**Thesis Project Portfolio**

**3D Lung Volume Calculation for Scoliosis Patients**

(Technical Report)

**An Evaluation of the Ambulatory Classification Levels and Reimbursement Methodologies of the Prosthetics Industry**

(STS Research Paper)

An Undergraduate Thesis

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Bachelor of Science, School of Engineering

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## Sociotechnical Synthesis

The marketisation of healthcare can often lead to those who belong to smaller demographic groups, such as people with disabilities, receiving suboptimal levels of care. These small pockets exist across the US healthcare system, from children with rare scoliosis to scattered amputees forced to work within an outdated system. In order to address larger issues within the healthcare system, it is critical to first uncover why these small populations consistently experience adverse healthcare outcomes and work to understand how to confront the dislocations that have occurred.

For those with early onset neuromuscular or syndromic scoliosis, the existing techniques for measuring and tracking total lung capacity (TLC) are insufficient and can make a physician's decision regarding the timing of spinal fusion surgery difficult. The growth of neural networks in the past few years has created the opportunity to segment and label ribs and determine lung volume through analysis of biplanar X-rays alone. That is the task the technical portion of this report sought to undertake. Total lung capacity was calculated through subtracting the mediastinum volume from the rib cage volume, the former being determined through a multivariate linear regression and the latter determined via a convolution neural network. The mediastinum volume was able to be predict with a relatively high accuracy compared to previous work and the convolution neural network was able to identify the ribcage with limited success.

For many of the 2 million Americans living with a missing limb, the current policies in place within the orthotics and prosthetics sector of healthcare have inhibited their access to potentially life changing devices due to high costs, negatively affecting their physical, financial, and physiological health. The research section of this report identifies the policies that restrict access to these advanced devices, the benefits of these devices as well as their true cost.

Although the biplanar ribcage identification presented in the technical portion of this report was not accurate enough to progress further in lung volume calculation, significant advancements were made in mediastinal volume calculations. As the capacity of neural networks continue to improve every year, the possibility of a more inclusive and affordable lung volume calculation technique grows closer for future teams to strive towards. Furthermore, the evidence presented in the research section of this report has the potential to increase public awareness and provides recommendations for future research that in combination could assist in in the facilitation of policy change that would change hundreds of thousands of lives.

**3D Lung Volume Calculation for Scoliosis Patients**

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**3D Lung Volume Calculation for Scoliosis Patients**

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**Abstract**

Early onset scoliosis is a three-dimensional curvature of the spine that occurs in patients 10 years or younger. Physicians tend to pursue non-surgical options first. If these are unsuccessful, surgical intervention becomes necessary. In scoliosis cases, physicians use total lung capacity as the metric for determining the optimal time for surgery. Current standards of treatment do not offer an accurate way for physicians to measure total lung capacity for early onset scoliosis patients. This project offers a potential solution to this problem. The total lung capacity can be calculated by subtracting the mediastinum volume from the rib cage volume. A multivariate linear regression was used to create a predictive equation with patient demographics as input variables to predict the mediastinum volume. This equation predicted mediastinum volume at a higher accuracy compared to previous work and had a multiple $R^2$ of 0.87. To calculate the rib cage volume, a convolutional neural network was built. Using X-ray images, a computer could train itself to identify the rib cage. Although the rib cage volume was not calculated, the convolutional neural network was able to identify the rib cage to a limited degree. The model built here can be further improved upon to calculate a volume. If successfully calculated, the mediastinum and rib cage volumes could be combined to calculate the total lung capacity.

Keywords: Early Onset Scoliosis, Lung Volume, Predictive Equation, Convolutional Neural Network

## Introduction

Early onset scoliosis (EOS) is a spinal deformity that presents itself before 8-10 years of age[1]. The four types of EOS are idiopathic, congenital, neuromuscular, and syndromic[2]. Idiopathic scoliosis has no known cause. Congenital scoliosis is present at birth. Neuromuscular scoliosis is caused by a systemic condition such as cerebral palsy or muscular dystrophy. When scoliosis is part of a larger condition, such as Marfan's Syndrome, it is called syndromic scoliosis. While the overall prevalence of EOS is unknown, scoliosis has an incidence of two to three percent of the US population[3,4]. While 80% of scoliosis cases are idiopathic, idiopathic EOS cases make up less than one percent of all scoliosis cases[4,5]. Although EOS is a rare condition, a treatment plan needs to be created for each patient. If left untreated, EOS can bring about an early death due to pulmonary complications[1].

Non-surgical options are often initially used to treat EOS to slow progression of the disease[6]. A common surgical option is spinal fusion, which corrects the spinal deformity and curvature seen in scoliosis patients. An incision is made either through the back or the side of the patient, and two metal rods are then placed alongside the vertebrae to force it to straighten[7]. If this procedure is performed too early, the patient can develop restrictive pulmonary disease[8]. For this reason, spinal fusion is not a routine procedure at a young age. In order to proceed with this surgery, it is crucial to determine the total lung capacity (TLC) of the lungs. TLC allows the physician to determine if the patient will have proper pulmonary function after spinal fusion surgery. Two common methods for measuring TLC are spirometry or pulmonary function testing (PFT), and computed tomography (CT)[9]. However, there are drawbacks to these methods. It is difficult for young children or those with disabilities to perform the PFT properly. CT scans also have multiple drawbacks. They are relatively expensive, subject patients to roughly ten times the amount of radiation of an X-ray[10]. The current options for determining TLC offer no clear set of rules or indications to perform surgery. Instead, the best option is to rely on the doctor's expertise and experience[6].

This project investigates the hypothesis that sagittal and coronal X-ray images can be used in combination with patient demographics to calculate TLC. While X-rays may not be able to identify the lungs, they do display the rib cage. By using a convolutional neural network, a computer can learn to detect the rib cage from images. From this the volume of the chest cavity can be calculated. Patient demographics are used to predict mediastinum volume. If the volume of the mediastinum, the central portion of the thoracic cavity that is not the lungs, is subtracted from the

volume of the chest cavity, TLC will be calculated.

## Results

### *Creating a Predictive Equation for Mediastinum Volume Using Patient Demographics as Inputs*

Calculation of Mediastinum Volume from CT Scans

Mediastinal volume was computed using the MATLAB software package Pulmonary Toolkit. Our work was built upon the code of the previous capstone group and needed to be debugged before it was able to run[11]. In order to make handoffs to future groups easier, comments were added to the code to make it easier to understand and modify.

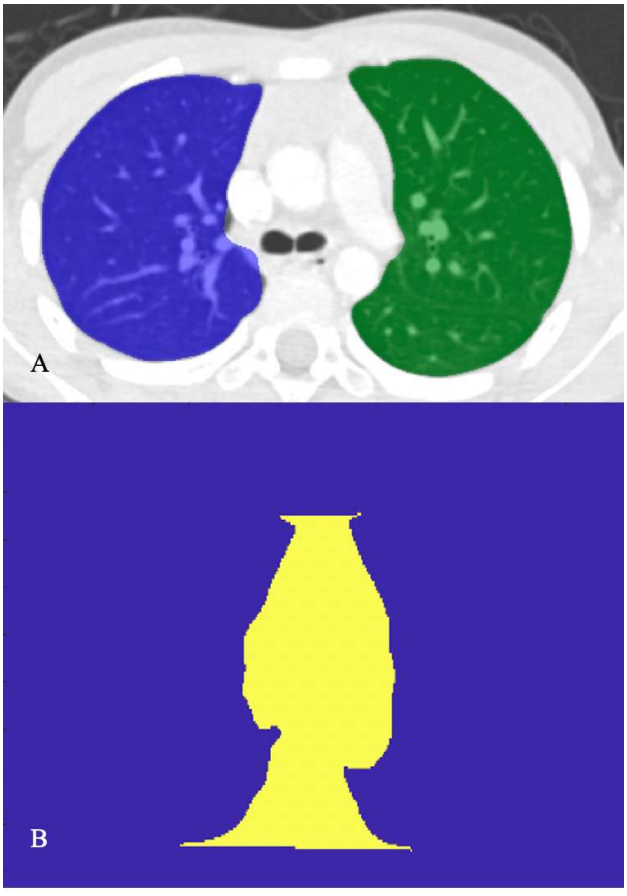


**Figure 1. Lung Segmentation and Mediastinum Area.** Both images are the result of lung segmentation using the Pulmonary Toolkit. Panel A is the segmentation of the lungs directly from the Pulmonary Toolkit and panel B is the area of the mediastinum (in yellow) from one of the CT slices.

The Pulmonary Toolkit uses DICOM files from CT scans as its input. It finds the boundaries of both the right and left lung and then segments them (Figure 1). Each slice of
the CT scan is examined and the area in between the lungs is calculated (Figure1). The mediastinum area of each slice is used to compute the volume.

Our group was provided with some initial calculated volumes but they lacked information on patient height. Our team hypothesized that height may be an important predictor of mediastinum volume, and in order to pair it with the appropriate volume, new volumes needed to be calculated. A total of 80 CT scans were used to create the predictive algorithm. Some scans were not used because they either lacked important patient demographics or were unable to be segmented.

Validating Mediastinum Volumes

CT scans can be used to estimate mediastinum volume, but they cannot provide the true value. Our team did not have access to the true mediastinum volumes, and without them it is difficult to validate the calculated volumes. The heart is the largest component of the mediastinum, and therefore, heart volumes from literature were used to make sure our calculated values were reasonable[12]. The volumes from the literature are reported in averages and are organized by weight and gender. Since cardiac volume is an underestimate of mediastinum volume, it is expected that our calculated volumes should be greater than the cardiac volumes. Our calculated data set did not have enough data points to compare exact weights so ten pound ranges centered on the target weight were used. As seen in Supplemental Table 1, most of the calculated mediastinum volumes were found to be significantly greater than the cardiac volumes. The calculated mediastinal volumes being larger than their component part does not completely verify them, but it shows that our data is not a gross underestimate. An underestimate of mediastinum volume would lead to an overestimate of TLC. This could have negative repercussions for the patient if their operation resulted in restrictive pulmonary disease due to their actual TLC being too low for the operation. The larger p-values in Supplemental Table 1 are likely due to small sample sizes and ten pound weight ranges. The large amount of N/As for females in the upper weight ranges can be attributed to both a small sample size and lower average female weights.

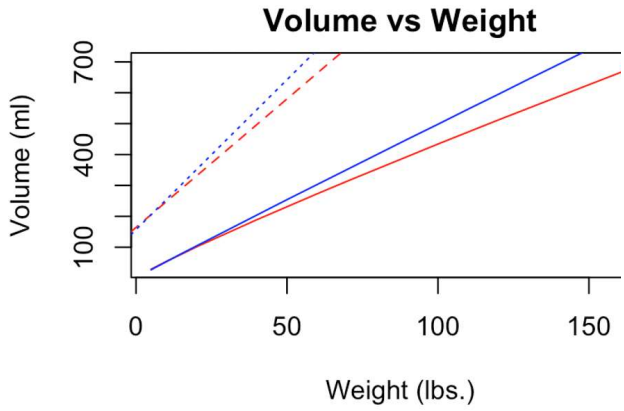


**Figure 2. Mediastinal and Cardiac Volume vs Weight.** Both calculated mediastinal volumes (ml) and cardiac volumes (ml) fi literature are plotted against weight (lbs.). Red lines denote the the female subset while blue denotes males. Solid lines are the c volumes from literature and the dashed lines are lines of best fit calculated mediastinal volume.

Since the heart is the largest component of the mediastinum, mediastinum volume trends should mirror those of cardiac volume. As seen in Figure 2, both cardiac and calculated mediastinal volume increase as weight increases with males having larger volumes in both cases. The similarity in trends suggests that our calculated data may be representative of mediastinum volume.

Linear Regressions Using Individual Variables

Individual variables were plotted against mediastinum volume so that potential inputs to a predictive equation could be identified and so that comparisons can be made against previous results[11]. Specifically, we analyzed how height, age, weight, and gender related to mediastinum volume. We found that age, weight, and height were positively correlated and that on average males had larger mediastinum volumes than females. The regression curves shown in Supplemental Figure 1 show that weight had the highest correlation coefficient, 0.85, and height had the lowest at 0.74. As seen in Supplemental Table 2, our linear regressions had much higher R squared values than the previous year for all measured variables. This is likely due to a narrowed patient age range.

Predictive Model

All four available patient demographics correlated with mediastinum volume and were included in the initial multivariate predictive models. The random forest (RF), multivariate adaptive regression splines (MARS), and multivariate linear regression (MVLR) models were tested to find the model that best fit the data. As seen in Table 1, the multivariate linear regression model is the highest performing model across all metrics. The correlation coefficients, intercept, and their respective p-values for the multivariate linear regression model can be found in Supplemental Table 3. All coefficients in the equation except the intercept were statistically significant at a significance level of $\alpha = 0.01$. Since this equation will not be used when all variables are at or near zero, a non-significant intercept is not problematic. Each of the coefficients from patient demographics are positive indicating that an increase in them will result in an increase in mediastinum volume. This was expected due to the positive linear correlations described earlier. The multivariate linear regression model takes weight, age, and gender as its inputs. Age and height were found to be redundant variables and age provided for a slightly better predictive model. For this reason, height was excluded from the final predictive equation.

**Table 1. Comparison of Predictive Models.** For each model $R^2$, mean absolute percent error, and root mean square error (RMSE) are displayed. Models are listed by descending $R^2$.

| Model | $R^2$ | Mean Absolute Percent Error | RMSE |
|---|---|---|---|
| **Multivariate Linear Regression** | 0.87 | 15.16% | 175.26 |
| **Random Forest** | 0.83 | 16.13% | 247.23 |
| **Multivariate Adaptive Spline Regression** | 0.71 | 18.66% | 319.45 |

### *Rib Cage Identification*

Generating Masks

To train a U-Net model, masks of input images are required, which in this case are the biplanar X-rays. Masks are the specified boundaries the U-Net model uses to learn the desired region of interest. For example, a boundary was drawn along the rib cage. From the original image and the mask, the model can learn where the desired object is located. Our dataset did not contain masks; therefore, they were made manually. The VGG Image Annotator developed by the Visual Geometry Group was used to create the masks. An example of the masks can be seen in Figure 3.

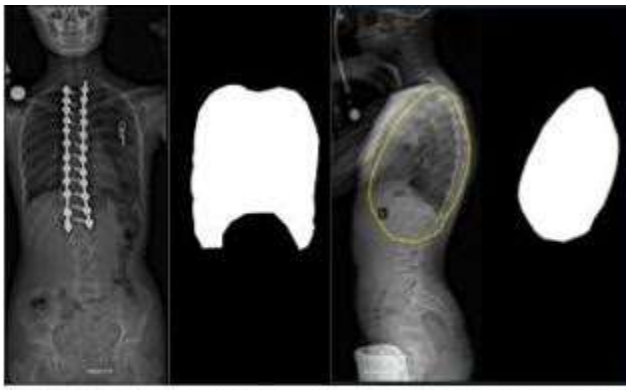

**Figure 3. Example of Generated Mask.** The image display examples of generated masks, along with the original image, for both sagittal and coronal plane X-rays. Additionally, the coronal image shows a yellow line, which is the annotation used to generate the mas

Final Model Specifications

The Adam compiler, which uses the default Adam algorithm, in the keras library was used to construct the optimal model. The final model consisted of an input layer, 4 downsampling layers, 4 max pooling layers, 5 bottleneck layers, 4 upsampling layers, 4 concatenating layers, and one output layer. The model trained itself on the same images over multiple epochs. In one epoch, the model trains itself once on the training images. Therefore, with multiple epochs. the model learns from each run and retrains itself. The model attempts to improve its predictions after each run. A total of 9 epochs were used for the sagittal model. A varying learning rate was also introduced to the model. The learning rate alters how quickly the model changes its prediction based on accuracy. If the accuracy remained constant, the learning rate would decrease. Additionally, the model would cease training when the same accuracy was obtained after successive epochs. The model stopped training after 9 epochs because of the constant output accuracy.

Jaccard Index and Dice Coefficient

The model output two accuracy measurements: the jaccard index and Dice coefficient. The Jaccard index is found by dividing the area of overlap between the prediction and actual values divided by its union. Therefore, the Jaccard index indicates how well the predicted region covers the actual region of interest. The Dice coefficient is found by dividing the area of overlap by the total number of pixels then multiplying this value by 2. The Dice coefficient indicates how much of the total area is covered by the area of overlap. The Jaccard index obtained from the sagittal model was 0.691364 and 0.66833 from the coronal model. The Dice coefficients obtained were 0.5 and 0.5485 from the sagittal and coronal models respectively.

## Discussion

The correlation coefficients for the regressions we made this year were much higher than the previous year's[11]. This is likely due to the exclusion of patients outside of the pediatric age range. The goal of predicting TLC is to determine if the lungs have sufficiently developed, and this is not a large concern for older patients. Furthermore, our focus is on the pediatric population. These older patients were also outliers for the previous group, and this explains why our correlation coefficients were higher.

A study using pulmonary function tests for two patient groups whose average ages were 14.3 and 15.4 years old found that the worst PFTs had TLCs of 3L and the best were 3.9L. Our RMSE was 175.26 ml, and this is 0.058% of the worst TLC[13]. On its own, the error from the mediastinum volume prediction makes it difficult to rely on this method as the sole measure of TLC for surgery, but it may be accurate enough to provide a physician a general idea of their patient's TLC. This may allow a physician to not subject the patient to unnecessary CT scans if their predicted volume is much lower than the threshold. After chest volume is able to be calculated, the error for TLC will likely be higher and the equation for mediastinum volume prediction may need to be further optimized.

The obtained Dice coefficient value was not as high as we had aimed. In the aforementioned study, Wessel et al. was able to get a dice coefficient equivalent to 0.73 for identification from sagittal X-rays[14]. The two U-Net models produced Dice coefficients near 0.5. The larger Jaccard index values may indicate that the model was working effectively. Future tuning of the U-Net model could improve the model's accuracy.

### *Limitations*

For both the mediastinum and rib cage volume calculations, there were no actual measurements of volume. Therefore, the obtained measurements could not be compared to actual values. Using cardiac volumes for mediastinum volume validation made it difficult to judge how accurate the predicted volumes were. It could only be found that the predicted volumes were within reason. This raises the possibility that the predictive model was created on inaccurate data. For the rib cage identification algorithm, there was no true mask for the rib cage. Instead, masks were manually generated. This manual creation introduces human error. The model would then be trained on incorrect data.

The metadata from the CT scans provided a limited amount of patient demographics and some had incomplete metadata that caused them to be excluded from analysis. Additional patient demographics and complete CT metadata would allow for more potential input variables and data points respectively.

Additionally, the U-Net model was unable to output image predictions on the testing data. This lack of information does not allow a visualization of the rib cage prediction. Therefore, it can not be stated with certainty that the model is actually predicting the region of interest with 69% or 66% accuracy in the sagittal or coronal planes respectively.

### *Future Work*

In future work, an emphasis should be placed on improving the accuracy of the rib cage identification algorithm. One possible solution would be acquiring a large dataset that contained both CT scans or spirometry data along with the patient's biplanar X-ray images. First, this would allow a comparison between the predicted volume measurements and the actual measurements. Second, a larger dataset could improve the accuracy of the rib cage identification model. For instance, the coronal model was only trained on 57 images. More data could improve the model's prediction accuracy. Additionally, further model tuning could improve its accuracy. One method would be to further augment the data. There are many data augmenting techniques that were not pursued. These methods have the potential to improve the model.

Finally, creating a unified algorithm and simple software for both rib cage identification and mediastinum volume calculation would provide physicians an easy tool to use in clinical practice. The rib cage identification and mediastinum calculations were written separately.

## Materials and Methods

### *Predicting Mediastinum Volume*

Dataset

Dr. Keith Bachmann provided a data set of deidentified CT scans of patients primarily in the pediatric age range . The CT scans were DICOM files and patient information could be found in the files' metadata.

Mediastinum Volume Calculation

The Pulmonary Toolkit MATLAB package was used to calculate mediastinum volume. The package found the boundaries of the lungs and segmented them. The right and left lung boundaries were identified. The code starts at the top of the lungs (closer to the head) and moves downwards until it finds the start of the both of the lungs. These indexes are used to create the upper boundary of the central mediastinum. If one lung is tilted higher than the other, the interior upper edges of both are found and connected using Bresenham's line package. Given endpoints, Bresenhams's line can calculate intermediate points which will form part of the upper boundary.

The lower boundary of the mediastinum is found by finding the slice in the xz-plane that has the greatest lung area. This slice is used as it will likely be from a central portion of the lung and representative of the lower boundary. The code finds the z position at which the x component of the xz slice is discontinuous, and this marks the beginning of the diaphragm and the lower boundary of the mediastinum. The lungs curve around the diaphragm so a straight line along the x axis would be discontinuous.

After the boundaries have been identified, the slices are stepped through and the area between the lungs is calculated. Any gaps in the area are filled in and the area of all the slices is used to calculate mediastinal volume.

Predictive Model

The predictive model was created using mediastinal volume as the response variable and weight, age, gender, and height as the initial input variables. The data was cleaned in excel and then imported into R for analysis. Initial linear regressions were performed to determine the linearity of the relationship between input variables and mediastinum volume and to serve as a benchmark to previous work. The patient population was trimmed to a pediatric age range as this range is relevant to EOS.

The dataset was randomly divided into a training and testing dataset. Three predictive models were tested on the testing dataset RF, MARS, and MVLR. Each individual variable had a close fit to a linear regression when compared against mediastinum volume. This is the reason for the testing of the MVLR. The MARS model builds upon the MVLR model to make it more flexible and better fit non linear trends. This was used in case our initial impressions of the data were incorrect. The RF model is a machine learning model that can be used for regression and is not prone to overfitting. Three different models were so that any unseen trends in the data could be caught.

***Rib Cage Identification***

Dataset

For the rib cage identification, a dataset was given by Dr. Keith Bachmann. The dataset consisted of a set of biplanar X-ray images taken of scoliosis patients. Biplanar means for each patient there was both a sagittal and coronal image. The images were in DICOM format.

Convolutional Neural Network

The first step in completing the rib cage identification was to identify the optimal convolutional neural network (CNN) for image segmentation. A study illustrated that Mask R-CNN had the potential to identify the rib cage. Although this study was successful, it was only implemented on posterior-anterior X-ray images[14]. There was trouble implementing this network due to its dependency on older libraries and packages. Therefore, other CNN architectures were examined. U-Net is a CNN that was initially trained on medical images. Therefore, the network should train well on this dataset. The U-Net architecture consists of two parts. The first is typical of a traditional CNN. It involves downsampling and pooling the most important features of the training dataset. The second part involves upsampling and concatenating the images. At each layer, the feature map obtained from the downsampling is cut in half [15].

The code for rib cage identification was implemented in Python. It was written on Google Colab Notebooks to allow collaborative coding. Sci-kit learn and keras, which are Python libraries and software, were used to develop the model. The pydicom library was used to convert the images from DICOM to PNG files.

Since the dataset consisted of biplanar X-ray images, two separate models were created. The first model was trained on the sagittal dataset, while the second was trained on the coronal images. Additionally, this involved splitting the original images into their respective image group. In order to train the model, some images had to be removed due to their poor quality. In some cases, parts of the rib cage were not in the image or had objects obstructing its view as seen in Supplemental Figure 2. Eleven images were removed from the posterior-anterior dataset and 28 images from the lateral dataset.

Finally, to train the model each image needed to be the same size. Therefore, the images were all resized to 224 by 224 dimensions. The resizing also helps the model run more efficiently. The model will run faster with a smaller dataset versus larger images. The dataset needed to be split into training, testing, and validation images. The model uses the training and validation images to teach itself. The testing images are used to observe how accurate the model is after creation. The dataset was randomly split.

## End Matter

### *Author Contributions and Notes*

T.A., S.S., and W.F. designed research, T.A., S.S., and W.F. performed research, T.A., S.S., and W.F. wrote software, S.S. analyzed data; and T.A., S.S., and W.F. wrote the paper. The authors declare no conflict of interest.


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## References


1. Skaggs, D. *et al.* Early Onset Scoliosis Consensus Statement, SRS Growing Spine Committee, 2015. *Spine Deform.* **3**, 107 (2015).
2. Blanco, J. Early Onset Scoliosis: Overview. *Hospital for Special Surgery* https://www.hss.edu/conditions_early-onset-scoliosis-overview.asp (2018).
3. Riseborough, E. J. & Wynne-Davies, R. A Genetic Survey of Idiopathic Scoliosis in Boston, Massachusetts. *JBJS* **55**, 974–982 (1973).
4. Scoliosis – Symptoms, Diagnosis and Treatment. https://www.aans.org/.
5. Beauchamp, E. C., Anderson, R. C. E. & Vitale, M. G. Modern Surgical Management of Early Onset and Adolescent Idiopathic Scoliosis. *Neurosurgery* **84**, 291–304 (2019).
6. Cunin, V. Early-onset scoliosis – Current treatment. *Orthop. Traumatol. Surg. Res.* **101**, S109–S118 (2015).
7. Spinal Fusion for the Treatment of Idiopathic Scoliosis in Children. https://orthop.washington.edu/patient-care/articles/childrens/spinal-fusion-for-the-treatment-of-idiopathic-scoliosis-in-children (2009).
8. Karol, L. A. Early definitive spinal fusion in young children: what we have learned. *Clin. Orthop.* **469**, 1323–1329 (2011).
9. Delgado, B. J. & Bajaj, T. Physiology, Lung Capacity. in *StatPearls* (StatPearls Publishing, 2020).
10. Mettler, F. A., Huda, W., Yoshizumi, T. T. & Mahesh, M. Effective doses in radiology and diagnostic nuclear medicine: a catalog. *Radiology* **248**, 254–263 (2008).
11. Wang, D. *et al.* Three-Dimensional Modeling of Lung Volumes in Application to Scoliosis. (2020).
12. Nghiem Quang X., Schreiber Melvyn H., & Harris Leonard C. Cardiac Volume in Normal Children and Adolescents. *Circulation* **35**, 509–522 (1967).

13. Ledonio, C. G. T. *et al.* Pulmonary function tests correlated with thoracic volumes in adolescent idiopathic scoliosis. *J. Orthop. Res. Off. Publ. Orthop. Res. Soc.* **35**, 175–182 (2017).
14. Wessel, J., Heinrich, M. P., von Berg, J., Franz, A. & Saalbach, A. Sequential Rib Labeling and Segmentation in Chest X-Ray using Mask R-CNN. (2019).
15. Ronneberger, O., Fischer, P. & Brox, T. U-Net: Convolutional Networks for Biomedical Image Segmentation. in *Medical Image Computing and Computer-Assisted Intervention – MICCAI 2015* (eds. Navab, N., Hornegger, J., Wells, W. M. & Frangi, A. F.) vol. 9351 234–241 (Springer International Publishing, 2015).

## Supplemental Material

**Supplemental Table 1. Hypothesis Testing Results.**
This table shows the p-values from the hypothesis test where $H_0$ = Mediastinum volume equals mean cardiac volume and $H_a$ = Mediastinum volume is greater than cardiac volume. N/A denotes weight ranges that did not have enough samples to perform a hypothesis test.

| Weight (lbs.) | Female p-value | Male p-value |
|---|---|---|
| **30** | 0.00233** | 0.001*** |
| **40** | 0.01225* | 0.003174** |
| **50** | 0.00002631*** | 0.03384* |
| **60** | 0.01588* | N/A |
| **70** | N/A | 0.01176* |
| **80** | N/A | 0.08368 . |
| **90** | 0.03485* | 0.001861** |
| **100** | 0.07832 . | N/A |
| **110** | 0.01129* | N/A |
| **120** | N/A | 0.01326* |
| **130** | 0.05733. | 0.002025** |
| **140** | N/A | N/A |
| **150** | N/A | 0.005204** |
| **160** | N/A | 0.002022** |
| **170** | N/A | 0.0005806*** |

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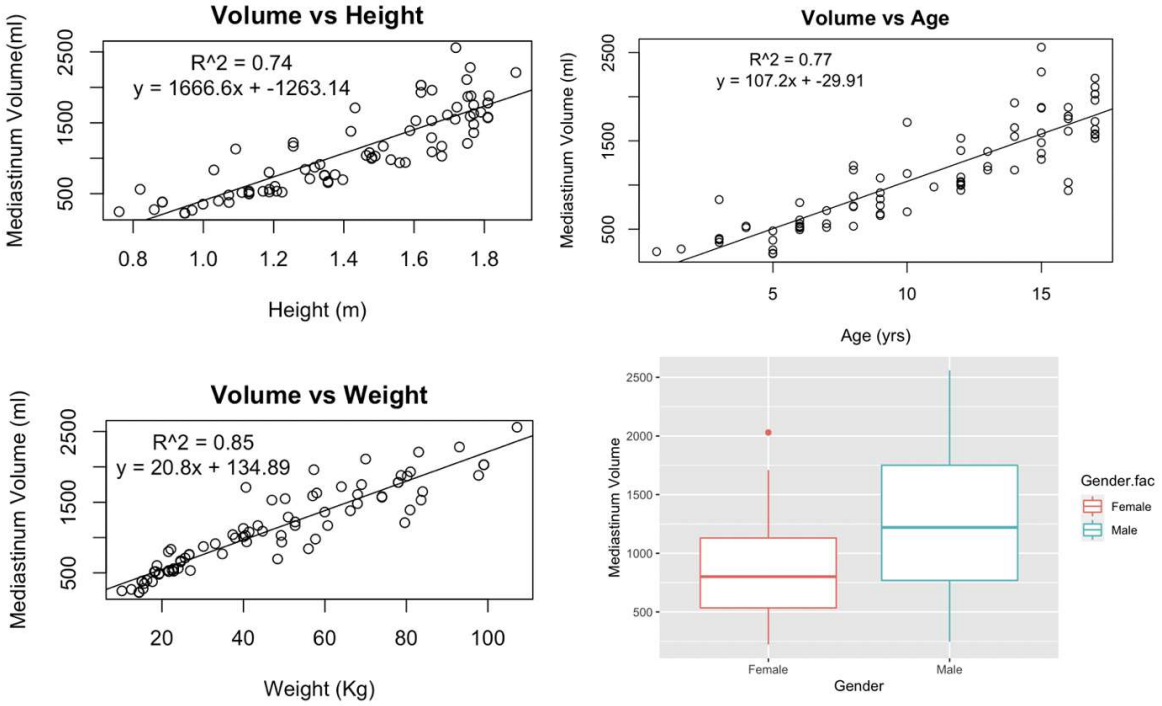


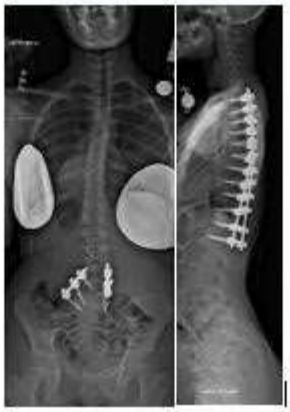

**Supplemental Figure 1. Correlating Individual Variables with Mediastinum Volume.** These graphs show trends between individual patient demographics and mediastinum volume.

**Supplemental Table 2. Comparison of Linear Regressions from this Year and the Previous Year.** Mediastinum volume was plotted against individual demographic variables and their $R^2$ values are displayed in the table. Old $R^2$ denotes last year's data and New $R^2$ denotes this year's data[11]. N/A is written if there is no data for that variable.

| Y vs X | Old $R^2$ | New $R^2$ |
|---|---|---|
| Volume vs Weight (M) | 0.54 | 0.88 |
| Volume vs Weight (F) | 0.23 | 0.79 |
| Volume vs Age (M) | 0.50 | 0.81 |
| Volume vs Age (F) | 0.18 | 0.72 |
| Volume vs Height (M) | N/A | 0.77 |
| Volume vs Height (F) | N/A | 0.67 |

**Supplemental Table 3. Multivariate Linear Regression Coefficients.** The values of the model's regression coefficients and their respective p-values are shown below.

| Coefficient | Estimate | P-value |
|---|---|---|
| **Intercept** | -55.645 | 0.46 |
| **Weight** | 14.665 | 1.2*10^-7 |
| **Age** | 35.916 | 0.0035 |
| **Gender** | 180.169 | 0.0056 |



**Supplemental Figure 2. Removed Images from Rib Cage Identification Data.** The image on the left shows objects that impede the view of the rib cage. Further, the image on the right illustrates an example when part of the rib cage is not within the X-ray scan.

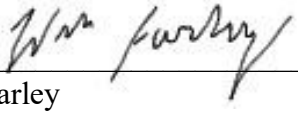
**An Evaluation of the Ambulatory Classification Levels and Reimbursement Methodologies of the Prosthetics Industry**

A Research Paper submitted to the Department of Biomedical Engineering

Presented to the Faculty of the School of Engineering and Applied Science University of Virginia • Charlottesville, Virginia

In Partial Fulfillment of the Requirements for the Degree Bachelor of Science, School of Engineering

On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

Signed:  Date: 5/6/2021
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## Introduction

Each year, over 150,000 Americans lose a lower limb (Molina and Faulk 2021). Undergoing a transfemoral or transtibial amputation is a life-altering experience that can be devastating for one's physical, financial, and psychological wellbeing. Those who sustain an amputation encounter significant challenges during their recovery, rehabilitation, and reintegration into their homes and their communities. The loss of ability to support self and family drives patients towards various psychiatric disorders at incredibly alarming rates. The levels of stress and trauma induced on a patient are so dramatic that researchers in the field typically equate it with the death of a spouse or loss of a home. When one loses a limb, there is a very real possibility that they lose their own perception of wholeness and sense of self. That is why prostheses are so incredibly important. The right prosthetic limb can give a patient the hope that they can overcome their newfound limitations and potentially regain some semblance of the life they lived prior to their amputation. Oftentimes, that hope can make all the difference. Studies have found that the perceived loss of one's ability to engage in previous vocational, avocational, sexual, leisure, and social activities can play a greater role in postamputation quality of life than the absence of the limb itself (Roberts et al. 2006).

Traditional mechanical knee joints lack the responsiveness and fine motor control necessary to replicate the complexities of the human knee. Prosthetic limb users have no choice but to compensate for this with tremendous amounts of concentration and energy. For transfemoral amputees, activities that used to be simple—such as walking on a level surface—now require up to 65% more energy (Traugh, Corcoran, and Reyes 1975). The passive control of flexion and extension during gate also does not provide sufficient stability, leading to a high incidence of dangerous falls.

Considering the shortcomings of mechanical prostheses, when Ottobock introduced the C-Leg in 1997, the world's first microprocessor-controlled leg prothesis, it was coupled with considerable expectations of the possibility of patients regaining some of their potential to live an active life. Unlike the earlier non–microprocessor-controlled (NMPK) prosthetic knees, the C-Leg offered dynamic control of both flexion and extension during a swinging or a standing phase. Utilizing sensors in the shin of the prosthesis, the device continually assesses the position of the leg in space, feeding data to a microprocessor in the knee that instructs a hydraulic damper to adjust and optimize knee stiffness throughout the entire gait cycle. For patients, this was nothing short of revolutionary. However, despite the C-Leg offering more intuitive control while requiring less user effort as well as marked safety improvements, the device was and still is entirely unattainable for many of the two million Americans living with an amputated limb.

In recent years, news and media outlets have lauded the advancements in robotic prosthetics. Multinational joint research efforts have led to incredible developments such as the creation of mind controlled neuromusculoskeletal prostheses, devices that connect to the user's nerves, muscles and skeleton to grant them the sensation of touch in the prosthetic hand itself (Ortiz-Catalan et al. 2020). These remarkable breakthroughs, however, lie in stark contrast to an industry brimming with inequity and adverse healthcare outcomes. As a result of high prices and poor insurance coverage, the reality for many amputees is more similar to that of Robert Riiber, a bilateral transfemoral amputee who lost his legs following complications from aortic aneurysm surgery unable to afford two C-Legs with the insurance he had. Riiber reported falling a total of 25 times with his NMPK prostheses, once while crossing an intersection (Hostetler n.d.). He was forced to quit his job so he could become eligible for Medicare, as Medicare would cover 80 percent of the cost of the devices.

In the United States, patient access to appropriate prosthetic care and rehabilitation services. Gender, age, geographical barriers, race, socioeconomic position, and cost all contribute to healthcare disparities. There is a growing body of evidence that those disparities not only obstruct access to the most appropriate prosthetic and rehabilitative care but contribute to prosthetic abandonment, reduced quality of life, psychological problems, and unsuccessful return to meaningful community participation. Major limb amputation is associated with a higher incidence of secondary health complications, and more than half of those who have a leg amputated will require amputation of the contralateral limb (Ephraim et al. 2005). Black Americans are four times more likely to under an amputation than white Americans and 2.5 times as likely to have to undergo a secondary amputation, even when controlling for age, sex, and diabetes severity (Pasquina, Carvalho, and Sheehan 2015).

Currently, restrictive patient ambulatory classification levels and dated reimbursement policies not only jeopardize the health of patients but increase the financial burden on the healthcare system at large while limiting the potential for innovation. An open dialog among stakeholders could help address these dislocations that are perpetuating inequity and help strike the right balance between controlling healthcare costs and improving clinical outcomes. This is where robust evidence needs to play a role, particularly the incremental value of advanced prosthetics in comparison to conventional prosthetics. Payers have a fiduciary obligation to contain ever-expanding healthcare costs; however, they also should ensure patient access to advanced technologies with proven health benefits, especially it can be demonstrated that providing access can reduce the patient's long-term financial burden on the healthcare system and therefore the insurers.

**The Need for Increased Access: Enabling Progress**

The US healthcare payment system has not yet evolved simultaneously with the rapid progress in advanced technologies, treating prosthetics as commodity products and emphasizing cost-cutting rather than value added for the cost. Currently, the Centers for Medicare and Medicaid Service (CMS) and private insurers restrict reimbursement of prosthetics based on the Medicare Functional Classification Level (MFCL), an index for classifying the functional mobility and productivity potential of individuals with lower limb loss. The system was designed in 1995 with the goal of aiding in the prosthetic component selection and reimbursement process by classifying rehabilitation potential; however, certain characteristics of the MFCL have led to questions (Borrenpohl n.d.) regarding the systems validity and rigidity. Within Medicare, amputees have to pay 20% of the device cost out-of-pocket when they purchase a new prosthesis. Private insurers pay even less, typically setting their reimbursement rates as percentages of what Medicare pays. Furthermore, if a prosthetic device is in a higher MFCL and therefore not covered, amputees have to pay for the entire device out of pocket. Consequently, patients often choose low-cost prosthetic devices at the beginning of their rehabilitation process and never fully realize their functional mobility potential (Chen et al. 2018).

Since their creation, studies have continually demonstrated that microprocessor-controlled knees (MPKs) such as the C-Leg and microprocessor-controlled feet (MPFs) elicit better results when compared to their convention NMPK counterparts, These advantages include easier negotiation of stairs and uneven terrain, higher user satisfaction, decreased difficulty multitasking (Hafner et al. 2007), decreased frequency of stumbles and falls, lower exertion levels (Perry et al. 2004), as well biomechanical advantages such as enhanced gait smoothness,

decreased hip work production levels, and lower peak hip flexion(Johansson et al. 2005). MPKs and MPFs can be a vital, necessary and important means to improve rehabilitation outcomes and quality of life. Evidence strongly supports their use, showing demonstrable improvements in safety, energy requirements, and long-term cost effectiveness(Sedki and Fisher 2015). Despite this, a large number of patients are ruled ineligible. Due to microprocessor-controlled joints coming at relatively high initial and ongoing costs compared to NMPKs, insurers will not provide reimbursement for the higher-quality limbs for patients below a certain ambulatory potential, determined by the patients' MFCL.

The MFCL consists of five discrete K levels (K0-K4) that broadly define levels of patient mobility. The exact wording of the level descriptors for each of these levels can be found in Table 1. By objectively classifying components and assigning K-levels, the process of matching a patient's functional level to a proper component should become easier and more consistent; however, the increasing variety of commercially available MPKs has led many to argue that the five-tier system no longer adequately represents the complexities of the matching process. In a survey administered to over 200 medical professionals involved in the K-level determination process, nearly 70 percent of respondents indicated that they did not believe the current K-level classification system is sufficient to accurately assign a level of rehabilitation potential for lower-limb prosthetics patients (Borrenpohl n.d.). Nevertheless, due to third party payers placing increased scrutiny on documentation to justify prosthetic component recommendations, MFCL determination has become a critical step in the process.

**Table 1. Descriptors of the Medicare Functional Classification Level and Recommended Components for Each K-level(Andrews, Nanos, and Hoskin 2017)**

| K Level | Descriptor | Foot/Ankle | Knee |
|---|---|---|---|
| K0 | This patient does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility. | Not eligible for prosthesis | Not eligible for prosthesis |
| K1 | This patient has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence - a typical limited or unlimited household ambulator. | External keel, SACH feet or single axis ankle/feet | Single-axis, constant friction knee |
| K2 | This patient has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces - a typical community ambulator. | Flexible-keel feet and multiaxial ankle/feet | Single-axis, constant friction knee |
| K3 | The patient has the ability or potential for ambulation with variable cadence - a typical community ambulator with the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic use beyond simple locomotion. | Flex foot and flex-walk systems, energy storing feet, multi-axial ankle/feet, or dynamic response feet | Fluid and pneumatic control knees |
| K4 | The patient has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels - typical of the prosthetic demands of the child, active adult, or athlete. | Any ankle foot system appropriate | Any ankle knee system is appropriate |

The current process of assigning K levels relies heavily on the experience and opinions of the practitioner. The particular levels and their descriptors were created arbitrarily—not attached to any scientific validation. For example, according to official guidelines of the Center for Medicare and Medicaid Services (CMS), an individual who can negotiate two stairs using a handrail receives a K2 designation while an individual capable of negotiating three or four stairs will receive a K3 designation and qualify for an MPK. MFCL evaluations are conducted over the six months that follow an amputation (Andrews, Nanos, and Hoskin 2017). Considering it can take up to two months for the wound to properly heal and for swelling to abate and up to an

entire year (Above-the-Knee Leg Amputation n.d.) for a patient to relearn activities, balance, and coordination as they recondition and rehabilitate their muscles, a physicians decision at six months of whether a patient will be capable of walking up a single additional step can be largely subjective.

The K level system fails to takes into account a considerable number of factors have an impact on the mobility level of a lower limb prosthesis user—specifically the prosthesis itself. This is of particular importance for the K2 – K3 distinction. Two separate studies found that after accommodating K2 patients to the C-Leg, their MFCL improved to K3 status in 44 – 50 percent of subjects (Hafner et al. 2007; Kahle, Hubbard, and Highsmith 2008). In other words, the mere act of simply granting patients access to the MPK technology that has been on the market for nearly a quarter century results in half of the patient population markedly improving. Compared to NMPKs, MPK use results in significant improvements in balance and balance confidence (Wong, Wilska, and Stern 2012). This confidence increase is noteworthy as one's perceived loss of ability has been demonstrated to play a greater role in postamputation quality of life than the loss of limb itself (Roberts et al. 2006).

**Total Cost of a Knee: Combining Clinical and Economic Benefits**

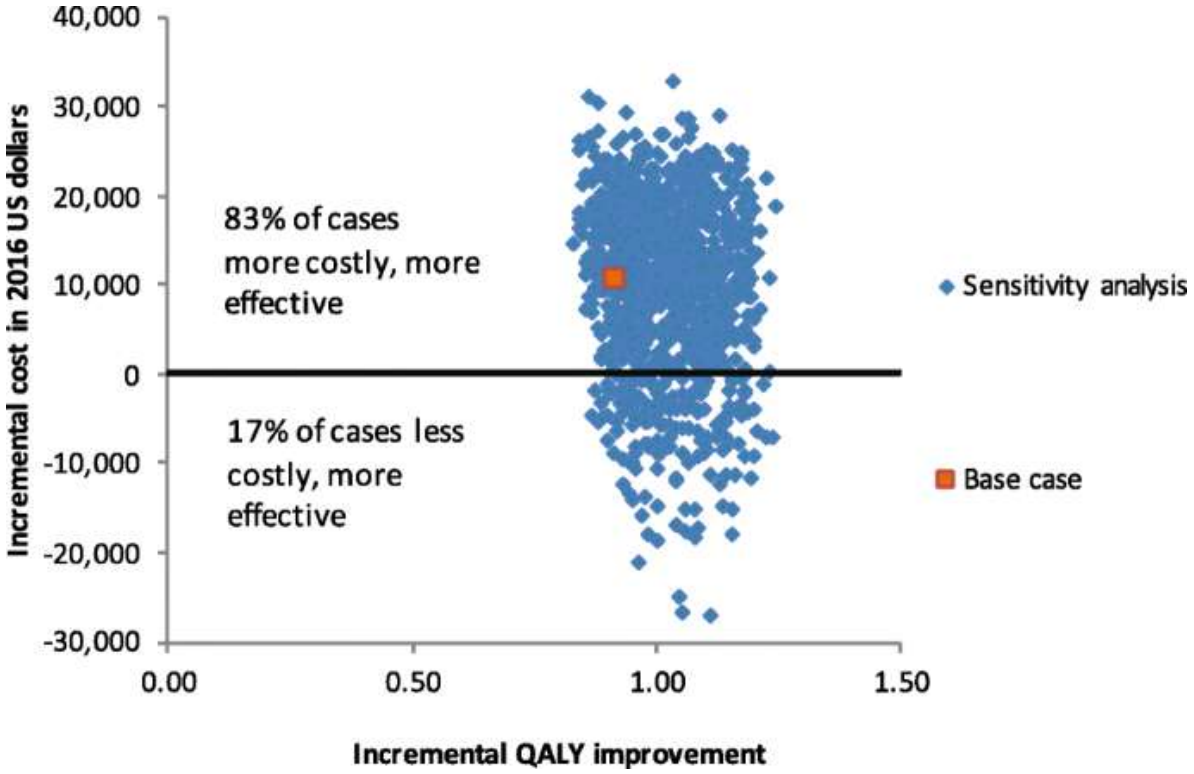
The benefits of increasing access to the advanced prosthetic knees extend beyond allowing for more dynamic movement and enhancing mobility. According to a recent clinical practice guideline, granting K2 ambulators MPKs results in a substantial reduction of uncontrolled falls (Stevens and Wurdeman 2019). In K2 above-knee amputees, MPK use may reduce uncontrolled falls by up to 80 percent while significantly improving indicators of fall risk(Kahle, Hubbard, and Highsmith 2008). These findings were echoed by a simulation model developed by Chen et. al that used estimates from published literature and expert input to

determine healthcare outcomes for unilateral transfemoral Medicare amputees with a MFCL K3 designation. Compared to NMPK users over a ten-year time period, the results demonstrated that for every 100 persons: MPK use results in 82 fewer major injurious falls, 62 fewer minor injurious falls, 16 fewer incidences of osteoarthritis, and 11 lives saved. According to literature, a major injury due to a fall costs $24,845, a minor injury costs $1,332, and a fall-related death costs $27,338 (Chen et al. 2018).

On a per person per year basis, an MPK reduces direct healthcare cost by an estimated $3676 and indirect cost by $909. When factoring in higher device acquisition and repair costs, the study estimates MPKs to have an incremental cost of $10,604 for each quality-adjusted life-year (QALY) gained (Chen et al. 2018). For patients with previous NMPK experience such as K2 ambulators who upgrade to MPKs, decision-analytic models have determined the cost per QALY gained to be $3,800 (Brodtkorb et al. 2008).

The most comprehensive sensitivity analysis on the incremental cost effectiveness of MPKs compared to NMPKs to date was published by the Rand Corporation in 2018. Using their base case input values and combined clinical benefits, economic benefits, and device acquisition and repair cost together, for a ten-year time period, they found MPKs resulted in an average incremental cost effectiveness ratio (ICER) of $11,606 per QALY for the K3/K4 population (Liu et al. 2017). The probabilistic sensitivity analysis is displayed in Figure 1. In comparing NMPKs to MPKs, the latter was more effective in every situation, but also more costly 83 percent of time. The sensitivity analysis resulted in an ICER range of -$25,355 – $36,357 per QALY. In 17 percent of scenarios, MPKs dominate NMPKs, resulting in a lower total cost and greater health outcomes simultaneous, at best saving $25,355 while adding a quality year of life when compared to an NMPK.

**Figure 1: Incremental Cost and Effectiveness of MPK in Comparison to NMPK in K3/K4 Amputees, Note: all costs are in 2016 US dollars (Liu et al. 2017).**




In the worst scenario, the ICER is still well below the $50,000 cost-effective threshold, as outlined in Table 2. This holds true in their K1 and K2 populations as well, where MPKs have an ICER of $13,568 per QALY. In both cases, the health benefits provided by MPKs in terms of cost per QALY added would classify it as a 'Very Cost-Effective' treatment, as seen in Table 2.

**Table 2: Established Incremental Cost Effectiveness Ratios for Therapies in ($/QALY) (Zhong et al. 2015).**

| Very Cost-Effective | Cost-Effective | Marginally Cost-Effective | Not Cost-Effective |
|---|---|---|---|
| ≤$25,000 | $25,001 - $50,000 | $50,001 - $100,000 | >$100,000 |

While there are some cases where medical intervention proves to lead to net cost savings, such as the 17 percent of instances found in the Rand study, most often a new medical innovation will lead to better health but cost more than existing technologies. In the United States, the Institute for Clinical and Economic Review, which conducts drug cost-effectiveness analyses, values one QALY at $50,000 to $150,000(The "QALY" shouldn't be used in drug cost-effectiveness reviews 2019). Total knee arthroplasty and prophylactic cardioverter defibrillator implantation have an ICER of $14,572 and $76,396 per QALY, respectively, and are covered by all insurers. The median ICER of the nearly 500 published diabetic therapies is roughly $17,200 per QALY gained (Zhong et al. 2015). There is a substantial body of evidence that MPKs are more cost effective than each of these therapies, yet insures continue to restrict access.

Another consideration not taken into account by existing simulations due to a lack of data is that transtibial amputation patients develop secondary conditions related to sound limb overuse, prosthetic malalignment, and other factors, including degenerative joint disease, osteopenia, postural issues, low back pain, and others. Each of these secondary complications has health care utilization and cost implications that are unexplored with regard to this population. For example, the development of knee or hip problems from walking incorrectly could cost $80,000-$150,000 to fix with surgery or amputees may also suffer from wrist, elbow, and shoulder problems from crutch overuse, which can cost $7,500-$25,000 (Snowe 2010). Furthermore, these estimates do not take into account the long-term economic burden of the sedentary lifestyle adopted by those with an ineffective prosthesis, both in terms of productivity lost and healthcare complications. Each year an estimated $21 billion in costs of missed work days is lost due to absenteeism and reduced productivity of diabetic amputees (Association 2018). Medicare spends $143 billion per year on critical limb ischemia—a significant portion of

which is secondary amputation costs for the 55 percent of diabetic amputees who require another amputation within 2 - 3 years of their first due to rest pain, ulcers, and gangrene (Annual U.S. Economic Burden of Critical Limb Ischemia Exceeds $200 Billion 2019; Ephraim et al. 2005). K1 and K2 patients account for approximately 35 percent of the patient demographic in the US (DaVanzo 2013). Granting them access to MPK prostheses with demonstrated cost-effective health benefits may help to lower the incidence of secondary amputation and better manage the oncoming wave of diabetic amputees entering the US health system.

In the United States, every 17 seconds someone is diagnosed with diabetes, and everyday 230 Americans with diabetes will suffer an amputation. After years of decline, the rate of amputations increased by 50% between 2009 and 2015 (Diabetic Amputations May Be Rising in the United States n.d.). Nearly half of the amputations that occur each year in the US are due to diabetes and 85 percent of amputations that take place worldwide are the result of diabetic foot ulcers (Diabetic Amputations May Be Rising in the United States n.d.). The economic burden of the diabetes epidemic in the US is only going to increase. Approximately $414 billion of the total $1.7 trillion in US health expenditures in 2017 was incurred by people with diabetes, reflecting 1 in 4 of all health care dollars and an amount that's only expected to increase (Association 2018). Increasing access now can help not only reduce future burdens on the health system but also ensure that the US is more prepared to face the outcomes of the diabetes epidemic.

The K-level system should be used only as a predictor of the appropriate equipment an amputee will receive rather than a final judgement. That decision should involve the patient and their prosthetists and incorporate the patient's ability and willingness to rehabilitate with the assistance of the advanced device. Data strongly suggests that many K2 amputees are unfairly restricted and would greatly benefit from MPK's the Department of Veterans Affairs considers

"under-prescribed" (Kahle, Hubbard, and Highsmith 2008). Increasing access to MPKs and MPFs will not only give hundreds of thousands of Americans the hope that accompanies finally being properly equipped to work to regain the parts of their life they lost following their amputation, but will also provide cost effective treatment that reduces the short- and long-term economic burden on the healthcare system.

**Addressing Reimbursement Flaws**

Prostheses are reimbursed to providers through Level II Healthcare Common Procedure Coding System (HCPCS) codes, created by Blue Cross Blue Shield in the late 1970s and commonly referred to by prosthetists—or others in the prosthetics industry—as L Codes. Each bill for a prosthesis will consist of multiple L Codes that have an associated price. That price—determined by the Centers for Medicare & Medicaid Services (CMS)—represents the amount that Medicare will reimburse the prosthetist for a feature or component, from which private insurers will then reimburse at a percentage of that cost. The reimbursement amount "frequently does not accurately reflect real-world costs" (Fairley 2008), and in some cases is so low that prosthetists cannot provide devices for patients. For example, United HealthCare wished to reimburse prosthetic-fitting company Biometrics 45% less that what Medicare would. United HealthCare would then only reimburse Biometrics $15,649 for the same C-Leg for which Medicare would reimburse $28,454. Because the reimbursement offered by United HealthCare is lower than the wholesale cost Biometrics pays for the device, they are simply unable to provide in-network services to United HealthCare members.

Furthermore, prosthetists cannot bill for time or adjustments unless they replace a specific billable part. As a result, all costs to the business: the time of the practitioner, the technicians, the receptionist, the rent of the building, the highly specific tools needed by

practitioners to make adjustments for which they cannot be compensated, the toner for the printer, everything—must be paid for through the cost of the prosthesis(Upper Limb Prosthetics Information n.d.).

Under-compensation of prostheses is rather commonplace. As seen in Table 3, the prostheses for transfemoral K3 and K4 level ambulators are considerable, due in part to the substantial cost of MPKs, which can range from $16,000 to $47,000 in wholesale cost (Reimbursement Issues | AOPA – AMERICAN ORTHOTIC & PROSTHETIC ASSOCIATION n.d.). Despite this, CMS has concluded that these knees are similar in function and therefore all are equally reimbursed using a combination of codes seen in Figure 2 totaling $28,454.

**Table 3: Transfemoral and Transtibial device costs per ambulatory level**(Reimbursement Issues | AOPA – AMERICAN ORTHOTIC & PROSTHETIC ASSOCIATION n.d.)**.**

| K Level | Mobility Level | Transtibial Prosthesis Price | Transfemoral Prosthesis Price |
|---|---|---|---|
| K0 | Minimal | N/A | N/A |
| K1 | Household Ambulator | $3,000 - $6,000 | $5,000 - $12,000 |
| K2 | Limited Community Ambulator | $5,000 - $10,000 | $6,000 - $20,000 |
| K3 | Community Ambulator | $8,000 - $40,000 | $14,000 - $70,000 |
| K4 | Athletic Ambulator | $8,000 - $40,000 | $30,000 - $150,000 |

**Figure 1: MPK L code Reimbursement Levels**(Retired n.d.)

**MPK L Codes**

| | | | |
|---|---|---|---|
| L5856 | MPK Swing And Stance Phase | $ | 22,843 |
| L5858 | MPK Stance Phase Only | $ | 17,658 |
| L5859 | MPK Powered And Programmable Flexion/Extension Assist Control | $ | 13,867 |
| L5857 | MPK Swing Phase Only | $ | 8,127 |
| L5840 | 4-Bar Linkage Pneumatic Swing Phase Control | $ | 3,560 |
| L5814 | Polycentric Hydraulic Swing Phase Control, Mechanical Stance Phase Lock | $ | 3,529 |
| L5613 | 4 Bar Linkage, With Hydraulic Swing Phase Control | $ | 2,564 |
| L5728 | Single Axis, Fluid Swing And Stance Phase Control | $ | 2,543 |
| L5610 | Above Knee, Hydracadence System | $ | 2,269 |
| L5726 | Single Axis, External Joints Fluid Swing Phase Contro | $ | 1,915 |
| L5822 | Single Axis, Pneumatic Swing, Friction Stance Phase Control | $ | 1,755 |
| L5724 | Single Axis, Fluid Swing Phase Control | $ | 1,677 |
| L5614 | 4 Bar Linkage, With Pneumatic Swing Phase Control | $ | 1,603 |
| L5780 | Single Axis, Pneumatic/Hydra Pneumatic Swing Phase Control | $ | 1,191 |

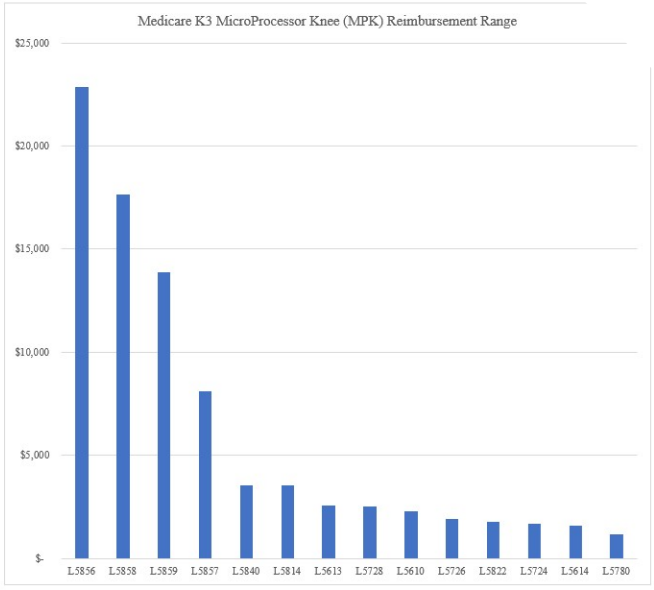
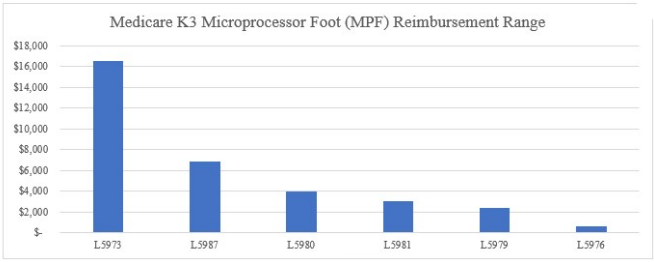



Figure 2: MPF L code Reimbursement Levels(Retired n.d.)

**MPF L Codes**

| | | | |
|---|---|---|---|
| L5973 | MPFoot Controlled Feature, Dorsiflexion and/or Plantar Flexion Control | $ | 16,562 |
| L5987 | Shank Foot System With Vertical Loading Pylon | $ | 6,835 |
| L5980 | Flex Foot System | $ | 3,959 |
| L5981 | Flex-Walk System Or Equal | $ | 3,027 |
| L5979 | Multi-Axial Ankle, Dynamic Response Foot | $ | 2,397 |
| L5976 | Energy Storing Foot | $ | 600 |




The overgeneralization of device costs that leads to under-reimbursement is compounded by issues within the billing categorization process. Because the application process is so slow and hesitant to create new codes for new devices, oftentimes older L Codes or a combination of miscellaneous codes are reused for the devices. In some cases, it is unclear what L code to use for a device. Ottobock recommends that prosthetists use a combination of miscellaneous codes and L Codes for the C-Leg Genium; however, the practice of assigning miscellaneous codes in prohibited by the Durable Medical Equipment Medicare Administrative Contractor in regions such as the Northeastern US. Medicare recommends using the exact same codes for reimbursement for the C-Leg and C-Leg Genium, despite the latter being significantly more

advanced and costing almost twice as much. Consequentially, patients who want advanced features such as the ability to safely take more than two steps backwards have no choice but to cover the price difference themselves.

Even patients who opt for more conservative devices still have to pay a substantial amount. Medical insurance plan quotes from a selection of large insurers, including Medicare can be found in the appendix. Patients can end up paying anywhere from $5,000 - $39,000 in out-of-pocket costs for each artificial limb. For some policies there is a limit on the number of prosthetic or prosthetic related devices that can be purchased per calendar year. This limitation has serious repercussions. For instance, Robert Riiber, the bilateral transfemoral amputee was unable to purchase two C-Legs with his insurance plan as mentioned in the introduction. For Riiber, quitting his job so that he only had to cover 20 percent of each C-Leg—an out-of-pocket cost of approximately $40,000—was the most affordable option. Even patients who lose only a single limb have trouble with these prosthetic caps. Oftentimes temporary prosthetics are given to patients for the first several months while swelling abates before they switch to a permanent prosthesis. With some policies, If the temporary prosthetic is bought with an insurance plan that only covers a single device per calendar year, the amputee may have to wait a full year before receiving their permanent device. Additionally, if a single part on the prosthesis were to break, these policies may inhibit an amputee from receiving replacement parts in a timely manner. These expenses add up, and the lifetime direct out-of-pocket costs for a lower limb amputee is estimated to be $509,272 (Miller and Jr. 2020).

It’s recommended that the limbs are replaced every 3-5 years, but with the high out-of-pocket costs created by under-reimbursement, few patients can afford that. The combination of the high costs and the adjustment policy creates a positive feedback loop wherein compensation

for the expenses of past free adjustment sessions is included in the initial price of the device, deterring those in need of a new device from purchasing one and instead opting to make do with free adjustments. With the amount reimbursed to Orthotics and Prosthetics (O&P) practices by insurers being fixed per device, as more patients decide to prolong the lifetime of their device through free adjustments, the out-of-pocket costs for other patients has to rise to compensate for this. In a recent interview, executive vice president and COO of the national Hanger Clinic network Sam Liang echoed this, stating that current policies and constant reimbursement rate reduction from payers has made it increasingly difficult to keep clinics profitable (Ferrendelli 2020).

Insurance companies reserve the right to conduct time and resource consuming audits on the use of miscellaneous codes. Although practices are rarely found guilty or even fined, they still have to absorb expensive legal fees. Due to payers constantly reducing O&P rates over the year while simultaneously increasing audit rates, providers are reluctant to try to maximize reimbursement for their patients and risk an audit as they cannot afford to leave any value on the table themselves.

The strong industry headwinds created by payers have significant implications. Increasing out of pocket costs has driven more patients to compromise on the fit and walkability of their prostheses and in turn their own health. Only 47 percent of patients with ischemia who undergo primary amputation successfully rehabilitate to near pre-amputation levels of mobility (Ponticello 2016). Consequently, nearly half of all amputees in America enter the persistent high-cost population that accounts for the estimated 22 percent of the $2.6 trillion dollars in annual health care expenditures that is related to potentially avoidable complications, such as hospital admissions for diabetic patients with gangrenous limbs that require amputation

(Aldridge and Kelley 2015; Emanuel 2012). Approximately one in every 170 Americans is currently living with the loss of a limb. There is evidence that unchecked, this number may double by 2050 (Ziegler-Graham et al. 2008). The currently model of deferring to suboptimal healthcare outcomes for amputees in order to save in the short-term has the potential to become incredibly costly in the near future.

**The L Code Application Process: Inhibiting Innovation**

A major hurdle in prosthetic billing is the L Code application and verification process. Currently, the billing code verification process is time consuming and creates significant barriers to entry that prevent new devices from entering the market, forcing the industry to skew towards oligopolistic tendencies. Unless these are addressed, innovators within the industry will increasingly allocate more resources and capital to tangential ventures within the industry, slowing device development and growth.

The application process itself can be quite lengthy. When a new prosthetic device is invented, and it functions differently than any other categorized device, then a new billing code is required before Medicare or other insurers will cover the device. Demonstration of national programmatic need is required in order to create a new code, use a miscellaneous code, or use an existing code a substitute. The HCPCS defines National Programmatic Need as "At least one insurance sector, public (Medicare or Medicaid) or private (commercial insurers) identified a program operating need to separately identify the item and that need is common across the sector"—i.e., nationally (HCPCS - General Information | CMS n.d.). Essentially, a code cannot be assigned to a device unless a national insurer deems it that it is unique and necessary.

Additionally, before an L Code is established a new device must meet paradoxical volume and marketing requirements. The HCPCS defines volume and marketing criteria as there being "sufficient claims activity or volume in 3 percent of the affected population, as evidenced by 3 months of marketing activity" (HCPCS - General Information | CMS n.d.). For Ottobock and Össur, the respective manufacturers of the two most popular MPKs, the C-Leg and the Rheo Knee, this means leveraging their expansive networks of providers. For smaller manufacturers, that means convincing enough clinics that they may not have an existing relationship with to risk an audit by using miscellaneous codes that they are able to reach a 3 percent market share, a nearly impossible task.

Manufacturers are beginning to realize importance of such networks with regard to the potential of device approval, creating further stratification between large, established manufacturers and upstart innovators. In the past few years, Ottobock and Össur have quietly been making inroads into the O&P clinical care market in the United States (Ferrendelli 2020). While consolidation is occurring across all healthcare sectors in the US, the O&P industry remains the only example of manufacturers acquiring patient care facilities. Since 2018, Össur has acquired Virginia Prosthetics & Orthotics, Bulow Orthotic & Prosthetic Solutions, Next Step Bionics & Prosthetics, SRT Prosthetics & Orthotics, and many other providers across the country. Ottobock has followed suit, with each company leveraging their preexisting clinic service networks to generate acquisition momentum (Ferrendelli 2020).

While the acquired clinics have enjoyed the increased access that accompanies joining such a network, many within the industry are fearful that these recent moves from manufacturers are more indicative of a concerning paradigm shift. With manufacturers increasingly deploying capital and resources towards patient care versus innovation and research and development,

leaders within the industry such as the aforementioned Sam Liang are asking: "Are manufacturers signaling that there is no more innovation in O&P?" (AOPA 2020).

As troubling of a concept as that is, Liang's concerns are valid. Demonstrably unique devices are increasingly being lumped in with old L codes that severely undercompensate the prothesis, forcing the cost disparity onto patients (Highsmith et al. 2016). If this continues, it will become increasing difficult for large and small manufacturers alike to justify the costs of developing new devices and as a result innovation within the industry will grow stagnant.

**Conclusion**

There has not been a push for prosthetic parity laws since Maryland's failed Senate Bill 98 of 2008, the Prosthetic Parity Act. Under the proposed prosthetic parity laws, if the same device was purchased in the same year by two different amputees from the same billing region, patient A with Medicare, and patient B with a private insurer, then the amount that patient A must pay plus the amount that Medicare must pay will equal the amount that patient B must pay plus the amount that their private insurance must pay. As a result, the clinic will be reimbursed an equal amount for the two same prosthetics regardless of the insurer. This will allow prosthetists to offer MPKs to more of their patients, potentially increasing the demand for the devices and decreasing the price while increasing the overall availability (Program (CHBRP) 2006).

Aside from indirectly increasing access to MPKs, one of the significant arguments in favor of parity laws is the fact that requiring private insurance to use the same fee schedules as Medicare will increase premiums by only $1.44 - $4.20 per year per policy holder (Program (CHBRP) 2006). However, despite the financial, social, and medical benefits of advanced

prosthetic devices such as MPKs outlined in the Bill, it still failed to pass as the Department of Health was unable to make a fully informed recommendation due to two areas of concern: a lack of specific data provided by the applicant to Washington and ambiguous language in the proposed legislation that could support a variety of interpretations (Prosthetics and Orthotics Coverage Mandated Benefit Sunrise Review 2011).

In the years following the rejection of the bill, those within the prosthetics industry have build a substantial body of evidence include some of the studies cited in this report. In order to convince payers to increase access to MPKs, providers need to continue to increase data collection and leverage benchmarking to demonstrate clear differences in health outcome between MPK users and NMPK users and the long-term health and economic consequences of the under prescription of the devices. Meaningful change will only be able to occur with sufficient specific and robust evidence. With the finding reported in recent years, hopefully that change will occur within the next decade, and more amputees will be given the hope that they can overcome their limitations and regain their sense of self.

## Appendix:

A: Samples of Various National Insurance Plans

| Aetna | | | | |
|---|---|---|---|---|
| **Plan** | **Category** | | **In Network** | **Out of Network** |
| **Open Access Managed Choice 1500** | **Deductible** | Individual | $1,500 | $3,000 |
| | | Family | $3,000 | $6,000 |
| | **Coinsurance Maximum** | Individual | $3,500 | $7,000 |
| | | Family | $7,000 | $14,000 |
| | **Out-of-Pocket Maximum** | Individual | $5,000 | $10,000 |
| | | Family | $10,000 | $20,000 |
| | **D.M.E** | Coinsurance | 40% | 50% |
| | | $2000 per calendar year max | | |
| | **Specialist Visit** | Copay/ Coinsurance | $45 | 50% |
| | **Physical Therapy** | Coinsurance | 40% | 50% |
| | | 24 visits per year | | |

| Plan | Category | | In Network | Out of Network |
|---|---|---|---|---|
| **Open Access Managed Choice 2500** | **Deductible** | Individual | $2,500 | $5,000 |
| | | Family | $5,000 | $10,000 |
| | **Coinsurance Maximum** | Individual | $2,500 | $5,000 |
| | | Family | $5,000 | $10,000 |
| | **Out-of-Pocket Maximum** | Individual | $5,000 | $10,000 |
| | | Family | $10,000 | $20,000 |
| | **D.M.E** | Coinsurance | 40% | 50% |
| | | $2000 per calendar year max | | |
| | **Specialist Visit** | Copay/ Coinsurance | $45 | 50% |
| | **Physical Therapy** | Coinsurance | 40% | 50% |
| | | 24 visits per year | | |

| Plan | Category | | In Network | Out of Network |
|---|---|---|---|---|
| **Open Access Managed Choice 5000** | **Deductible** | Individual | $5,000 | $10,000 |
| | | Family | $10,000 | $20,000 |
| | **Coinsurance Maximum** | Individual | $5,000 | $2,500 |
| | | Family | $10,000 | $5,000 |
| | **Out-of-Pocket Maximum** | Individual | $10,000 | $12,500 |
| | | Family | $20,000 | $25,000 |
| | **D.M.E** | Coinsurance | 20% | 50% |
| | | $2000 per calendar year max | | |
| | **Specialist Visit** | Copay/ Coinsurance | $45 | 50% |
| | **Physical Therapy** | Coinsurance | 20% | 50% |
| | | 24 visits per year | | |

# Assurant (default non-customized plans)

| Plan | Category | | In Network | Out of Network |
|---|---|---|---|---|
| Value Plan | Deductible | Individual | $5,000 | $6,000 |
| | | Family | $5,000 | $6,000 |
| | Coinsurance Maximum | Individual | $4,000 | $10,000 |
| | | Family | $8,000 | $20,000 |
| | Out-of-Pocket Maximum | Individual | $9,000 | $16,000 |
| | | Family | $23,000 | $38,000 |
| | D.M.E | Coinsurance | 50% | 50% |
| | | Deductible & Coinsurance Maximum | | |
| | Specialist Visit | Coinsurance | 50% | 50% |
| | Physical Therapy | Coinsurance | 50% | 50% |
| | | Unlimited Visits | | |

| Plan | Category | | In Network | Out of Network |
|---|---|---|---|---|
| One Deductable PPO HAS | Deductible | Individual | $5,000 | $5,500 |
| | | Family | $10,000 | $11,000 |
| | Coinsurance Maximum | Individual | $0 | $1,000 |
| | | Family | $0 | $2,000 |
| | Out-of-Pocket Maximum | Individual | $5,000 | $6,500 |
| | | Family | $10,000 | $13,000 |
| | D.M.E | Coinsurance | 100% | 80% |
| | | Deductible & Coinsurance Maximum | | |
| | Specialist Visit | Coinsurance | 100% | 80% |
| | Physical Therapy | Coinsurance | 100% | 80% |
| | | Unlimited Visits | | |

| Plan | Category | | In Network | Out of Network |
|---|---|---|---|---|
| PPO X-tra Plan | Deductible | Individual | $5,000 | $6,000 |
| | | Family | $5,000 | $6,000 |
| | Coinsurance Maximum | Individual | $2,500 | $10,000 |
| | | Family | $5,000 | $20,000 |
| | Out-of-Pocket Maximum | Individual | $7,500 | $16,000 |
| | | Family | $20,000 | $38,000 |
| | D.M.E | Coinsurance | 50% | 50% |
| | | Deductible & Coinsurance Maximum | | |
| | Specialist Visit | Coinsurance | 50% | 50% |
| | Physical Therapy | Coinsurance | 50% | 50% |
| | | Unlimited Visits | | |

# Anthem Blue Cross Blue Shield

| Plan | Category | | In Network | Out of Network |
|---|---|---|---|---|
| Premier | Deductible | Individual | $500 - $10,000 | $500 - $10,000 |
| | | Family | $1,000 -$20,000 | $1,000 -$20,000 |
| | Coinsurance Maximum | Individual | $0 - $3,000 | $7,500 |
| | | Family | $0 - $6,000 | $15,000 |
| | Out-of-Pocket Maximum | Individual | $3,500 - $10,000 | $8,000 - $17,500 |
| | | Family | $7,000 - $20,000 | $16,000- $35,000 |
| | D.M.E | Coinsurance | 0 - 20% | 30% |
| | | Deductible & Coinsurance Maximum | | |
| | Specialist Visit | Coinsurance | $40 | 30% |
| | Physical Therapy | Coinsurance | 0 - 20% | 30% |
| | | 20 visits per year | | |

| Plan | Category | | In Network | Out of Network |
|---|---|---|---|---|
| SmartSense | Deductible | Individual | $750 - $12,000 | $750 - $12,000 |
| | | Family | $1,500 - $24,000 | $1,500 - $24,000 |
| | Coinsurance Maximum | Individual | $0 - $4,000 | $7,500 |
| | | Family | $0 - $8,000 | $15,000 |
| | Out-of-Pocket Maximum | Individual | $4,750 - $12,000 | $8,250 - $19,500 |
| | | Family | $9,500 - $24,000 | $16,500- $39,000 |
| | D.M.E | Coinsurance | 0 - 50% | 30 - 50% |
| | | Deductible & Coinsurance Maximum | | |
| | Specialist Visit | Coinsurance | $30 for first three | 30 - 50% |
| | Physical Therapy | Coinsurance | 0 - 50% | 30 - 50% |
| | | 20 visits per year | | |

| Plan | Category | | In Network | Out of Network |
|---|---|---|---|---|
| Lumenos HAS Plus | Deductible | Individual | $1,500 - $5,950 | $1,500 - $5,950 |
| | | Family | $3,000 - $11,900 | $3,000 - $11,900 |
| | Coinsurance Maximum | Individual | $0 - $1,000 | $3,500 - $5,950 |
| | | Family | $0 - $2,000 | $7,000 - $11,900 |
| | Out-of-Pocket Maximum | Individual | $2,500 - $5,950 | $5,000 - $11,900 |
| | | Family | $5,000 - $11,900 | $10,000- $23,800 |
| | D.M.E | Coinsurance | 0 - 20% | 30 - 40% |
| | | Deductible & Coinsurance Maximum | | |
| | Specialist Visit | Coinsurance | 0 - 20% | 30 - 40% |
| | Physical Therapy | Coinsurance | 0 - 20% | 30 - 40% |
| | | 20 visits per year | | |

| Medicare | | |
|---|---|---|
| **Plan** | **Category** | **Costs** |
| **Part B** | **Deductable** | $140 |
| | **Coinsurance Maximum** | N/A |
| | **Out-of-Pocket Maximum** | N/A |
| | **D.M.E** | 20% of the Medicare approved cost plus the difference between the approved cost and the actual cost. |
| | **Specialist Visit** | |
| | **Physical Therapy** | 60 visits per year |

## Works Cited


"Above-the-Knee Leg Amputation: What to Expect at Home." https://myhealth.alberta.ca:443/Health/aftercareinformation/pages/conditions.aspx?hwid=ug3839 (April 1, 2021).

Aldridge, Melissa D., and Amy S. Kelley. 2015. "The Myth Regarding the High Cost of End-of-Life Care." *American Journal of Public Health* 105(12): 2411–15.

Andrews, Karen L, Katherine N Nanos, and Tanya L Hoskin. 2017. "Determining K-Levels Following Transtibial Amputation." *International Journal of Physical Medicine & Rehabilitation* 05(02). https://www.omicsonline.org/open-access/determining-klevels-following-transtibial-amputation-2329-9096-1000398.php?aid=87586 (April 1, 2021).

"Annual U.S. Economic Burden of Critical Limb Ischemia Exceeds $200 Billion." 2019. *DAIC*. https://www.dicardiology.com/content/annual-us-economic-burden-critical-limb-ischemia-exceeds-200-billion (April 1, 2021).

AOPA. 2020. "2020 October O&P Almanac." *Issuu*. https://issuu.com/americanoandp/docs/10_-_october_275d42c57bcdc7 (April 15, 2021).

Association, American Diabetes. 2018. "Economic Costs of Diabetes in the U.S. in 2017." *Diabetes Care* 41(5): 917–28.

Borrenpohl, Dylan. "A Survey-Based Study on the Professional Opinion of the Medicare Functional Classification Level and the Utilization of Outcome Measures in K-Level Assignment." : 29.

Brodtkorb, Thor-Henrik, Martin Henriksson, Kasper Johannesen-Munk, and Fredrik Thidell. 2008. "Cost-Effectiveness of C-Leg Compared With Non–Microprocessor-Controlled Knees: A Modeling Approach." *Archives of Physical Medicine and Rehabilitation* 89(1): 24–30.

Chen, Christine et al. 2018. "Economic Benefits of Microprocessor Controlled Prosthetic Knees: A Modeling Study." *Journal of NeuroEngineering and Rehabilitation* 15(Suppl 1). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6157253/ (March 31, 2021).

DaVanzo, Dobson. 2013. "Retrospective Cohort Study of the Economic Value of Orthotic and Prosthetic Services Among Medicare Beneficiaries." : 67.

"Diabetic Amputations May Be Rising in the United States." *AJMC*. https://www.ajmc.com/view/diabetic-amputations-may-be-rising-in-the-united-states (April 1, 2021).

Emanuel, Ezekiel J. 2012. "Where Are the Health Care Cost Savings?" *JAMA* 307(1): 39.

Ephraim, Patti L. et al. 2005. "Phantom Pain, Residual Limb Pain, and Back Pain in Amputees: Results of a National Survey." *Archives of Physical Medicine and Rehabilitation* 86(10): 1910–19.

Fairley, Miki. 2008. “L-Codes: Are They Meeting the Needs of O&P? - OPEDGE.COM.” https://opedge.com/Articles/ViewArticle/2008-08_01 (November 5, 2020).

Ferrendelli, Betta. 2020. “The Changing Landscape: Manufacturers Enter the US Clinical Care Market - OPEDGE.COM.” https://opedge.com/Articles/ViewArticle/2020-05-01/the-changing-landscape-manufacturers-enter-the-us-clinical-care-market (April 14, 2021).

Hafner, Brian J. et al. 2007. “Evaluation of Function, Performance, and Preference as Transfemoral Amputees Transition from Mechanical to Microprocessor Control of the Prosthetic Knee.” *Archives of Physical Medicine and Rehabilitation* 88(2): 207–17.

“HCPCS - General Information | CMS.” https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo (April 15, 2021).

Highsmith, M. Jason et al. 2016. “ECONOMIC EVALUATIONS OF INTERVENTIONS FOR TRANSTIBIAL AMPUTEES.” *Technology and innovation* 18(2–3): 85–98.

Hostetler, A. J. “Amputees Seek Coverage from Insurers for Prosthetics.” *Richmond Times-Dispatch*. https://richmond.com/news/amputees-seek-coverage-from-insurers-for-prosthetics/article_7a683097-306a-50c2-9a44-ba9d97154a1a.html (April 7, 2021).

Johansson, Jennifer L. et al. 2005. “A Clinical Comparison of Variable-Damping and Mechanically Passive Prosthetic Knee Devices.” *American Journal of Physical Medicine & Rehabilitation* 84(8): 563–75.

Kahle, JT, SL Hubbard, and MJ Highsmith. 2008. “Comparison of Nonmicroprocessor Knee Mechanism versus C-Leg on Prosthesis Evaluation Questionnaire, Stumbles, Falls, Walking Tests, Stair Descent, and Knee Preference.” *Journal of Rehabilitation Research and Development* 45(1): 1–14.

Liu, Hangsheng et al. 2017. *Economic Value of Advanced Transfemoral Prosthetics*.

Miller, Ronald V. and Jr. 2020. “Limb Amputations and Their Lifetime Costs.” *Baltimore Injury Lawyer Blog*. https://www.millerandzois.com/blog/limb-amputations-and-their-lifetime-costs/ (November 5, 2020).

Molina, Cesar S., and JimBob Faulk. 2021. “Lower Extremity Amputation.” In *StatPearls*, Treasure Island (FL): StatPearls Publishing. http://www.ncbi.nlm.nih.gov/books/NBK546594/ (April 1, 2021).

Ortiz-Catalan, Max, Enzo Matsinu, Paola Sassu, and Oskar Aszmann. 2020. “Self-Contained Neuromusculoskeletal Arm Prostheses | NEJM.” https://www.nejm.org/doi/10.1056/NEJMoa1917537 (May 6, 2021).

Pasquina, Colonel Paul F., Antonio J. Carvalho, and Terrence Patrick Sheehan. 2015. “Ethics in Rehabilitation: Access to Prosthetics and Quality Care Following Amputation.” *AMA Journal of Ethics* 17(6): 535–46.

Perry, Jacquelin, Judith M. Burnfield, Craig J. Newsam, and Phil Conley. 2004. “Energy Expenditure and Gait Characteristics of a Bilateral Amputee Walking with C-Leg Prostheses

Compared with Stubby and Conventional Articulating Prostheses." *Archives of Physical Medicine and Rehabilitation* 85(10): 1711–17.

Ponticello, Mario. 2016. "Limb Salvage Versus Amputation: A Closer Look At The Evidence, Costs And Long-Term Outcomes." *Podiatry Today*. https://www.podiatrytoday.com/limb-salvage-versus-amputation-closer-look-evidence-costs-and-long-term-outcomes (November 5, 2020).

Program (CHBRP), California Health Benefits Review. 2006. "Analysis of Assembly Bill 2012 - Amended: Orthotic and Prosthetic Devices." https://escholarship.org/uc/item/8566s2wz (April 15, 2021).

"Prosthetics and Orthotics Coverage Mandated Benefit Sunrise Review." 2011. : 93.

"Reimbursement Issues | AOPA – AMERICAN ORTHOTIC & PROSTHETIC ASSOCIATION." https://www.aopanet.org/coding-reimbursement/reimbursement-issues/ (April 1, 2021).

"Retired: Correct Coding and Billing for Electronic/Microprocessor-Controlled Knee (MPK) Systems – February 2013 Revision." *CGS Medicare*. https://www.cgsmedicare.com/jc/pubs/news/2013/0113/cope21117.html (April 8, 2021).

Roberts, Toni L. et al. 2006. "Limb Deficiency and Prosthetic Management. 4. Comorbidities Associated with Limb Loss." *Archives of Physical Medicine and Rehabilitation* 87(3 Suppl 1): S21-27.

Sedki, Imad, and Keren Fisher. 2015. "Developing Prescribing Guidelines for Microprocessor-Controlled Prosthetic Knees in the South East England." *Prosthetics and Orthotics International* 39(3): 250–54.

Snowe, Olympia J. 2010. "Text - S.3223 - 111th Congress (2009-2010): Prosthetics and Custom Orthotics Parity Act of 2010." https://www.congress.gov/bill/111th-congress/senate-bill/3223/text (April 8, 2021).

Stevens, Phillip M., and Shane R. Wurdeman. 2019. "Prosthetic Knee Selection for Individuals with Unilateral Transfemoral Amputation: A Clinical Practice Guideline." *Journal of prosthetics and orthotics: JPO* 31(1): 2–8.

"The 'QALY' Shouldn't Be Used in Drug Cost-Effectiveness Reviews." 2019. *STAT*. https://www.statnews.com/2019/02/22/qaly-drug-effectiveness-reviews/ (April 8, 2021).

Traugh, G. H., P. J. Corcoran, and R. L. Reyes. 1975. "Energy Expenditure of Ambulation in Patients with Above-Knee Amputations." *Archives of Physical Medicine and Rehabilitation* 56(2): 67–71.

"Upper Limb Prosthetics Information." http://www.upperlimbprosthetics.info/index.php?p=1_15_Insurance-and-Billing (November 5, 2020).

Wong, Christopher, Julie Wilska, and Michelle Stern. 2012. “Balance, Balance Confidence, and Falls Using Nonmicroprocessor and Microprocessor Knee Prostheses: A Case Study After Vascular Amputation With 12-Month Follow-Up.” *JPO: Journal of Prosthetics and Orthotics* 24: 16–18.

Zhong, Yue et al. 2015. “Cost-Utility Analyses in Diabetes: A Systematic Review and Implications from Real-World Evidence.” *Value in Health* 18(2): 308–14.

Ziegler-Graham, Kathryn et al. 2008. “Estimating the Prevalence of Limb Loss in the United States: 2005 to 2050.” *Archives of Physical Medicine and Rehabilitation* 89(3): 422–29.

**Prospectus**

**Three-Dimensional Lung Modeling from X-Ray Images Using Neural Network**
(Technical Topic)

**An Audit of the Broken Reimbursement Methodologies of the Prosthetics Industry**

(STS Topic)

By

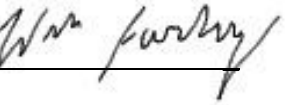
Will Farley

November 5, 2020

Technical Project Team Members:

Anthony Albini, Sam Schach

On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

Signed: 

Technical Advisor: Dr. Keith Bachmann
STS Advisor: Sean Ferguson

## Introduction

For a significant portion of early onset scoliosis patients (EOS) such as those with neuromuscular or syndromic scoliosis, the existing techniques for measuring and tracking total lung capacity (TLC) are insufficient and can make a physician's decision regarding the timing of spinal fusion surgery more difficult. This project aims to address the need for a more accurate and accessible TLC measurement technique through developing a convolution neural network (CNN) that is capable of segmenting and labeling ribs and building a three-dimensional model through analysis of biplanar X-rays alone. Aside from advances in imaging, one of the most significant breakthroughs in management of EOS in the past decade has been the introduction of magnetically controlled growing rods (MCGRs). Though MCGR implants are significantly more expensive, they minimize surgical scarring, surgical site infection, and psychological distress due to multiple surgeries needed in the traditional growing rods system, thus not only improving quality of life but saving health care costs (La Rosa et al., 2017). As a result, many insurers encourage the more costly procedure and MGCRs have rapidly emerged as the new standard of care for EOS patients within a remarkable short timeframe. This is in stark contrast to the adjacent prosthetics industry, where the standard of care lags significantly behind innovation. Inhibitive and dated insurance policies place the bulk of costs on patients, and while these policies allow insurers to largely shirk upfront costs, they may actually be costing them more through creating a persistent high cost population.

**Technical Topic**

EOS is a three-dimensional rotational deformity of the spinal column that exceeds 10 degrees and presents itself before a patient reaches 10 years of age (*Early Onset Scoliosis Consensus Statement | Scoliosis Research Society*, n.d.). Children with EOS are at risk for impaired pulmonary function due to the high prospect of progressive spinal deformity and thoracic constraints during a critical time of lung development. For children with severe progressive EOS, non-surgical options are often initially used to treat and slow the progression of the disease but early spinal fusion is the most common eventual treatment. Fusion surgery corrects scoliosis, but it also limits spine and thoracic growth, leading to adverse pulmonary outcomes such as restrictive pulmonary disease where forced vital capacity is less than 50% of normal (Karol, 2011).

The best way to promote lung development and optimize pulmonary function post-surgery is to maximize the amount of time the lungs have to develop before the fusion. However, during adolescence the likelihood of the spinal deformity worsening becomes significantly higher (Yang et al., 2016). To accommodate these two contrasting timelines, physicians try to operate as soon as they can confirm that a patient has reached a sufficient total lung capacity (TLC) that will not cause long term issues. If surgery is deemed necessary, TLC is typically measured through pulmonary function testing (PFT) or computed tomography (CT) scans (Delgado & Bajaj, 2020).

It is often difficult for young children or those with developmental disabilities to perform PFTs properly. CT scans are expensive, subject patients to roughly ten times more radiation than an X-ray, and difficult for children with neuromuscular EOS in particular as they may require a sedative to remain still for the duration of the exam (Kilbaugh et al., 2010; Mettler et al., 2008).

Current methods for determining whether a patient has reached a safe TLC are clearly insufficient, as evidenced by restrictive pulmonary disease occurring in 43% to 64% of patients who undergo early fusion surgery (Karol, 2011). That is the problem this project seeks to address.

EOS patients regularly receive biplanar X-rays to track the progression of their spinal growth and the imaging is already an integral part of preoperative assessment. If a neural network is developed that can use the combined angles of the scans to segment and label the ribs and model them in three-dimensions, TLC can be accurately calculated in a more accessible, more cost effective, and more safe manner.

To build the network, we will be working with Dr. Keith Bachmann, an orthopedic surgeon in the UVA health system. Dr. Bachmann has provided a library of biplanar X-ray images from which we can train and test our network and corresponding CT scans that can be used to confirm the accuracy of our algorithm.

There have been many attempts to find a novel approach to lung volume measurement, several of which attempted to do so using X-rays. As early as 1995, studies were being conducted to calculate TLC from radiographs alone (Schlesinger et al., 1995). Although the team achieved some level of success, their method required twenty-one separate images and was too cumbersome to inspire further pursuit. Because rib cage volume has a high correlation with TLC, rib cage identification has become a popular research subject in recent efforts to calculate lung volume. These new attempts have largely been made possible by advances in computer-aided image processing.

The prospect of using convolution neural networks (CNNs) for ribcage analysis has gained significant momentum in the past decade. These artificial intelligence algorithms have

been used to assess the developmental stage of bones and even segment and label ribs in the coronal plane with promising accuracy.

The most accurate of such studies to date employed the state-of-the-art Mask R-CNN network architecture developed by Facebook's AI research arm and was conducted by a team at the Institute of Medical Informatics at the University of Lubeck. The breakthrough work was able to segment the top nine pairs of ribs in the coronal plane with millimeter level accuracy, as seen in Figure 1.

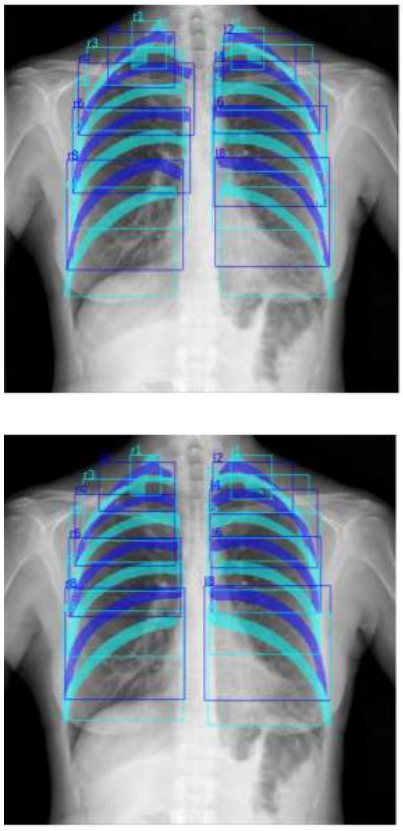


**Figure 2:** Application of the adapted Mask R-CNN algorithm to a chest X-ray image (Wessel et al., 2019). The ground truth is shown on the top and the prediction is on the bottom.

The goal of this project is to employ the pixel level segmentation of Mask R-CNN and the sequential processing scheme enhancements introduced by Wessel et. al to not only segment every rib in posterior-anterior X-ray images but to segment and label the ribs in lateral X-rays as well while achieve comparable levels of accuracy. The scans will then be merged to create three dimensional models from which mediastinal volume calculations can be used to accurately estimate TLC. It is my role to develop the CNN, and as such I have been in contact with the team from the University of Lubeck in order to gain insights into the process. Our network will be deemed successful when its TLC estimates calculated from the biplanar X-rays provided by Dr. Bachmann equal the actual TLC values from the provided CT scans for both typical patients and scoliosis patients.

**STS Topic**

The United States spends fifty percent more on health care in terms of share of GDP than any other developed country. This is largely because the U.S. health care landscape is dominated by private health insurance, which covers more than half of the American population. Aside from efforts for Medicare for all, the current strategy for addressing the ballooning spending problems within the U.S. health care system is to introduce small changes that will make it function more like a traditional consumer-driven "perfect market" (Iii, 2008). However, this is all based on the assumption that health care should be treated as a private consumable product rather than a public good, a premise that virtually no other developed country operates under.

There are several instances where non-uniform, privatized healthcare not only slows innovation, but increases cost to patients while decreasing quality of care. This paper cannot and will not serve as a critique of the entire for-profit health care complex, but rather it will be an audit of the dislocations that occur in niches that are overlooked by the greater private healthcare machine. Specifically, analysis will be performed on the dated billing practices in the prosthetics industry that create prohibitive upfront costs and disincentivize innovation.

Except for repairs to existing devices, prosthetists cannot bill for their time, even when making and fitting device adjustments. The only thing they can bill for is the device that they deliver to the patient. As a result, all costs to the business: the time of the practitioner, the technicians, the receptionist, the rent of the building, the highly specific tools needed for practitioners to make adjustments for which they cannot be compensated, even the toner for the printer, everything—must be accounted for in the cost of the prosthesis (*Upper Limb Prosthetics Information*, n.d.).

This already high cost is worsened by dated reimbursement practices. Prostheses are billed exclusively through "L Codes", which were created by Blue Cross Blue Shield in the late

1970s. Each bill will consist of multiple L code has an associated price that varies slightly with location and practice quality (Fairley, 2008). That price—determined by the Centers for Medicare & Medicaid Services (CMS)—represents the amount that Medicare will reimburse the prosthetist for a feature or component. Almost all other insurance companies follow the guidelines and prices outlined by Medicare.

Unless congress passes a bill to change prices, L Code prices will continue to increase annually with the consumer price index (CPI), as they have since being set in 1987. This does not account for the comparative inflation of health care spending, as U.S. annual per capita healthcare spending has ballooned over 250% above the CPI inflation rates adjusted for by the CMS since 1987 (California Health Care Foundation, 1967; Letsch et al., 1988; *Value of 1987 US Dollars Today - Inflation Calculator*, n.d.). In addition, to further inhibit the path to commercialization for devices in development, any new component has to go through a multiyear fee determination process, during which it will not be covered by Medicare or private insurance. Once CMS has determined that they have sufficient information to set a price, they deflate the fee back to the 1987 base period and then reinflate according to the increases mandated by Congress. The new calculated fee "frequently does not accurately reflect real-world costs" (Fairley, 2008).

This bulk of this price discrepancy comes at a direct out-of-pocket cost to patients. The two million amputees in America pay somewhere between $5,000 —$50,000 each time they buy a new prosthetic limb. It's recommended that the limbs are replaced every 3-5 years yet so few patients can afford that. A study conducted by the Department of Veteran's Affair's determined that the first and third 5-year quartile costs for veterans who lost their lower limbs in combat are $82,251 and $228,665, respectively (Blough et al., 2010). The average lifetime cost for

prosthetics and medical care for loss of a single leg for a veteran of the Iraq or Afghanistan wars is more than $1.4 million (*How Much Does a Prosthetic Leg Cost?*, n.d.). The Johns Hopkins Center for Injury Research and Policy estimates the direct total lifetime costs to be $509,272 (Miller & Jr., 2020). Regardless of the exact cost, it is an exorbitant figure to expect a patient with a disability to pay out of pocket.

There may be a way to incentive insurance companies to help foot the bill. Recent commentary has suggested that an estimated 22% of the $2.6 trillion dollars of annual health care expenditures are related to potentially avoidable complications, such as hospital admissions for diabetic patients with gangrenous limbs that require amputation (Aldridge & Kelley, 2015; Emanuel, 2012). The true cost of amputation must also take into account the loss of function and independence, reduced quality of life and the increased mortality rate. Only 47% — 67% of patients with ischemia who undergo primary amputation successfully rehabilitate to near pre-amputation levels of mobility (Ponticello, 2016). If L codes can be reworked so that Medicare and insurers bear more of the upfront cost, this could potentially increase the portion of patients who successful rehabilitate, which not only improves their quality of life but decreases their likelihood of becoming a member of a persistent high-cost population, therefore saving Medicare and private insurers money in the long run.

**Next Steps**

Moving forward, the most important focus is understanding L Code policy. It is critical to know as much as possible about its formation, its history, how it is currently used, how it is currently abused, and its most obvious shortcomings. From there, thorough analysis is required of the *Practice Analysis of Certified Practitioners in the Disciplines of Orthotics and Prosthetics* report released by the American Board for Certification in Orthotics, Prosthetics & Pedorthics, which

has a trove of data on how practitioners allocate their time and how exactly they make their money. That data will then be analyzed against long-term cost data from the department of Veteran's Affairs to identify dislocations surrounding L code policy and expenses. As noted by Ponticello, there is no published data on long-term wheelchair-bound healthcare costs, so the data will be compared to that of Aldridge and Kelley and sensitivity analysis will be ran to discern the scenarios where it is financially beneficial to all parties for the insurer to contribute more to the cost of the prosthetic.

**Works Cited**


Aldridge, M. D., & Kelley, A. S. (2015). The Myth Regarding the High Cost of End-of-Life Care. *American Journal of Public Health*, *105*(12), 2411–2415. https://doi.org/10.2105/AJPH.2015.302889

Blough, D. K., Hubbard, S., McFarland, L. V., Smith, D. G. ., Gambel, J. M., & Reiber, G. E. (2010). Prosthetic cost projections for servicemembers with major limb loss from Vietnam and OIF/OEF. *The Journal of Rehabilitation Research and Development*, *47*(4), 387. https://doi.org/10.1682/JRRD.2009.04.0037

California Health Care Foundation. (1967). *Health Care Costs 101, 2019: Spending Keeps Growing*. 50.

Delgado, B. J., & Bajaj, T. (2020). Physiology, Lung Capacity. In *StatPearls*. StatPearls Publishing. http://www.ncbi.nlm.nih.gov/books/NBK541029/

*Early Onset Scoliosis Consensus Statement | Scoliosis Research Society*. (n.d.). Retrieved November 4, 2020, from https://www.srs.org/about-srs/quality-and-safety/position-statements/early-onset-scoliosis-consensus-statement

Emanuel, E. J. (2012). Where Are the Health Care Cost Savings? *JAMA*, *307*(1), 39. https://doi.org/10.1001/jama.2011.1927

Fairley, M. (2008, August 1). *L-Codes: Are They Meeting the Needs of O&P? - OPEDGE.COM*. https://opedge.com/Articles/ViewArticle/2008-08_01

*How Much Does a Prosthetic Leg Cost?* (n.d.). CostHelper. Retrieved November 5, 2020, from https://health.costhelper.com/prosthetic-legs.html

Iii, G. B. M. (2008). The U.S. Health Care Non-System, 1908-2008. *AMA Journal of Ethics*, *10*(5), 324–331. https://doi.org/10.1001/virtualmentor.2008.10.5.mhst1-0805.

Karol, L. A. (2011). Early definitive spinal fusion in young children: What we have learned. *Clinical Orthopaedics and Related Research*, *469*(5), 1323–1329. https://doi.org/10.1007/s11999-010-1622-z

Kilbaugh, T. J., Friess, S. H., Raghupathi, R., & Huh, J. W. (2010, July 20). *Sedation and Analgesia in Children with Developmental Disabilities and Neurologic Disorders* [Review Article]. International Journal of Pediatrics; Hindawi. https://doi.org/10.1155/2010/189142

La Rosa, G., Oggiano, L., & Ruzzini, L. (2017). Magnetically Controlled Growing Rods for the Management of Early-onset Scoliosis: A Preliminary Report. *Journal of Pediatric Orthopedics*, *37*(2), 79–85. https://doi.org/10.1097/BPO.0000000000000597

Letsch, S. W., Levit, K. R., & Waldo, D. R. (1988). National health expenditures, 1987. *Health Care Financing Review*, *10*(2), 109–122.

Mettler, F. A., Huda, W., Yoshizumi, T. T., & Mahesh, M. (2008). Effective doses in radiology and diagnostic nuclear medicine: A catalog. *Radiology*, *248*(1), 254–263. https://doi.org/10.1148/radiol.2481071451

Miller, R. V., & Jr. (2020, January 4). *Limb Amputations and Their Lifetime Costs*. Baltimore Injury Lawyer Blog. https://www.millerandzois.com/blog/limb-amputations-and-their-lifetime-costs/

Ponticello, M. (2016, February 24). *Limb Salvage Versus Amputation: A Closer Look At The Evidence, Costs And Long-Term Outcomes*. Podiatry Today. https://www.podiatrytoday.com/limb-salvage-versus-amputation-closer-look-evidence-costs-and-long-term-outcomes

Schlesinger, A. E., White, D. K., Mallory, G. B., Hildeboldt, C. F., & Huddleston, C. B. (1995). Estimation of total lung capacity from chest radiography and chest CT in children: Comparison with body plethysmography. *American Journal of Roentgenology*, *165*(1), 151–154. https://doi.org/10.2214/ajr.165.1.7785574

*Upper Limb Prosthetics Information*. (n.d.). Retrieved November 5, 2020, from http://www.upperlimbprosthetics.info/index.php?p=1_15_Insurance-and-Billing

*Value of 1987 US Dollars today—Inflation calculator*. (n.d.). Retrieved November 5, 2020, from https://www.inflationtool.com/us-dollar/1987-to-present-value

Wessel, J., Heinrich, M. P., Berg, J. von, Franz, A., & Saalbach, A. (2019, April 10). *Sequential Rib Labeling and Segmentation in Chest X-Ray using Mask R-CNN*. International Conference on Medical Imaging with Deep Learning -- Extended Abstract Track. https://openreview.net/forum?id=SJxuHzLjFV

Yang, S., Andras, L. M., Redding, G. J., & Skaggs, D. L. (2016). Early-Onset Scoliosis: A Review of History, Current Treatment, and Future Directions. *Pediatrics*, *137*(1). https://doi.org/10.1542/peds.2015-0709