of curvature. According to the model, as condylar angle increases, the average surface stress does as well. This fact is evident when observing the surfaces stresses in M3 versus the other TAR models. It lacks condyles and has some of the lowest surface stresses seen in any of the models. According to the model, increasing the angle of condylar curvature to 70° nearly doubles the stress in the liner. The p-value is less than 0.0001.
Figure 76: Average Surface Mises Stress vs. Force Application Area

Figure 76 shows the predicted linear plot of average surface stress of the liners as a function of the force application area. Interestingly, as force application area increases, the average surface stress does as well, increasing from 5 MPa to 7 MPa as force application area increases from 700 mm$^2$ to 1150 mm$^2$. The p-value is less than 0.0001. Equation 13 is the linear relationship between all three significant parameters and the average surface Mises stress.

$$\sigma_{SA} = 18.755 - 0.029A_S + 0.046\theta_C + 0.004A_F$$  \hspace{1cm} \text{Eq. 13}
VI B. Maximum Surface Stress

Figure 77 shows the fit of actual maximum surface stresses as a function of the predicted values obtained from the model. The P value for this fit was 0.005 and the $R^2$ value for the fit was 0.58. Figures 78 and 79 show the fit between maximum surface stress and the geometric parameters used to develop the characteristic prediction model seen in Eq. 14.

![Graph showing Actual Maximum Stress vs. Predicted Maximum Surface Stress](image)

**Figure 77:** Actual Maximum Stress vs. Predicted Maximum Surface Stress
Figure 78: Maximum Surface Stress vs. Condylar Angle of Curvature

The statistical model of the predicted relationship between maximum surface stress and condylar angle of curvature shows a linear increasing trend. This can be seen in Figure 78. The model produces a maximum surface stress below 15 MPa with no condyles and increases to approximately 22 MPa as the angle approaches 70°. The p-value for this study is 0.0017.
Figure 79: Maximum Surface Stress vs. Force Application Area

Figure 79 shows the predicted trend for maximum surface stress of the bearings as a function of the force application area. The figure illustrates that as force application area increases, the maximum surface stress decreases from roughly 25 MPa to less than 20 MPa as force application area increases from 700 mm$^2$ to 120 mm$^2$. The p-value is 0.0079. Equation 14 is the linear relationship between the significant parameters and the maximum surface Mises stress.

$$\sigma_{SM} = 28.518 + 0.125\theta_C - 0.0148A_F$$  \hspace{1cm} \text{Eq. 14}
VI C. Maximum Cross-Sectional Stress

Figure 80 shows the fit of actual maximum cross-sectional stresses as a function of the predicted values obtained from the model. The P value for this fit was less than 0.0001 and the $R^2$ value for the fit was 0.92. Figures 81-84 show the fit between maximum cross-sectional stress and the geometric parameters used to develop the characteristic prediction model seen in Eq. 15. The variable $T_C$ represents the thickness of that mobile bearing at the midpoint of the condyle (at its thinnest point).

**Figure 80:** Actual Maximum Cross-Sectional Stress vs. Predicted Maximum Cross-Sectional Stress
Figure 81: Maximum Cross-Sectional Stress vs. Condylar Angle of Curvature

The predicted relationship between maximum cross-sectional Mises stress and condylar angle of curvature can be seen in Figure 81. The figure shows a positive linear correlation between the two parameters when condylar angle of curvature is between 30° and 70°. The two extremes yield maximum cross-sectional stresses of approximately 15 MPa and 35 MPa, respectively. The p-value for this test was less than 0.0001.
Figure 82: Maximum Cross-Sectional Stress vs. Articulating Surface Area

Figure 82 shows a predicted negative linear relationship between maximum cross-sectional Mises stress and articulating surface area. This suggests that as articulating surface area increases, so too does the maximum subsurface stress in the bearing. The equation is defined between stresses of 15 MPa to 20 MPa and for areas between 600 mm$^2$ and 725 mm$^2$, respectively. The p-value for this test was less than 0.0001.
Figure 83: Maximum Cross-Sectional Stress vs. Force Application Area

Next, Figure 83 illustrates the predicted positive linear relationship between maximum cross-sectional stress and force application area. Therefore, according to the model, increasing force application area would likely increase the maximum cross-sectional stress in the liner. The p-value for this test was less than 0.0001.
Figure 84: Maximum Cross-Sectional Stress vs. Condyle Thickness

Figure 84 shows the trend of maximum cross-sectional stress of the bearings as a function of the bearing condyle thickness. The figure illustrates that as thickness increases from 5.5 mm to 9 mm, the maximum cross-sectional Mises stress decreases from 35 MPa to approximately 15 MPa. The p-value is less than 0.0001. Equation 15 is the linear relationship between the four significant parameters and the maximum cross-sectional Mises stress.

\[
\sigma_{MC} = 89.951 + 0.513\theta_C - 0.162A_s + 0.053A_F - 4.846T_C \quad \text{Eq. 15}
\]
VI D. Average Cross-Sectional Stress

Figure 85 shows the fit of actual average cross-sectional stresses as a function of the predicted values obtained from the model. The P value for this fit was less than 0.0001 and the R² value for the fit was 1. Figures 86-89 show the fit between the average cross-sectional stress and the geometric parameters used to develop the characteristic prediction model seen in Eq. 16.

![Figure 85: Actual Average Cross-Sectional Stress vs. Predicted Average Cross-Sectional Stress](image-url)
**Figure 86:** Average Cross-Sectional Stress vs. Condyle Thickness

The predicted average cross-sectional stress depends on condylar thickness, indicating that an increase in thickness increases the average cross-sectional stress in the liner. The P-value for this prediction curve is less than 0.0001, indicating significant correlation.
Figure 87: Average Cross-Sectional Stress vs. Cross-Sectional Area

Figure 87 shows the negative trend associated with average cross-sectional stress and cross sectional area. The trend predicts that increasing cross-sectional area of the liner decreases the average stress throughout the cross-section of the liner. The p-value for the regression is less than 0.0001, indicating significance of the regression.
The trend for average cross-sectional mises stress as a function of force application area can be seen in Figure 88. The linear regression line shows that increasing application area from a minimum of 700 mm$^2$ to a maximum of 1150 mm$^2$ would also increase the average cross-sectional stress in the liner from approximately 7.5 MPa to just over 9 MPa at the peak. The p-value for this fit is less than 0.0001, indicating that the effect from force application area significantly affects average cross-sectional stress.
Figure 89: Average Cross-Sectional Stress vs. Condylar Angle of Curvature

Figure 89 shows the predicted trend of average cross-sectional stress in the liners as a function of the condylar angle of curvature. The figure illustrates that as curvature angle increases from 0° to 70°, the average cross-sectional Mises stress increases from 6 MPa to approximately 9.5 MPa. The p-value is less than 0.0001. Equation 16 is the linear relationship between the four significant parameters and the average cross-sectional Mises stress.

\[
\sigma_{AC} = 10.086 + 1.924T_C - 0.115A_C + 0.004A_F + 0.055\theta_C
\]  
Eq. 16
VI E. Stress Depth

Figure 90 shows the fit of actual stress depths as a function of the predicted values obtained from the model. The P value for this fit was less than 0.0001 and the $R^2$ value for the fit was 0.97. Figures 91-94 show the fit between stress depth and the geometric parameters used to develop the characteristic prediction model seen in Eq. 17.

Figure 90: Actual Stress Depth vs. Predicted Stress Depth
Figure 91: Stress Depth vs. Force Application Area

The linear prediction line for stress depth as a function of force application area can be seen in Figure 91. The regression line shows that increasing application area would also increase the stress depth in the liner from approximately 5.5 mm to 7.5 mm by increasing the application area from approximately 775 mm$^2$ to 1150 mm$^2$. The p-value for this fit is less than 0.0001, indicating that the effect from force application area significantly affects average cross-sectional stress.
Figure 92: Stress Depth vs. Articulating Surface Area

Figure 92 shows a predicted negative linear relationship between stress depth and articulating surface area. This suggests that as articulating surface area increases, so too does the maximum subsurface stress depth in the bearing. The equation is defined between stress depths of 5.5 mm to 8.5 mm and for areas between 550 mm$^2$ and 725 mm$^2$, respectively. The p-value for this test was less than 0.0001.
Figure 93: Stress Depth vs. Condylar Angle of Curvature

Figure 93 shows the predicted trend of stress depth in the liners as a function of the condylar angle of curvature. The figure illustrates that as curvature angle increases from $10^\circ$ to $70^\circ$, the stress depth increases from 5.5 mm to approximately 7.2 mm. The p-value is less than 0.0001.
Figure 94: Stress Depth vs. Force Application Area

Figure 94 shows the predicted trend of stress depth in the liners as a function of the force application area on the tibial component. The figure illustrates that as force application area increases, the stress tends to increase as well. The p-value is less than 0.0001. Equation 17 is the linear relationship between force application area, surface area, and condylar angle of curvature and the average cross-sectional Mises stress.

\[ D_\sigma = 12.271 + 0.004A_F - 0.017A_S + 0.028\theta_C \]  \hspace{1cm} \text{Eq. 17}

VI F. Optimization Parameters

Finally, based on the derived optimization equations, a list of realistic parameters for articulating surface area, condylar angle of curvature, force application area, cross-sectional thickness, and cross-sectional area are given that would minimize the Mises
stresses in subsequent TAR liner designs. These parameters were chosen based on design choices taken from all seven TAR designs analyzed. The values for the parameters, as well as the mathematically derived stresses for this new liner can be found in Table 20.

<table>
<thead>
<tr>
<th>Optimized Geometric TAR Parameters</th>
<th>Articulating Surface Area (A_F) (mm²)</th>
<th>Condylar Angle of Curvature (θ_C) (°)</th>
<th>Force Application Area (A_F) (mm²)</th>
<th>Center Cross-Sectional Thickness (T_C) (mm)</th>
<th>Cross Sectional Area (A_C) (mm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>703.22</td>
<td>0 (No Condyles)</td>
<td>1148.38</td>
<td>9.375</td>
<td>225.806</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Optimized Mises Stresses and Stress Depth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum Surface Mises Stress (MPa)</td>
</tr>
<tr>
<td>Average Surface Mises Stress (MPa)</td>
</tr>
<tr>
<td>Maximum Cross-Sectional Mises Stress (MPa)</td>
</tr>
<tr>
<td>Average Cross-Sectional Mises Stress (MPa)</td>
</tr>
<tr>
<td>Maximum Cross-Sectional Mises Stress Depth (mm)</td>
</tr>
</tbody>
</table>

* indicates that these parameters don’t fit for this particular model
VII. DISCUSSION

VII A. Finite Element Analysis

Statistically, neither friction coefficient nor talar/tibial component material significantly affected stresses or stress depths in the Ohio TAR bearings. However, Makola and Goswami [120] and Elliott and Goswami [125] reported material properties of two contacting materials played a significant role in the contact stresses in the case of hip implants. Furthermore, it was found by Rubin, et al. that friction coefficient plays a large role in characterizing stresses in contact situations [126]. It is possible that a significant correlation between these properties and Mises stresses were not found because in this case the implant geometry played a much greater role. All FEA stress and stress depth values can be found in Table 16.

The results of the FEA of the seven Ohio TARs show that maximum Mises stresses for the contact surfaces ranged from 12.4 MPa for M3 with CoCr talar and tibial components to 28.63 MPa for model M1 with stainless steel metallic components. Overall, it can be gathered from the data that the M3 model has the lowest contact surface stresses while model M1 saw the highest. This is largely due to the smaller force that M1 is under when compared to M3. M3 doesn’t have condyles like the other mobile bearings. Instead, it features a continuous arc that allows it to be almost completely congruent with the talar component.
Figure 95: Maximum Surface Stress Comparison

Figure 95 shows the comparison between maximum surface stresses in the WSU TAR models with those found in the literature. Interestingly, of the second generation models that all feature the same mobile bearing designs, model N1 saw the lowest surface stresses even though it also had the smallest force application area of the four models. In comparison to other studies, the stresses observed in the Ohio TARs are reasonably close to those found in other studies. In Galik’s study of Mobility TARs with varying talar component widths, he found that maximum surface stresses approached 14 MPa [10]. However, it is important to note that in Galik’s study, a maximum load of 3335.4 N was used, while in the study of Ohio TARs a maximum load of 4385.78 N was used. Furthermore, a study of stresses in TKRs found that Mises stresses can peak as high as 28 MPa [124].

Figure 96 shows a comparison of the average surface stresses between the seven models. Average surface stresses were found to be from 4.7 MPa to 9.9 MPa for model
M1 and model M2, respectively. Therefore, on average the stresses in all of the Ohio TAR bearings did not exceed the yield criteria set (10 MPa). In contrast, the maximum surface stress in model M1 almost tripled that value.

**Figure 96: Average Surface Stress Comparison**

Contact pressures observed for the models ranged from 55.28 MPa for model N1 to 96.84 MPa for Model N3. An important note is that both N1 and N3 share the same mobile bearing and N1 has a much smaller force application area than N3. Therefore, the best possibility for this discrepancy is a difference in contact position between the two. The results show that N3 and N1 are the extremes in terms of contact pressure. However, model N4 had the lowest average contact pressure at 17.5 MPa, while N3 had the largest average contact stress at 32 MPa. These results are higher than those found in the literature for contact pressure. Espinoza et al. [88] found maximum average contact
pressures exceeding 18 MPa while Galik [10] found maximum contact pressures to be as high as 38 MPa.

Figures 97 and 98 compare the maximum and average cross-sectional stresses in the WSU TAR models, respectively. Maximum cross-sectional stresses were always found in the condyle region of the liner except in M3, which is continuous and does not have condyles. This fact is evident in Figure 67 and Figure 68, where the highest stresses are clearly toward the outer edges of the implants where the condyles are located. In fact, the M3 model had the lowest maximum cross-sectional stress at 18.2 MPa. Conversely, N3 had the highest peak cross-sectional stress at 33.1 MPa. The maximum stresses occurred at 6.9 mm and 6.2 mm depths, respectively.

![Maximum Cross-Sectional Mises Stresses](image)

**Figure 97: Maximum Cross-Sectional Stress Comparison**

Figure 99 compares the depth of maximum stress between the seven models. Miller, et al. found that stress tended to decrease throughout the liner from articulating
surface to backside [89]. However, that was not the case in this research. Furthermore, Morra, et al. found that high subsurface stresses could develop in TKRs, exceeding the yield of the bearing [128]. The average cross-sectional Mises stresses obtained from the FEA ranged from 6.3 MPa to 14.9 MPa for model N1 and M2, respectively.

![Average Cross-Sectional Mises Stresses](image_url)

**Figure 98:** Average Cross-Sectional Mises Stress Comparison
VII B. Mathematical Analysis of Stress and Wear Rate

The theoretical contact pressure derived from the Hertzian model showed a higher average pressure over the entire gait cycle than was seen in FE analysis of the seven models. Furthermore, it is much higher than those contact pressures found in other studies such as Galik’s and Espinoza’s [10, 88]. However, when compared to the average maximum pressure seen between the seven Ohio TAR models, the maximum derived contact pressure was only 8.667% higher. Therefore, it is believed that the model presented here is an adequate predictor of the maximum contact pressure seen in TARs.

The maximum wear rate values in Table 18 (29.206 mm³/year – maximum derived contact pressure, 49.15 mm³/year – maximum FEA contact pressure) seem to be comparable to those found in the literature. The wear rates determined using the average FEA and average derived contact pressure were 0.876 mm³/year and 9.62 mm³/year, respectively. The reason for the discrepancy is more than likely because the gait does
not operate at peak force throughout the entire cycle. Therefore, average wear rates are lower than those found from maximum contact pressures. The maximum wear values also correspond to other studies where wear rates in TARs have been found to exceed 25 mm$^3$/million cycles, or roughly 50 mm$^3$/year [70, 107]. Therefore, new models developed in this research are applicable in design and in determining wear rate in TARs.

VII C. Optimization of WSU TARs

Based on the statistical analysis of average and maximum stresses in the TAR liners, several significant geometric parameters were identified. Contact area between the talar component and the polyethylene component has been identified by this research, as well as the research of others to be a significant contributor to stresses in total joint replacements. Kuster, et al. identified the liner contact area in TKRs as a leading factor in contact stress, finding that contact areas of 80 mm$^2$ to 300 mm$^2$ contributed to stresses as high as 60 MPa. They also found that in order to bring stress in the liner below yield that they would have to increase contact area to at least 400 mm$^2$, still far below the average contact area of a healthy joint; 750 to 1150 mm$^2$ [131].

Liner thickness was also found to determine the magnitude of maximum cross-sectional stress in a similar fashion to other studies. Bartel, et al. found that increasing the thickness of the liner tends to decrease the maximum stress that occurs in the liner. For a knee liner thickness of 4 mm and loaded with 1500 N, they found that the resulting maximum stress was nearly 60 MPa. However, when the liner thickness was increased to 24 mm, the maximum stress decreased to approximately 40 MPa [132].
Bartel, et al. also found that maximum subsurface stresses caused by shearing during indentation could occur at the surface of the liner or at some point below the surface at the center of contact [133]. However, no research discusses the geometric parameters that determine the depth that these stresses occur.

No literature was found that discussed the relationship between condylar angle of curvature or tibial plate surface area and contact stress in the liners. Furthermore, some variables may be linked in this research, such as liner thickness with cross-sectional area of the liner and condylar angle of curvature and contacting surface area. Further research will be needed to determine if this is the case.

Finally, based on the optimization equations and optimum parameters in Table 19, it’s possible that a new generation of TARs can be designed that will allow for reduced fretting wear and delamination in the UHMWPE liners through reduction of peak and overall stresses throughout the mobile bearings. The maximum surface Mises stress with this new optimization model is only 11.5216 MPa. This compared favorably to other studies conducted, where surface stresses ranged from 5.7 to 27 MPa [70]. However, due to the limitations of the prediction equations used, the maximum sub-surface stress could not be determined. Based on Equation 15, if one increases the liner thickness and articulating surface area, cross-sectional Mises stresses can be significantly decreased. This, in turn may lead to significantly decreased delamination in the liners, which is caused by sub-surface shear stresses [127].
VIII. CONCLUSIONS

This research is meant to bring finite element analysis together with characteristic mathematical models of stress and wear in order to effectively characterize and reduce the amount of wear in the mobile bearings of TARs. This is necessary in order to increase the life of the implants and drive down the number of revision surgeries caused either directly or indirectly by the wear of TAR bearings. The main conclusions drawn from this research are as follows:

- A characteristic axial force model for the stance phase of the ankle gait was developed in order to predict forces based on instantaneous times during the cycle.

- Linear viscoelastic parameters for UHMWPE were modeled during finite element analysis in order to simulate creep and stress relaxation that occurs in the material.

- Finite element models developed for this study were used to determine the contact and sub-surface stresses that develop as a result of geometric and kinematic interactions between the bearing and the talar component of the implant.

- Hertzian contact mechanics and Archard’s wear law were used to develop a model that predicts wear rates based on geometric principles of the implant and the resultant contact pressures produced due to the contact of
• the bearing and the talar component. In order to produce a more accurate model, certain parameters may be included in the mathematical model, such as accounting for friction between the bodies and using contact models that more closely resemble the interactions between a solid body and a viscoelastic one.

• The optimization equations determined from this study may provide a basis for the improvement of TARs and a new generation of Ohio TARs that are designed with low contact and subsurface stresses in mind. In doing so, the next generation of TARs may well have lifetimes exceeding those of the current generation.

• Limiting factors of the FEA research include the use of only axial in the FEA simulation and the use of fixed loading conditions on the tibial and talar components as opposed to simulating the ROM of the ankle during loading.

• Finally, Verification of the results obtained in this study, either through in vivo or biomechanical testing would allow for a much more accurate depiction of the biomechanical behavior.
IX. APPENDIX

Figure 100: Model M1 Mesh

Figure 101: Model M2 Mesh
**Figure 102**: Model M3 Mesh

**Figure 103**: Model N1 Mesh
Figure 104: Model N2 Mesh

Figure 105: Model N3 Mesh
Figure 106: Model N4 Mesh

Figure 107: Maximum Cross-Sectional Mises Stress Model: M1 Material: Ti6Al4V
**Figure 108:** Maximum Cross-Sectional Mises Stress Model: M1 Material: CoCr

**Figure 109:** Maximum Cross-Sectional Mises Stress Model: M1 Material: Stainless Steel
**Figure 110:** Maximum Cross-Sectional Mises Stress Model: M2 Material: Ti6Al4V

**Figure 111:** Maximum Cross-Sectional Mises Stress Model: M2 Material: CoCr
Figure 112: Maximum Cross-Sectional Mises Stress Model: M2 Material: Stainless Steel

Figure 113: Maximum Cross-Sectional Mises Stress Model: M3 Material: Ti6Al4V
**Figure 114:** Maximum Cross-Sectional Mises Stress Model: M3 Material: CoCr

**Figure 115:** Maximum Cross-Sectional Mises Stress Model: M3 Material: Stainless Steel
Figure 116: Maximum Cross-Sectional Mises Stress Model: N1 Material: Ti6Al4V

Figure 117: Maximum Cross-Sectional Mises Stress Model: N1 Material: CoCr
Figure 118: Maximum Cross-Sectional Mises Stress Model: N1 Material: Stainless Steel

Figure 119: Maximum Cross-Sectional Mises Stress Model: N2 Material: Ti6Al4V
**Figure 120:** Maximum Cross-Sectional Mises Stress Model: N2 Material: CoCr

**Figure 121:** Maximum Cross-Sectional Mises Stress Model: N2 Material: Stainless Steel
**Figure 122:** Maximum Cross-Sectional Mises Stress Model: N3 Material: Ti6Al4V

**Figure 123:** Maximum Cross-Sectional Mises Stress Model: N3 Material: CoCr
Figure 124: Maximum Cross-Sectional Mises Stress Model: N3 Material: Stainless Steel

Figure 125: Maximum Cross-Sectional Mises Stress Model: N4 Material: Ti6Al4V
Figure 126: Maximum Cross-Sectional Mises Stress Model: N4 Material: CoCr

Figure 127: Maximum Cross-Sectional Mises Stress Model: N4 Material: Stainless Steel
X. REFERENCES


12. Rho, Jae-Young, Kuhn-Spearling, Liisa, Zioupos, Peter, Mechanical Properties and the Hierarchal Structure of Bone, Medical Engineering & Physics, (1998) 20; 92-102


33. Mosekilde L., Danielsen C.C., Biomechanical Competance of Vertebral Trabecular Bone in Relation to Ash Density and Age in Normal Individuals, Bone, (1987) 8, 79-85


41. Anderson, Frank C., Pandy, Marcus G., Static and Dynamic Optimization Solutions for Gait are Practically the Same, Journal of Biomechanics, (2001) 34; 153-161


66. Vickerstaff, John A., Miles, Anthony W., Cunningham, James L., A Brief History of Total Ankle Replacement and a Review of the Current Status, Medical Engineering of Physics, (2007) 29; 1056-1064


76. BOX Total Ankle Replacement (www.finsbury.org) (Accessed 28 January 2008)


108. Hertz H., Uber die Berührung Fester Elastischer Koper, J. of Reine und Angewandte Mathematik, (1896) 92; 156-171

109. LeCain, Nicholas, Tutorial of Hertzian Contact Stress Analysis, College of Optical Sciences, University of Arizona, (2011)


111. Pruitt, Lisa A., Deformation, Yielding, Fracture, and Fatigue Behavior of Conventional and Highly Cross-linked Ultra High Molecular Weight Polyethylene, (2005), 905-915


143


