Amputations occur for a variety of reasons and affect all walks of life and all age groups. It is a destructive operation that does not cure, but rather leaves the patient with a physical loss.

The attempt to restore the function, that the amputation has removed, requires the use of a prosthesis. The value of the prosthesis is in its ability to fulfill the function lost in collateral terms of use, ease, and comfort.

The part of the prosthesis that is in direct contact with the residual limb is known as the prosthesis socket (figure 1).

The fitting of the prosthesis socket is foremost in the overall success of the prosthesis.

The design of the prosthesis socket is very complex due to numerous factors and considerations. At present, the socket's design is very labor intensive, and thus expensive.

This proposal addresses the research and developments of a device (namely the Residual Limb Digitizer, hereinafter known as the RLD) that shall improve current methods in the design and subsequent fabrication of the prosthesis's socket.

By providing a more optimal fitting socket, this device shall attribute to the value of the prosthesis and thereby to the physical and psychological well-being of the patient.
Background

As an example, this proposal uses a below-knee amputation (BKA) to demonstrate some of the problems presented by amputations and the solutions offered by the RLD device. However, all prostheses, (requiring custom designed sockets) would be equally advanced by the use of this device.

The major cause for amputation is vascular (of which atherosclerosis is the underlying disease process). Vascular disease accounts for over 60% of total amputations. Second to vascular disease is diabetes, which causes approximately 20% of all amputations. Third place is trauma and accounts for 10% of all amputations. The remaining 10% of causes for amputation include malignant growths, chronic infections, congenital deformities, and cosmesis (figure 2).

The level of amputation depends greatly upon the indication for amputation (figure 3).

The primary objective of amputation is to remove the portion of the extremities effected due to disease or trauma.

However, the secondary objective of amputation level is to select the most distal level that will permit primary healing and will provide the best location for prosthetic fitting.

Figure 2 - Amputation by Cause (Percent)

Figure 3 - Amputation Levels
The below-knee amputation is generally the most common level selected and its popularity is primarily due to its superiority in prosthetic rehabilitation.

The next most common amputation is the above-knee, and for very similar reasons. These two amputation levels far outnumber all other amputation levels combined (figure 4).

While the level of amputation is somewhat standardized, the method of surgical procedure is not.

There are many different surgical techniques used in amputations. These techniques can greatly affect the internal anatomical structures of muscle and bone as well as the external configurations of the residual limb. Therefore, the post-operative design of the prosthesis socket is directly dependent upon the type of surgical technique used.

In elective amputation (which is more common in vascular disease and diabetes) the surgeon has a greater degree of control in determining the level of amputation as compared to traumatic or congenital amputations.

Therein, the surgeon has become more aware of the types of prosthetic devices available to his patient. This has led to a general standardization in the levels of amputation and has focused prosthesis research and development.

Source: One year of amputations for Massachusetts General Hospital.

Figure 4 - Amputations by Type
Surgical Techniques for Amputation

When muscles retract during amputation (without directed reattachment procedures) they will retract a small distance and then reattach. However, considering that reattachment is not controlled, this may result in a partial bone and partial soft tissue attachment, or a total attachment to surrounding soft tissue. (This was a common practice in the older techniques of amputations.) This technique results in weak residual limb control, skin-puckering, bunching, and/or unwanted motion that compromises prosthetic fit or retention.

In the surgical procedure known as Myodesis, the muscles are cut, during amputation, to an adequate length and surgically anchored to the bone with sufficient tension. This provides more optimal sensory and motor performance of the muscles and thus more conducive to prosthetic fit.

In the surgical procedure known as Myoplasty, the muscles are thinned distally, during amputation, and overlapped over the cut end of the bone. This provides a soft cover for the stub and prevents a bulbous end (an undesirable feature in socket design).

The surgeon may elect a combination of Myodesis and Myoplasty surgical techniques during amputation.

In addition, the surgeon may choose to perform Osteoplasty. This is a process of creating a smooth synostosis (a placement of a bone portion) between the distal ends of the tibia and fibula. This prevents relative movement between the tibia and fibula; decreases distal fibular sensitivity; and provides a more competent end bearing platform for prosthetic support.

Furthermore, the length of the fibula, as compared to the tibia, is also subject to the surgeons' discretion (figure 5).

Note that if the fibula is slightly shorter than the tibia, then the residual limb shape is more cylindrical. Whereas, if the fibula is considerably shorter than the tibia, then the shape of the residual limb is more conical. The cylindrical shaped residual limb is less problematic than the conical shaped residual limb in prosthetic socket design.
Also, there are three primary configurations for skin flaps (figure 6):

1) A Circular skin incision, which is closed transversely (6 a);

2) A Fishmouth incision, which creates equal anterior and posterior flaps (6 b);

3) A Long Posterior Flap, which is brought forward and provides muscle over the distal tibial area. (6 c).

All three of these configurations produce significantly different internal arrangements of muscle tissue and thus affect the internal, as well as the external configurations of the residual limb. This is a major consideration in socket design.

There are many other surgical considerations not covered in this report that can affect the internal anatomical structure as well as the external configuration of the residual limb. All of these techniques correspondingly affect the configuration of the socket of the prosthesis.

In addition, the residual limb is obviously affected by the patient’s physiology. The weight, size, and physical activity of the patient greatly influences the internal and external configuration of the residual limb.

Therefore, due to the various amputation levels; numerous surgical techniques; and patient's physiology, the residual limb is an extremely complicated structure to study for socket design.
Present Socket Design Techniques

At present the socket is designed by measurement of the residual limb. Measurements include the anteroposterior and mediolateral dimensions at the mediotibial plateau (MTP) and a series of circumferential measurements. These measurements are made by simply using a tape measure.

After taking measurements, a plaster impression is made of the residual limb. A plaster impression can be made in a number of ways. The following is a description of a common four-stage casting technique:

Stage 1. A nylon stocking is applied over the residual limb. The stocking compresses the limb and provides a barrier between the limb and the plaster. Then plaster is applied over the stocking encasing the head of the fibula and the medial flare of the tibia. Controlled pressure, or vacuum, may be used to enhance the definition of the cast at this stage.

Stage 2. A circular wrap is then applied, with elastic plaster, below the popliteal crease of the knee. This draws, and compresses, the soft posterior tissues forward and locks the tibia into position in the cast.

Stage 3. The cast is then hand molded to provide a brim; a posterior trim line; and the hamstring tendon reliefs.

Stage 4. An optional stage may be employed by creating supracondylar suspension. This procedure takes the cast from the patient and mounts it in a gimbal-ring casting stand (figure 7).

After proper alignment, an alginate dental impression material is applied to the inner surface of the cast. The patient then places his residual limb back into the cast and bears his weight into it providing intimate pressure. After drying, the patient removes the residual limb and the cast is filled with plaster. The cast is removed leaving a master model of the patients residual limb.

The master model is then subjected to manual alterations based upon the type of socket to be made. There are two main types of sockets used at present. They are as follows:
The PTB technique designs the socket such that the forces of weight-bearing are focused on the patellar tendon (figure 8).

This is accomplished by bulging the socket wall between the inferior border of the patella and the insertion of the patellar tendon on the tibial tubercle. This places initial tension on the tendon thereby assuming greater pressure.

Weight-bearing is also borne over the medial, and lateral (to a lesser extent), tibial flare.

Relief’s are provided over the crest of the tibia; the anterior distal aspect of the tibia; and the lateral tibial condyle.

Figure 8 - PTB Socket Design
**TotalSurfaceBearing Socket (TBS)**

The TSB technique designs the socket such that the forces of weight-bearing are distributed over pressure tolerant tissues and relieved over tissues that are pressure sensitive.

The weight-bearing forces are distributed, within limits, equally over the entire residual limb surface (figure 9).

This is done by mounting the master model on a vacuum table and applying a heat-softened transparent plastic over it.

The transparent socket is then placed on the patient's residual limb and the prosthetist visually checks the fit of the socket. If the transparent socket exhibits areas that are not in contact with the patient's skin (i.e., assumed not weight-bearing), then the master model is modified and the entire process is repeated.

Once the transparent socket passes visual examination, then a final socket is manufactured (from the master model) for final placement in the prosthesis.

The purpose of this iterative procedure is to determine if the master model is a true representative of the patient's residual limb under weight-bearing forces.

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**Figure 9**  
Total Surface Bearing Socket Design

The TSB socket attempts to achieve the condition that no single spot, in the socket, bears more weight than any other.

The TSB technique continues the aforementioned casting process by creating a transparent socket from the master model.
Each of the aforementioned socket design techniques \((i.e., \text{PTB, TSB})\) produces weight-bearing sockets providing various degrees of comfort for the patient.

However, it is important to note that the success of these sockets is directly proportional to the skill of the prosthetist and to the amount of attention paid to detail. These techniques are time consuming and very "skilled-labor" intensive.

Each technique creates a plaster cast with various degrees of deferential compression, and testing, to resolve the surface weight-bearing configuration of the residual limb.

Both techniques require a four-stage casting procedure followed by considerable additional work. For example:

**PTB technique** alters the master model by "trial and error" to focus weight-bearing on the patellar tendon \((\text{and other areas})\) as well as providing relief to sensitive areas;

**TSB technique** requires a number of time consuming "fit-and-see" transparent sockets with subsequent alterations of the master model.

In addition, both techniques acknowledge that the residual limb has areas that are pressure tolerant and areas that are pressure sensitive.

However, neither the PTB or the TSB technique provides:

1. Any definitive attempt to define, through static or dynamic registering, the underlying anatomical structures;

2. Any quantitative data to analyze, catalog, or otherwise to rely upon for additional fittings or future prosthetic research.

3. Or, any patient's history of residual limb changes in physiology or changes in internal or external structure through past socket designs.

All of the aforementioned data would provide a substantial foundation for improving: prosthesis socket design; attention to patient care and comfort; and research and development of prosthetics.
The Residual Limb and "True" TSB Socket

The residual limb is a very complex and dynamic environment of localized areas of tissue and bone exhibiting differential pliabilities and pressure sensitive tolerances.

This produces a limb that exhibits different surface configurations for different stress and strain fields (figure 10). In other words, the residual limb's surface configuration changes (i.e., strain) disproportionately with applied pressure (i.e., stress).

Attempts to design a total surface bearing socket has received the most success and has shown the most promise in socket design.

However, to properly achieve a "true" total surface bearing socket, the residual limb must be evaluated under varying stress fields. Simply put, testing the residual limb under stress is the only way to be able to know how the limb will adjust to a specific stress field.

Please note that the aforementioned PTB and TSB "fit-and-see" procedures are simply "trial and error" attempts to obtain this identical information.

The RLD device, and it's method of application, are designed to register the anatomical structure of the residual limb under controlled stress fields.

Once this information is obtained, then the configuration of the residual limb, under actual stress fields, can be accurately described, modeled and modified through the computer to obtain an optimum socket fit.
Stress Field Generation

The residual limb must be subjected to controlled stress fields. This can be accomplished by the stress field generator.

The residual limb is fitted with a strain boot (i.e., stress field generator). As mentioned before, the limb must be subjected to stress to determine its actual anatomical dynamic structure.

The strain boot can be easily manufactured and would be a custom fit for each patient. This would be the only item within the RLD procedure that would be custom fitted other than the resultant prosthesis socket.

The strain boot is manufactured with small vacuum channels spaced at regular intervals around the limb. This can be accomplished by placing raised areas (i.e., netting) on the boot mold in the boot casting process and removing the netting afterwards.

The vacuum channels converge at the bottom of the boot and are attached to a controllable vacuum source (figure 11). A pylon could also be attached at the same location for additional support during digitization.

As the vacuum increases, the boot contracts and provides a controllable stress field around the strained residual limb.

Figure 11 - Vacuum Device
Residual Limb Digitizer

The RLD is a device designed to remotely record the spatial coordinates (i.e., x, y, & z) of the residual limb.

The RLD is composed of several different and separate components. Figures 12 and 13 show component configurations.

Item 1 - The digital camera records digital pictures which are composed of a vast array of pixels. Each pixel is separately defined and has a definite position within the digital photograph (i.e., x - horizontal & z - vertical).

Item 2 - The laser projects a vertically focused narrow beam upon the residual limb. This produces a reference trace for computer ID and computation.

Figure 12 - Isometric View of RLD

1. Digital Camera
2. Laser
3. Orbit
4. Laser axis
5. Camera axis
6. Camera field of view
7. Stump meridian
8. Vertical plane of laser
9. Vertical plane of camera
10. Camera trace
11. Reference trace
12. Device axis

1. Digital Camera

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3. Orbit

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7. Stump meridian

8. Vertical plane of laser

9. Vertical plane of camera

10. Camera trace

11. Reference trace

12. Device axis

a = Point: Intersection of vertical plane of camera and horizontal plane of stump meridian.

a' = Point: Projection of point "c" on the vertical plane of the camera and within the plane of the stump meridian.

b = Point: Intersection of vertical plane of camera, vertical plane of laser and horizontal plane of stump meridian.

c = Point: Intersection of vertical plane of laser and horizontal plane of stump meridian.

d = Point: Intersection of vertical plane of laser and vertical plane of camera and maximum stump extension.

x, y, z = coordinates for point c in terms of d as origin (0,0,0).

α = Angle defined by a,b,c.
**Item 3** - The orbit: holds the camera and laser at a fixed angle; provides incremental positioning; and RLD device support.

**Items 4, 5 & 12** - Are axis lines that are projected through the residual limb.

**Item 6** - The Camera field of view (i.e., the digital picture).

**Items 7, 8 & 9** - Are planes that are projected on, or through, the residual limb.

**Items 10 & 11** - Are traces produced by the projected planes on to the surface of the residual limb.

The reference trace (item 11) is critical in the digitization of the x, y, and z coordinates of point "c".

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**Figure 13 - Top View of RLD**

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1. Digital Camera  
2. Laser  
3. Orbit  
4. Laser axis  
5. Camera axis  
6. Camera field of view  
7. Stump meridian

\[ \alpha = \text{Angle defined by } a, b, c. \]

\[ x \text{ & } y = \text{coordinates for point } c \text{ in terms of } b \text{ (d) as origin } (0,0,0). \]

- **a** = Point: Intersection of vertical plane of camera and horizontal plane of stump meridian.
- **a’** = Point: Projection of point “c” on the vertical plane of the camera and within the plane of the stump meridian.
- **b** = Point: Intersection of vertical plane of camera, vertical plane of laser and horizontal plane of stump meridian.
- **c** = Point: Intersection of vertical plane of laser and horizontal plane of stump meridian.
- **d** = Point: Intersection of vertical plane of laser and vertical plane of camera and maximum stump extension.
**RLD Picture**

A picture taken from a digital camera, within the RLD, would be very similar in appearance as that shown in figure 14.

The orbit and other background items have been eliminated for illustration purposes.

Note that the reference trace is clearly present and is produced by the projection of a vertically focused narrow laser beam. This trace can be easily seen and identified by a computer analyzing the digital picture.

The contrast observed in figure 14 (i.e., black and white line drawing) can be easily obtained by computer analysis via threshold programming. Threshold algorithms are quite common in software drivers for computer scanning equipment.

The threshold technique is fairly simple, but would require custom programming for the RLD procedure.

**Figure 14 - Picture View**

- 1. Stump
- 2. Stump meridian
- 3. Camera trace
- 4. Reference trace

\[ z = 0 \]

\[ x \]

\[ z \]

\[ x \text{ & } z = \text{coordinates for point c in terms of d as origin (0,0,0).} \]
The digital picture is composed of a vast array of pixels. Each pixel is basically a dot that is electronically recorded in a spatial matrix (i.e., array). When this matrix is displayed through a monitor (i.e., CRT) then it assumes an apparent form of a conventional picture. This process is very similar to a common TV still-frame picture.

Figure 15 provides an example of how this process works. Note that the enlargement is illustrated as a set of boxes that are filled if data is present (i.e., the laser reference line and the physical edge of the residual limb).

Each "filled" pixel can be easily identified by a computer. For example: Is this pixel filled (contains data) or is it empty?

This pixel identification processes also provides the location of the pixel. In this example (Figure 15) the pixel noted (i.e., "c") has a vertical location of 159 pixels (in the z direction) and 20 pixels (in the x direction) right of the main axis of the camera.

The actual position of the "main axis" is not important. The only condition for the main axis is that it be consistent in each picture taken by the RLD.
**RLD Calculations**

The calculations for point "c" are very straightforward (Figure 16). Therefore, each point on the surface of the limb can be calculated.

For example: Calculating the x and z coordinates for point "c" is a simple matter of identifying the x and z coordinates, from the digital picture (Figure 15), and then multiplying the value of these coordinates by a simple scalar value to obtain correctly scaled distances.

To calculate the y coordinate requires a minor trigonometric calculation.

For example: The angle $\alpha$ is known. It is the angle subtended by the camera axis and the laser axis ($\text{angle abc}$). This angle can be physically measured from the device. In this example the angle is approximately 45 degrees.

As shown before, the distance $x$ ($a'$ to $c$) is measured and calculated. The distance $y$ ($b$ to $a'$) is simply the cotangent of $\alpha$ multiplied by the value of $x$.

\[
\frac{a' \text{ to } b}{a' \text{ to } c} = \cot \alpha
\]

\[
y/x = \cot \alpha
\]

\[
y = x \cot \alpha
\]

Note that the $x$, $y$, and $z$ coordinates are in terms of the intersection of the vertical planes of the camera and laser. This axis would be consistent from picture to picture.

![Figure 16 - Calculations for point "c"](image-url)
The proceeding calculations were for a single point (i.e., point "c"). However, this process can be repeated many times to obtain numerous points.

Figure 17 illustrates this concept and exhibits numerous longitudinal and meridian lines.

The meridian lines are simply trace representations of horizontal planes projected through the residual limb. (These lines do not appear on the digital pictures.)

Whereas, the longitudinal lines are reference traces (e.g., laser projections) are repeated at specific intervals around the residual limb.

This is accomplished by the RLD acquiring numerous pictures from different perspectives.

The node points are defined where the longitudinal lines and meridian lines meet.

At each node point, a separate "c" location position can be calculated and a specific location registered in terms of, x, y, and z.

Node points can be as close together as the resolution of the equipment permits.
The number of registrations (i.e., resolution) possible are dependent upon the limitations of the equipment.

For example: The reference trace is analog (e.g., vertical laser projection). Whereas, the digital picture of the reference trace is digital (e.g., composed of a finite amount of pixels). Therein lies an inherent limit to the number of vertical digitizing points possible.

To calculate the possible vertical resolution of the device, one need only to examine the capabilities, or resolution, of the digital camera.

A typical and commonly available digital camera produces a digital picture that is 640 by 480 pixels. This translates into one pixel per 0.01875 inches when viewing a 12 inch object (i.e., residual limb).

\[ 12"/640 = 0.01875" \]

A vertical resolution of less than .02 inches should be more than sufficient to properly resolve the structural dynamics of the residual limb.

However, if additional resolution is necessary, then higher resolution cameras are readily available.

The horizontal resolution of the RLD is somewhat more complicated to illustrate and compute. However, the horizontal digitization capacity of the RLD is considerably more than its vertical digitization capabilities.

The RLD operates by viewing the residual limb in a circular manner. In other words, the digitizing calculations and resolution are dependent upon the number of pictures taken and the subsequent amount of closure.

Clearly, the more digital pictures that are taken the more data points that are collected and the better the resolution.

However, the degree of closure of the operation also directly affects the resolution. It should be apparent that if one obtained a high number of spacial points in one hemisphere, that an accurate representation of the total digitized subject would not be possible (e.g., only one hemisphere would be represented).

However, if one sampled a sufficient number of points distributed around an object, one can accurately represent that object in three dimensions.

This is the basic theory for the digitizing concept of the RLD and its application.
Figure 18 illustrates a time elapsed operation of the RLD. In this example: A picture is taken at 0 degrees (camera facing up-page). A point "c" is then calculated. Then the orbit (with camera and laser) is moved 70 degrees (β) clockwise and another picture is taken and another point "c" is calculated. Note that this operation has produced two complete set's of "c" points (i.e., each set is composed of many samples taken along the z-axis).

This process is repeated as often as necessary. The choice of 70 degree increments (figure 18) was for illustration purposes only (smaller increments would have complicated the illustration).

To compute the horizontal resolution, one only needs to calculate the amount of incremental increase in angle β. Decrease in angle β results in an increase in horizontal resolution.

For example: If pictures were taken at every 12 degrees, while digitizing a six inch (in diameter) residual limb, then 30 pictures would be acquired (i.e., 360 degrees/12 degrees) with a horizontal resolution of 0.59 inches. Decrease angle β to 6 degrees and the horizontal resolution increases to 0.29 inches.

The horizontal resolution is dependent upon the number of pictures and data points acquired.
RLD Procedure

The process involves the patient wearing a strain boot. The boot would be digitized, by the RLD. The readings would be done at prescribed stress/strain intervals. For example:

A reading (set of digital pictures) would be done at rest to establish the "at-rest" potential of the residual limb. Then the stress device would be used to obtain a specific uniform stress reading (e.g., 2 ATM). Then another reading would be taken by the RLD. The process would be repeated (at increasing pressures) until a maximum stress level is obtained. It is estimated that the entire processes would be less than ten minutes to perform. (The amount of incremental pressure and maximum pressure would be subject to R&D.)

During the processes, the operator of the RLD device would be in communication with the patient as to any specific sensations and their locations (i.e., Sensations: -- discomfort, pain, pressure, Locations: -- fibular head, distal tibial, etc.). This information would be incorporated into a questionnaire as to the pressure tolerant and sensitive areas.

Please note that the entire testing process could be performed at a remote site. The data from the RLD could be sent to a computer through modem or physical diskettes by mail.

This would provide the centralization of the prosthetic socket manufacture which reduces the "on-site" expense of redundant equipment and personnel (i.e., computer, lathe, socket-making devices, numerous skilled attendants, etc.).

The entire data set would be contained within the digital pictures taken by the RLD. These pictures would then be forwarded to a computer capable of reading the pictures and computing the x, y, and z coordinates.

From these coordinates, the computer can analyze and design the optimum prosthesis socket. The socket design software can be programmed to allow for operator input (e.g., overrides) as to distributing weight-bearing to pressure tolerant areas and relieving areas that are pressure sensitive. However, it is believed that the computer, with proper designed software, can identify such areas and perform that task automatically. (The software design will be subject to R&D.)

After design of the socket, the computer simply provides the appropriate spacial configuration information to a computer controlled lathe and a master model is cut (i.e., CAD CAM).

From this master model, a final and "true" total surface bearing socket is made and attached to the prosthesis.
**RLD Summary**

The RLD is designed to computerize and optimize the design of the prosthesis socket.

- The RLD accumulates data during the application of controlled stress fields on the residual limb. From these data, the computer re-creates an accurate three-dimensional history of the residual limb at various known stresses. This history is a dynamic record of the residual limb configurations under stress and provides the means of analyzing the optimum stress/strain configurations within the prosthesis socket (*No other method presently exists for this type of socket analysis*).

- The RLD is a non-intrusive and safe technique. All digitation is performed remotely.

- The RLD provides the opportunity to analyze individual patient socket design history.

- The RLD provides actual quantitative data for the research and development of all prosthesis (*This is not provided by any present industry techniques*).

- The RLD can be used at remote sites where high cost equipment or technical personnel is cost prohibited or not available.

- The RLD will supplement and significantly advance the capabilities of present CAD CAM systems used in the industry by replacing the industry standard inaccurate and inflexible three dimensional data acquisition equipment.

- The RLD testing process is performed only once on the patient. The patient is only subjected to an initial testing and normal socket-to-prosthesis alignment procedures. The patient is not subject to lengthy hands-on casting procedures; followed by numerous "fit-and-see" trails; followed by "does-it-fit" testing as present methods.

- The RLD significantly reduces the skilled-labor attention presently required in designing the prosthetic socket. This will reduce the overall labor cost of the prosthesis.

- The RLD, *most importantly*, provides an optimally designed "true" total surface bearing socket that is more comfortable and efficient.

Considering the aforementioned benefits, the RLD shall greatly contribute to the value of the prosthesis and thereby to the physical and psychological well-being of the patient.

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