DESIGN AND OPTIMIZATION OF A PROSTHETIC MEDIAL COLLATERAL LIGAMENT

Justin Piccirillo
Department of Mechanical and Industrial Engineering
University of Massachusetts, Amherst

ABSTRACT
In today’s medical field, the use of artificial ligaments has obtained minimal success. Many doctors question the reliability of these substitutes over autogeneous tissue grafting [10]. Should the material in an artificial ligament break down and particles contaminate the knee joint, there could be horrific consequences to the patient [2]. Unfortunately, this choice is not taken without side effects. When a natural grafting procedure is undertaken, a portion of the patient’s patella tendon is removed and fashioned into a replacement ligament using bone plugs to secure either end. The recovery time in these operations tend to be, as one might envision, quite long and arduous.

It is this inherent danger to patients that prescribes the need for new and improved designs in artificial ligaments. Finite element modeling (FEM) provides an ubiquitous method in which computer-generated models (i.e.: pseudo-experiments) may be run to represent real-world biomechanical systems and macro-scale interfaces between organic and inorganic material structures. The ability of FEM to predict long-term material and structural characteristics in a benign realm of imaginary space and over short computing times provides ample rationale for its use in this context.

This report covers the design and subsequent optimization of a simplified prosthetic Medial Collateral Ligament (MCL).

INTRODUCTION
The medial collateral ligament is but one of ten ligaments which hold together the assemblage of the human knee. In the past considered a simple hinge joint mechanism, the knee provides far more complexity in its true design and operation [3]. Figure 1 depicts the MCL in an open view. In this picture, most of the soft tissue surrounding the ligament has been dissected and removed, leaving just the ligament in question and the attached bone structures of the femur and tibia, as well as some of the soft tissue between the joint.

Fig 1: The area surrounded in blue represents the MCL [4]

In general, ligaments perform much like a rope or cable. Stiffness and tensile strength components are highly orthotropic with respect to directions longitudinal and transverse of the main fiber direction. Under longitudinal strain, ligaments provide a majority of their holding capacity. In the transverse direction however, they are described as being completely limp and fold even under their own weight.

Figure 2 indicates the directional dependency for natural ligament material, where the modulus of elasticity in the longitudinal direction is 332.2 MPa and the degree of orthotropy is 0.0331. The degree of orthotropy is a ratio between the modulus of elasticity longitudinal and transverse fiber directions.

Fig 2: Transverse and longitudinal strain versus stress graph for a human MCL [9]
Anything but a homologous solid, ligaments are a complex structure, built up on a fiber arrangement to give varying stiffness in transverse and longitudinal directions. In Figures 3 and 4, the buildup of nano-fibers are shown in correlation to the macro-scale fibers that we can see under a light-powered microscope.

Fig 3: The nano- and micro-structures of natural ligaments are highly ordered fibers

Fig 4: A picture of the MCL in a healthy state (~20x magnification) [8]

The fibrous nature of ligaments is entirely beneficial to the operation of the knee. In the case of the MCL during normal gait, we ought not to worry about heavy loading transverse to the fiber direction. However, during a side-loading scenario upon the knee, the MCL becomes a major weight-bearing, length-wise-loaded member. It retains the femur and tibia from pulling apart vertically along the medial side. In a loading scenario where the knee might be pushed outward with respect to a planted foot, the MCL is placed in such a fashion to absorb much of the energy that might otherwise dislocate the knee joint.

In Figure 6, we see how an extreme horizontal load to the knee might work to split the knee joint and sever the MCL. Some calculations put the load capacity at the bone-to-ligament interface to be as high as 700 N [14].

Fig 5: The MCL is acutely prone to damage in any number of lateral loading scenarios [5]

One of the curious properties of ligaments are a result of their fantastic ability to retain water. As seen in the following graph, Figure 6, natural ligaments contain between 60 and 70% water. Much of this water is bound to collagen, which comprises a majority of the structural component of our fibers. The bound water-collagen relationship gives the effect on our ligaments of being almost entirely non-compressible.

Fig 6: Ligaments contain several types of collagen, some elastin, and other organic materials – a majority of the constitution, however, comes from water

CURRENT DESIGNS

Artificial ligaments have been proposed and used as a substitution to autogeneous and allografted tendons since the late 1950’s. Varying success has been shown with material selections as varied as catgut to polyethylene terephthalate (PET) [6,1]. The common trade name for PET is Dacron, which is often sold as fishing line. Dacron is a pliable, stretchy, and porous material. Most importantly, Dacron is biocompatible in the human body.

Porous materials are often incorporated into artificial implants when the potential exists for the body to integrate the implant as a naturally occurring feature of the body. It should a main goal in this or any implant design to be adopted rapidly and innocuously by the body.

Porosity is highly desired because of the body’s own capacity for regeneration. Microorganisms called fibroblasts reside within natural ligaments and act to repair damaged tissue. The rate of this repair is often a function of where and in which ligaments tears may have occurred. Ligaments being nearly or entirely avascular and have no blood flow to carry nutrients or oxygen for the fibroblasts. Nevertheless, fibroblasts are highly desirable since they will add natural
ligament. Natural ligaments undergo constant regeneration, whereas an implant will only degrade. The half-life of collagen is said to be 300 to 500 days. [7]

Additionally, if fibroblasts are not stimulated to the site of the implant, the risk of bodily rejection runs far higher. A lack of fibroblasts often indicates a precursor to infection. Should inflammation cells be sent to ward off the implant, severe and permanent damage to the knee could ensue in the form of arthritis and calcification. Some future artificial ligament designs might incorporate chemical stimulants to provide nutrients specifically aimed at encouraging ligament regrowth and attracting fibroblasts.

The most recent addition to the list of artificial ligament designs originates from France. The Ligament Advanced Reinforcement System (LARS) is a fiber web arranged in much the same way Chinese finger-cuff toys are meshed. See Figure 6 below.

![Fig 7: The LARS PET fiber mesh](image)

The main problem in these meshes arises as a direct result of friction between fibers. When one considers the millions of steps one might encounter over a lifetime, this amounts to great deal of chafing. According to Dr. Hill of the University of Colorado, the average person takes between 3,000 and 5,000 steps a day. At a high end, this would put our average person walking at 1.8+ million steps per year. In the following picture, Figure 7, we see what happens to the LARS system as testing approaches 8 million cycles.

![Fig. 8: The LARS artificial implant begins to break by 8 million cycles. After another 2 million cycles, it is almost completely frayed](image)

**FINITE ELEMENT CONCERNS**

If the lack of long-term patient data on the use of artificial ligaments does not scare off practitioners, Figure 8 should. The goal of this paper is to present a logical and formative decision process on how one might achieve an optimal design for an artificial ligament. The design that is given in the context of this report is purposefully simple - it does not contain or account for many of the factors in which an actual design must properly take into consideration. First and foremost, a proper material selection would be a bewildering complexity unto itself. Material selection must account for the numerous biological factors that are listed above.

From a structural standpoint, a proper material choice would require some degree of orthotropic or anisotropic behavior. This directional dependency would certainly be required in the case of the MCL, where the normal cyclic loading scenario is transverse to the length of MCL and requires great flexibility.

Should an isotropic material be chosen and aimed specifically at preventing failure during a lengthwise loading scenario, we could certainly envisage buckling within our artificial ligament design. In order to perform a finite element analysis on an orthotropic, or even anisotropic material, we become severely limited by the use of a global coordinate system. If our design incorporated a fiber matrix, nothing but the simplest axial member could align itself to the global coordinate system. We would, after all, require some portion of our design to incorporate fixation to the bone surfaces, and therefore a slightly complex geometry around this fixture. Finite element analyses of fiber matrices require an alignment of each element to its own coordinate system. It would be wise to match this alignment and that of our direction of highest elastic modulus to the maximum principal stress tensor at each element. The maximum principal stress tensor, it could be argued, represents an ideal fiber direction or direction of maximum stiffness. The complexity associated with fibers and directionally dependent material properties requires a fully populated stiffness matrix at each element.

At this point, we have yet to consider any of the real-life problems associated with wear, fatigue or the birth-and-death calculations of ligament regrowth by fibroblasts.

**SIMPLIFIED MODEL**

For the context of this report, we will consider a model like the one shown in Figure 9. This design considers an lengthwise loaded solid (non-fibrous, non-porous) isotropic material. The isotropic material we incorporate is somewhat arbitrary. For our simple case, a modulus of elasticity equivalent to the longitudinal properties of the natural ligament is used. Modulus of elasticity, $E$, is set at 332.2 MPa. Nota bene: in a fully considered design with a degree of orthotropy, it would be a good idea to set both parameters as being variable for the later design optimization.
Before we can go into the details of our design optimization, some discussion is required of the finite element analysis. In the design above, it should be obvious that several simplifications can be made. Because our design incorporates constant thickness, we can reduce a full-out 3D geometry down to a simple planar geometry. Additionally, lines of symmetry make it possible to cut our model evenly lengthwise and along the orthogonal direction. These reductions are shown in Figure 11.

**Fig 9:** A simply loaded artificial MCL design, fixed at either end by a titanium bone screw

Because we would like to be able to attach the artificial ligament with a quick and relatively painless procedure, we want to minimize the volume of our design. Often, arthroscopy and the use of small probes and tools are the preferred tools in knee surgeries. In this fashion, a prosthetic may be installed via small incision sites. These same incision sites may be used to removed damaged natural ligament, though for obvious reasons, prior to installation of the replacement.

The artificial design proposed here can be minimized in volume with respect to the five variable parameters shown in Figure 10. These parameters include the shank width, W_SHANK, shank filet radius, R_SHANK, the diameter of the fixator hole, D_IN, diameter geometry around the hole, D_OUT, and the thickness of our part, T.

**Fig 10:** The variable parameters on our axially loaded, isotropic artificial MCL

Choosing constraints for our model is of utmost importance in the case of this or any finite element analysis. One of the biggest areas of concern should be in the boundary touching our titanium bone screws. The modulus of elasticity on titanium 113.8 GPa, almost 350 times stiffer than the proposed prosthesis material [11]. For this fact, we should expect to see the ligament material stretch around the screw and deform tangentially around the circular screw geometry. Even if we could constrain the contact face from movement in a manner that was local to a single element on the contact face, it would be imprudent to do so.

Maintaining this shape requires one of two approaches. For both, a frictionless system is considered. The first implements a nonlinear contact analysis. This method was tried several times, though with varying success. ANSYS, being the FEA software available for this experiment, was found to yield unreliable results in several cases. Convergence of the results was unable to be determined, as the software often crashed with changes in mesh size or mesh geometry. One of the findings often seen was that of surface impingement, as shown in Figure 12.

**Fig 11:** A reduced geometry

This matter was rectified by the use of a little known, but invaluable analytic relationship. In Figure 13, a pin subjected to a load P via an eye-bar observes a defined stress at the surface of the pin. This loading scenario is analogous to that of our example of the lengthwise-loaded artificial ligament.

**Fig 12:** The geometry above represents a screw face being impinged upon by our model

This matter was rectified by the use of a little known, but invaluable analytic relationship. In Figure 13, a pin subjected to a load P via an eye-bar observes a defined stress at the surface of the pin. This loading scenario is analogous to that of our example of the lengthwise-loaded artificial ligament.
Here we observe the following relationship

\[
(\sigma_r)_{\theta=a} = -\frac{2P \cos \theta}{\pi \ a} \quad \text{for} \quad -\frac{\pi}{2} \leq \theta \leq \frac{\pi}{2}
\]

where \((\sigma_r)_{\theta=a}\) is exactly equivalent to the pressure distribution along the face of our titanium screw [13].

This pressure distribution was implemented in ANSYS as a piecewise linear approximation of a 700 N load along a series of 10-lines representing the contact face of the screw geometry. Figure 14 gives an adequate view of this representation.

Fig 14: A piecewise-linear approximation for the sinusoidal pressure distribution along the screw contact surface

Having an adequate understanding of the pressure distribution at the ligament–bone screw interface permitted a significant improvement in computing accuracy and speed over the nonlinear case. Additionally, it enabled the use of the design optimization algorithms contained within ANSYS. In the case of the nonlinear contact analysis, the model was too unstable and therefore unable to iterate properly the optimization process.

Because the solution now only took into account a single material type and the operations required for solving this system were linear, determination of convergence was made significantly more rapidly than if they had not been. Convergence on a viable initial solution was determined automatically through ANSYS and the “PRERR” command. The PRERR command initializes a calculation upon the variance between discrepancies in the calculated stress field and the globally continuous stress field. The error arises because the finite element method usually considers nodal displacement calculations to be continuous, while the same constraint is relaxed for stress and some error is permitted to occur. Generally, as the element size decreases, the overall error decreases. In our case, the initial design provided a percent error in the structural energy norm of just 1.04%. At the end of our design optimization, we found a discrepancy of 0.49%. From these figures, we can be reasonably sure that our solutions are free from large-scale residual error.

**DESIGN OPTIMIZATION**

The objective of the design and our optimization of it were to be able to package the artificial ligament design in the most compact volume possible without violating certain size and material constraints. In this regard, it becomes convenient to develop a general objective function.

\[
V = f(T, D_{IN}, D_{OUT}, W_{SHANK}, R_{SHANK})
\]

where \(V\) is our volume and \(f\) is a general function of our design variables.

Additionally, for our constraints,

\[
\sigma = g(T, D_{IN}, D_{OUT}, W_{SHANK}, R_{SHANK})
\]

where \(\sigma\) is the maximum von Mises stress and \(g\) is another general function of our design variables.

At this stage, we may also define our design limitations in the following manner.

\[
37.0 \text{ MPa} \leq \sigma \leq 38.75 \text{ MPa} \\
0 \text{ m} \leq T \leq 0.010 \text{ m} \\
0.027 \text{ m} \leq D_{IN} \leq 0.065 \text{ m} \\
D_{IN} \leq D_{OUT} \leq 0.020 \text{ m}
\]

We also provide an initial point with which our design shall begin the optimization. The design iterations are started with the design variable inputs shown in Table 1.

| \(D_{IN}\) | 0.006 m |
| \(D_{OUT}\) | 0.005 m |
| \(T\) | 0.0025 m |
| \(W_{SHANK}\) | 0.0045 m |
| \(R_{SHANK}\) | 0.025 m |

**Table 1:** Initial design variables

Considered the most accurate design optimization routine within ANSYS, a first order algorithm was used to provide a realistic estimation of a design with minimized volume. Anyone familiar with design optimization should know that we ought not to consider the resulting design to be a unique or even perfectly optimized. This method is not without its flaws,
and not guaranteed to provide perfectly optimal results. This is the same for almost any optimization technique. Given that it is a gradient-based method, we can only be assured of finding local minima in the objective function. That is not to say that our solution will not be a globally minimized solution. The overriding benefits to using the first order algorithm comes about when one examines its underpinnings from a mathematical prospective. The following formula describes the methodology of how our constrained problem is transformed into an unconstrained optimization.

\[
Q(x, q) = \sum_{i=1}^{n} P_{x}(x_{i}) + \sum_{i=1}^{m_{1}} P_{g}(g_{i}) + \sum_{i=1}^{m_{2}} P_{h}(h_{i}) + \sum_{i=1}^{m_{3}} P_{w}(w_{i})
\]

where \( Q \) is a dimensionless, unconstrained objective function, \( P_x, P_g, P_h, \) and \( P_w \) are penalties applied to the constrained design and state variables and \( f_0 \) is a reference objective function value that is selected from the current group of design sets. [12]

This method is most aptly described as an interior-exterior penalty method, where search directions focus down the gradient of our objective function, but are weighted heavily as to the relative location of the iteration step with respect to the real-space location of the feasible region. In other words, if at any iteration, the resulting objective is determined to be infeasible, the weighting function will attempt to pull the direction of the next iteration towards the feasible space.

The results of our optimization can be seen in the following diagrams, Figures 15-17. In Figures 15 and 16, it should be noted that our initial design parameters were significantly smaller than what was required to affect a maximum nodal von Mises stress of 38.75 MPa. Within just one or two iterations, the design variables were carried into a feasible region by increasing their dimensions. Furthermore, in terms of a visual determination of optimization convergence, our design and state variables, and the objective function plateau around iteration number 67.

\[\text{Fig 16: Maximum nodal von Mises stress with respect to iteration number (values in Pa)}\]

\[\text{Fig 17: The objective function, volume, with respect to iteration number (values in m}^3\text{)}\]

Convergency was handled within ANSYS by comparing the objective function at the \( i \) and \( i+1 \) iteration steps. Once the difference in these two values became lower than a user defined setting, iterations stopped and convergence could be declared.

Final design variables are shown in Table 2.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>D_IN</td>
<td>0.54543E-02 m</td>
</tr>
<tr>
<td>D_OUT</td>
<td>0.44688E-02 m</td>
</tr>
<tr>
<td>T</td>
<td>0.81421E-02 m</td>
</tr>
<tr>
<td>W_SHANK</td>
<td>0.49948E-02 m</td>
</tr>
<tr>
<td>R_SHANK</td>
<td>0.21393E-01 m</td>
</tr>
</tbody>
</table>

\[\text{Fig 15: Design variables with respect to iteration number (values in m)}\]
The final design achieved by our optimization is one that makes intuitive sense. We would expect that our shank radius, R_SHANK, might be large to dissipate any stress concentrations in the area of the shank-to-eyelet attachment. Additionally, from the example of our natural ligament, we might come to expect that our design would obtain some resemblance in terms of the dimensions for width and thickness. The natural ligament is about 0.5 cm at its thickest point and about 0.75 cm wide in that same region (at the femur-tibia interface). Here we can say that our shank provides nearly the same cross-sectional area (0.406 cm$^2$ in the design versus ~0.375 cm$^2$ for natural).

Deflection and von Mises stress distributions are shown in Figures 18 and 19, respectively. Notice how the form of the contact area between the ligament design and the screw retains its initial shape. This further indicates that the model was an accurate representation of the real-world design.

**CONCLUSIONS**

The modeling and subsequent optimization of a simple artificial MCL design was performed and of accurate representation of its idealized application. Additionally, the first-order optimization method provided within ANSYS was shown to be a useful optimization tool. On a reverse note, it is highly recommended that one not use ANSYS surface analyses for its lack of convergence and dependability.

The real-world scenario will take far more design preparation that must include analyses of fatigue, natural ligament regrowth, wear, friction, directional dependency upon material properties, crazing, (potentially creep) and the use of fibers.

Given the fact that all these analyses will take some time to perform, it may be wisest to utilize a Design of Experiments (DOE) or Taguchi Method® based regression analysis approach to optimization.

**ACKNOWLEDGMENTS**

I would like to thank Dr. Jeff Weiss of the University of Utah for his excellent advice and exceptional contribution to the study of ligaments.

**REFERENCES**

4. Image courtesy of Dr. Jeff Weiss, Dept. of Biomedical Engineering, University of Utah
5. Image courtesy of the Medical Multimedia Group
12. Source: ANSYS documentation.