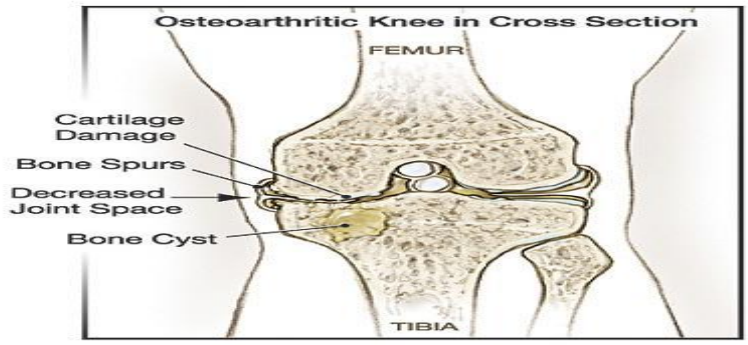
Osteoarthritis

Senior Capstone Design Project

Submitted to:
Dr. Miguel Bagajewicz
University of Oklahoma

"The Hyaluronan Solution to a Devastating Problem"



By:
Chris Clark And Kim Fink

Spring 2006

Executive Summary

The primary goal of this project was to create a treatment for osteoarthritis that is superior to those currently found on the market. There are nearly 23 million of people in the US alone that suffer from this degenerative joint disease, and this number is continually increasing. Although most people with osteoarthritis are over the age of 65, anyone is susceptible and can develop the disease for a number of reasons including impact injury, obesity, and genetic defects. The actual mechanism for the development of osteoarthritis is not fully understood but one thought is that the viscoelastic properties of synovial fluid, the fluid that separates the articular surfaces of the knee joint, are reduced. Since the actual cause of the disease is unknown, current treatments are not able to stop or reverse the degeneration. One of the newest treatments being used is viscosupplementation in which derivatives of hyaluronic acid, the primary component of synovial fluid, is injected into the knee to restore the viscoelastic properties. These current treatments must be administered once per week for 3-5 weeks and only last for approximately 6 months. This leads to accumulating costs in addition to the inconvenience to patients causing an increase in demand for more successful treatments. Therefore, our task was to create a novel solution to provide longer-lasting effects over other products.

The treatment being proposed is more stable – meaning less likely to degrade – than current treatments due to a novel crosslinker being introduced. A hyaluronic acid derivative will be made through "bottom-up" synthesis and modified with 2-vinyl. Then ammonium peroxydifulfate will be introduced as a crosslinker to create a hydrogel. This treatment will use hyaluronan as a basis for the structure due to its chemical properties and biocompatibility. Through the properties of hyaluronan and the crosslinking associated with the structure a viscosity of around 16 Pa·s will be reached under moderate shear rates. This value of viscosity has been found to be adequate through the lubrication theory. The structure will have a molecular weight around 3 million Daltons which will consist of approximately 6700 monomers and 1000 crosslinks.

It has been found through economic analysis of the competition that in order for our product to be competitive our product would have to cost around $2,400 per total treatment. Through the application of microeconomics equations it has been found that the demand for our product at this price should range from 350,000 people in the beginning all the way up to 625,000 people. Using this expected demand and looking at the possibility that the expected demand could be wrong by a deviation of 200,000 people, risk was assessed to the Net Present Value. It was found that the mean expected Net Present Value was around $240 million after 10 years. We also aim to receive approval from the FDA and modeled this process by looking at different possible scenarios. By analyzing the risk of failure it was found that it would be most profitable and less risky to have 10 workers and 85 experiments to go through each module of the FDA process.