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PRINCIPAL INVESTIGATOR: Roy D. Bloebaum, Ph.D.
Kent Bachus, Ph.D.
Derinna Kopp

CONTRACTING ORGANIZATION: Western Institute for Biomedical Research
Salt Lake City, UT 84148

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Roy D. Bloebaum, Ph.D.
Kent Bachus, Ph.D.
Derinna Kopp
Email: roy.bloebaum@hsc.utah.edu

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14. ABSTRACT
This is the first year annual report of this four year research program to develop osseointegrated implants for amputees. This research will provide the basic foundations for the safe and efficacious design of implants for above the knee active amputees. These implants will allow for direct loading of the bone and have a safety release mechanism to prevent abutment and bone-implant interface failure and bone fracture. The first year of research focused on determining morphometric variations in the internal structure of the human femur as a function of gender, age, and ethnic background. Anthropometric studies were conducted along the length of the femur to develop sizing and design criteria. It has been a productive and challenging first year. The challenge of obtaining human cadaver specimens delayed our timeline but we will complete the task within the first quarter of the second year. We believe we have established the imaging principles for developing customized osseointegrated implants.

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Osseointegration, amputees, Implant design

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Introduction

The ultimate goal of this research is to bring warriors with lower extremity amputations back to pre-amputation activity levels. This research proposal will provide the basic foundations for the safe and efficacious design of skeletal implants for active above the knee active amputees. These implants will allow for direct loading of the bone and have an overload protection device to prevent abutment and bone-implant interface failure and bone fracture. There are three hypotheses being tested:

- Hypothesis 1: There will be distinct morphological variations of the medullary canal between gender, age and ethnic groups (Task 1, Years 1-2).
- Hypothesis 2: A variable adjustment mechanical release mechanism can be designed to protect the bone-implant interface and initial attachment strength over a range of implant and residual limb lengths (Task 2, Years 2-4).
- Hypothesis 3: A large animal weight bearing amputation model will allow for assessment of infection prevention strategies, tissue ingrowth into the implant, and biomechanical attachment strength of an osseointegrated implant over time (Task3, Years 2-4).

To address these hypotheses the research will determine morphometric variations in the internal structure of the human femur as a function of gender, age, and ethnic background (Task 1, Year 1). Conduct anthropometric studies along the length of the femur to develop sizing and design criteria for an implant (Task 1, Year 1). Design and test prototype femoral implants for fit and fill and intramedullary mechanical attachment strength for various biomechanical lengths along the femur (Tasks 1 and 2, Years 1-3). Design and mechanically test a variable adjustment safety release mechanism (Task 2, Years 3-4). Conduct an IACUC approved sheep amputation model to determine rate and amount of soft tissue and bone ingrowth into the implant and attachment strength over time (Task 3, Years 2-4).

Body

The first year of the research centered on Task 1 of the approved Statement of Work. Task 1 was to design and develop a size range of safe and efficacious implants for above knee amputees in the human cadaveric femur and sheep metacarpal III bone model. The following milestones are associated with the first year of research.

Milestones

A. Sizing studies for design of sheep implant trials. **(YEAR 1, QUARTER 1):**

To perform the sizing studies for the sheep implants an IACUC exempt morphometric study was conducted using cadaveric sheep metacarpal III bones, n=9, from the same heard to be used in the animal model. The sample size of n=9 was established based on known overall body size variation within the sheep heard to be used for the animal model (R. Olsen, Personal Communication). Following the collection of standard osteometrics (length, anterior-posterior and medial-lateral diameters), the bones were radiographed in a standardized position in both anterior and lateral views with a

calibration standard of known dimensions (Figure 1). Using a DICOM viewer and analysis program (CD Viewer 4.5.1, Agfa-Gevaert 2001) anterior, posterior, medial, lateral cortical thicknesses, as well as external and medullary diameters were measured at 25%, 50%, and 75% of the total length to gain an understanding of variation along the length of the metacarpal III bone (Figure 1). A known calibration standard was used to determine that the contact radiographs had a 2% magnification and the final measurements were adjusted accordingly.

The morphometric study indicated that the sheep metacarpals tended to fall into two groups based on maximum length (Figure 2). The analyses indicated that the variation in the geometry of the medullary canal was significant within the general population (Table 1 and Figures 3 and 4). This information dictated that a modular implant design will be needed to accomplish the fit and fill requirements to assure consistent skeletal and durable attachment.

As part of a collaborative agreement, Zimmer Corp. was to design and manufacture the sheep implants. To facilitate this, Zimmer designers and engineers conducted their own sheep morphology study using our data and concluded that there should be multiple sizes or modular implants to account for the size variation seen in the metacarpal III bone.

B. Manufacture sheep implant trials. (**YEAR 1, QUARTER 2):**

When this research program was submitted Robert Cohen (President of Zimmer Trabecular Metal) had made a commitment to provide sheep and eventually human implants for research development and implementation. With a year of receiving the funding Zimmer had effectively reorganized their management team, Robert Cohen departed, and the corporate response to our requests slipped on the priority list.

Initially, Zimmer designers and engineers conducted morphological analyses of the sheep metacarpal III and produced a sheep implant design. Our research team was provided with Delrin implant trials and a few complete titanium-tantalum implants for fit-fill analysis (see next section). These implants were beneficial to our implant design team since it was apparent that the surgical resection would need to be moved more distal to the original resection line.

With Zimmer management becoming unresponsive, Dr. Bloebaum contacted Mr. Marc Richelsoph, who he had worked with in the past to develop an implant system. Mr. Richelsoph is the president and CEO of his own company. Previously Mr. Richelsoph directed the custom implant program for Wright Medial Inc. He also previously held the position of Vice President for Research for the U.S. operations of Aesculap in Memphis TN. He is an expert in custom implant design, intellectual property, FDA submissions, and implant designs for animal and human use. He has been in constant communication with our team and is passionate about helping our program being successful.

Unlike Zimmer, where most committed management departed, Mr. Richelsoph is the top person within the company we are dealing with. He has access to state of the art technology and his response times have been either ahead of schedule or on schedule.

The change in corporate commitment will not compromise the research, access to the state of the art biomaterials or the quality of the implant system. A safe and efficacious implant system will result from this program. In fact, our probability of developing an implant system in a timely manner had increased.

To date we have forwarded CT images, radiographs, and molds of the medullary canal (Figure 5) to Mr. Richelsoph and he has begun fabricating an implant design for our initial sheep studies. He will meet with our team in Salt Lake City on 28 August 2007 for review of the implant system, the program and timelines.

Finally, Mr. Richelsoph has committed to attending our pilot animal surgeries and several of the initial study surgeries to assure the implant system meets the study needs. We are deeply indebted to Mr. Richelsoph for his passion and commitment to making this program successful for our warriors with amputations.

C. Insert sheep implant trials into metacarpal III. **(YEAR 1, QUARTER 3-4):**

Once the Zimmer implants were designed, Delrin trial implants (Figure 6) were produced and inserted into n=4 (2 large, 2 small) sheep metacarpals. After initial preparation of the bones for insertion of the implants including resection of the bone at the appropriate amputation level and removal of excess cancellous bone. It was observed that the distal end of the implant trials by Zimmer, the end that would be made of Tantalum in the final metal implants, was not fitting in the bone as intended (Figure 7). The Delrin trial implants provided by Zimmer were too thick in the both anterior-posterior and medial-lateral dimensions at the distal end for the bones and fractured the bones when fully inserted. Discussions were had with Zimmer designers to re-design the distal part of the implant to better fit the resection location. We were informed that the distal morphology of the implant was dictated by the material constraints of tantalum, but that the Zimmer engineers and designers would reduce the size of that region as much as they could. It should be noted that the response times were quite slow which lead to our redirecting the program to Mr. Marc Richelsoph.

D. Confirm fit/fill of sheep implant trials into metacarpal III. **(YEAR 1, QUARTER 4 – YEAR 2, QUARTER 1):**

Zimmer eventually then provided titanium-tantalum implants (Figure 8) for fit and fill analyses. These analyses were conducted by our orthopaedic surgeon, Dr. James Beck. A radiograph of a test metal implant in a metacarpal III bone is shown in Figure 9. During this analysis, Dr. Beck noted that the stiffness and length of the implant in conjunction with the thin posterior cortical bone of the metacarpal III (Figure 4 and Table

1) would almost certainly lead to fracture of the bone in this region and failure of the implant system.

It was shortly after this time that Dr. Bloebaum brought Mr. Richelsoph onto the team to design and manufacture the implants. Working with Dr. Beck, it was decided that the implant should be longer in length and that the resection level of the bone should be moved slightly more distal on the diaphysis of the metacarpal III bone. Mr. Richelsoph is taking both of these design factors into account in the new implant design and will present his design for final review at the 28 August 2007 meeting.

As mentioned above, Mr. Richelsoph will meet with the team on 28 August 2007 to discuss the final implant design and study timeline. After the implant design has been agreed upon by Mr. Richelsoph, Dr. Beck, Dr. Hofmann, Dr. Bloebaum, and Dr. Bachus, Delrin trials, followed by metal trails, will be manufactured and again tested in the bones. It is anticipated that these analyses will occur on schedule during the first quarter of year 2.

E. Characterize human morphometric variations due to age, due to gender, and due to ethnicity. **(YEAR 1, QUARTER 1 – 4):**

This aspect of the research consists of two IRB exempt related studies. Study 1 is to develop a bone imaging protocol that will provide for accurate 3-D reconstruction of the diaphysis and medullary canal of the human femur to allow for collection of data metric analysis and computer-aided 3-D fit-fill analyses of the human implant prototypes. In Study 2 morphometric variation between age, gender, and ancestry is assessed for implant design considerations.

Study 1 included the imaging of 25 cadaveric femora via standard radiography, CT, and MRI followed by statistical analyses to identify the best imaging protocol. To accomplish this, the fresh frozen cadaveric femora were manually dissected of any adhering tissues. Standard anthropological osteometrics, including biomechanical length (Ruff 1981 and Kuo et al. 1998) and anterior-posterior and medial lateral diameters at 20%, 35%, 50%, 65% and 80% (Figure 10) of biomechanical length were then taken for each femur. The orientation marks for standard anatomical positioning (Ruff 1981) of each femur were also noted at this time.

Medical images (Radiographs, CT, and MRI) were collected from the fresh frozen femora at the Salt Lake City Veterans Administration Hospital. All cadaveric specimens were thawed prior to scanning, a requirement for MRI. Each skeletal element was plain radiographed in AP and lateral views (Figures 11 and 12) prior to CT or MRI imaging. Digital contact radiographs were taken on a Philips Bucky Diagnost machine at 60 Kv, 4 Mass, and a working distance of 47 inches. Each element was then CT and MRI scanned in anatomic position (Ruff 1981) (Figures 10, 11, and 12) along the entire length of the bone following standard imaging protocols for each modality that had been optimized for imaging cadaveric bone. CT images were taken with a GE High Speed CTI single slice

helical scanner, 1 millimeter thick slices were taken every millimeter along the entire length of each bone at a pitch of 1 (1x1x1), with Mass=100 and Kv=100. MRI images were taken with a GE 1.5 TESLA machine. Images were taken using an Axial T2 Fast Spin Echo (FSE) scanning protocol. A pilot study revealed that 3mm slices using a torso or body coil provided the highest resolution and best detail of the cadaveric femora on this machine, thus 3mm slices were taken along the entire length each bone. Additional scanning parameters for MRI imaging include TE 65, TR 4000, FOV 14, Skip= 0, Freq. 256, Phase 192, NEX 3.00, Freq Direction: A/P, and Center Freq: Water.

MRI imaging required the cadaveric bones be placed in warm water for scanning to allow for the bone to be visualized since all soft tissues had been removed. Therefore all bones were placed in a Plexiglas water tight container (Figures 11 and 12), the containers were filled with warm water, and then all images were obtained.

The X-Ray, CT and MRI data were saved as DICOM images for computer 3-D modeling and reconstruction of the bone and medullary canal. The contact radiograph images were analyzed using a DICOM viewer and analysis program (CD Viewer 4.5.1, Agfa-Gevaert 2001). Anterior, posterior, medial, lateral cortical thicknesses, as well as external and medullary diameters were measured at 35%, 50%, and 65% of the biomechanical length of each femur. Anterior-posterior curvature or bow relative the frontal plane was also calculated from the radiographs following standard techniques (Kuo et al. 1998). The known calibration standard was used to determine that the contact radiographs had a 1-3% magnification and the final measurements were adjusted accordingly.

CT and MRI DICOM files were exported and stored on CD+R media, on a password-protected personal computer, and archived on a remote sever. Image slices were imported into image analysis software (Mimics, Materialise, USA) where thresholding techniques were used to define periosteal and endosteal boundaries in each slice. These (bitmap format) periosteal and endosteal traces were then imported into custom-written software (MATLAB, Mathworks, USA) for osteometric analysis. For each slice, geometric variables were calculated. Calculations of cortical moment of inertia, major and minor axis orientation, and center of mass (centroid) were made based on the assumption that each pixel constituting the cortical area is of equal mass. A calibration object of known dimension was scanned with each image set and used to scale pixel size to metric units (mm). To calculate the moment of inertia, axis orientation and centroid of the medullary canal, each pixel contained in the canal was also assumed to be of equal mass. Cortical thickness was calculated for anterior, posterior, medial, and lateral cortices. Cortical thickness is defined as the distance between the intersection of the axes with the endosteal and the periosteal boundaries.

An error in our CT scanning procedure was discovered approximately two-thirds way through the bone imaging and analysis phase of Study 1. There were two different CT technicians working with our team to CT scan the bones, and while both technicians were using the “Large” FOV (field of view) designation on the scanning set-up screen of the CT scanner program it was discovered, unfortunately only after the images had been

imported to the Mimics image analysis software and then run through the custom-written Matlab software, that the two technicians were in fact scanning the bones at two different fields of view (FOV's of 30 and 16).

After investigating how the different FOV's arose it was discovered that the technicians has each chosen slightly different scanning protocols (Research_9.3 and Research_9.7) and this resulted in the different FOV's. While both protocols scanned what the program considered a "Large" FOV, they did have different FOV's. Scan protocol Research_9.3 scanned a FOV of 30 and Research_9.7 scanned a FOV of 16. The FOV's dictated the number of pixels per mm in each scan slice with the larger FOV of 30 resulted in fewer pixels per millimeter (mm), and since the custom-written Matlab program calibrated each measurement off the number of pixels per mm the scans with the larger FOV were not read by the program.

It was decided that the bones that had been scanned with the larger FOV (approximately 1/3 of the bones scanned to that date) should be rescanned to limit any measurement error associated with the different number of pixels per mm. The re-scanning of this portion of bones set Study 1 back approximately two and a half months, and subsequently the scanning and collection of data for Study 2 as well. All bones for Study 1 and Study 2 have now been scanned under the Research_9.7 scanning protocol with a FOV of 16. The data presented here is therefore only that for the bones scanned with a FOV of 16 and scanned under Research_9.7 scanning protocol.

The 3-D reconstruction Study 1 data revealed that while MRI has the advantage of no radiation exposure, the modality did not provide the most accurate data for 3-D reconstruction of cadaveric bones (Figures13 and 14). The signal to noise ratio in the MRI scanning, while reduced as much as possible by the use of the smallest coil possible for the size of the bone, proved to be a limiting factor in the MRI imaging of cadaveric bones. Due to the signal to noise ratio the MRI was unable to accurately acquire scans of the proximal and distal ends, where three is very thin cortical bone and mostly cancellous bone, of most bones, this resulted in incomplete and distorted 3-D reconstructions (Figure 13). Additionally, the MRI scanning did not provide as accurate imaging of the diaphyseal cortical bone or endosteal surface of the medullary canal compared to CT data (Figures 13 and 14).

Statistical analyses of the MATLAB data obtained from the CT and MRI scans similarly revealed that the MRI scans did not provide statistically similar data as the CT scans (Figures 15 and 16, Tables 2 and 3). The MRI data had greater standard deviations and variances for nearly every geometric measurement. In fact the MRI scans required much more computer operator manipulation before they could be analyzed in the MATLAB program than the CT scans, increasing the possibility for observer introduced error. For every MRI image the operator had to manually alter the threshold to ensure all the bone and only bone was included in the reconstruction, and erase any marrow or other areas inside the medullary canal. The CT data did not require this much processing prior to MATLAB analysis.

Our primary reason for exploring the use of MRI was to limit radiation exposure to future patients. However, we recently learned that many of the possible future patients may still have metal shrapnel embedded in their residual limbs and that MRI would not be appropriate for these patients (Dr. Charles Scoville, Personal Communication). The poor reconstructions and data provided by MRI were bolstered by this information and we can report that MRI does not provide the best protocol for 3-D reconstruction of cadaveric bones for the purposes of this research proposal.

We will be submitting abstracts for presentation to the Orthopedic Research Society and American Association of Physical Anthropologists in September 2007 with the complete data analysis from this study.

Initially we proposed to perform bootstrap analyses to identify the best scanning protocol, defined as the one that contained the minimum number of images while maintaining the highest degree of reconstruction accuracy. This research goal was based on our limited understanding of the imaging modalities at the time the research proposal was written. Since that time our research team has gained a greater understanding of the imaging modalities and the physics behind the capturing of images, and we have come to the realization that that particular research goal was in error. It is the slice thickness that is significant for 3-D analyses for both CT and MRI imaging. As mentioned above, we took 1mm CT slices and 3mm MRI slices because pilot work indicated that those would provide the highest degree of resolution. A full scale study should be conducted to compare CT/MRI scanning protocols with different slice thickness (i.e. 1mm, 3mm, 5mm) and the effect slice thickness has on 3-D reconstruction. Our budget and time-line did not permit us to conduct such a study under this grant, however, Kopp and Bloebaum have a grant in submission at this time to conduct such analyses to the Otto Bock Corporation.

The original research plan for both Study 1 and 2 required the purchase of cadaveric femora to image and analyze. These femora would then be used in the computer-aided 3-D and actual fit-fill analyses with the human implant trials. After an exhaustive search of accredited tissue banks from across the country that lasted the entire first year of the study, it was painfully obvious that, while we could obtain ample Caucasian femora, we would fall short in the number of African American, and Hispanic femora required for Study 2. Study 2 requires a total of 72 bones (n=12 for white males, white females, black males, black females, Hispanic males, and Hispanic females each). A decision was made to borrow femora from a modern skeletal collection that would be imaged and then returned, and then continue to purchase cadaveric material required for the computer-aided 3-D and actual fit-fill analyses with the human implant trials. Skeletal femora were borrowed from the William M. Bass Donated Skeletal Collection from the University of Tennessee. This modern skeletal collection with complete life history backgrounds on each individual is unique in the United States and accordingly research access limited. We obtained special access to this rare collection due to Derinna Kopp's close affiliation with the Department of Anthropology at University of Tennessee.

To date we have been able to purchase 62 white male bones, 20 white female bones, 10 black male bones, 6 black female bones, 4 Hispanic male bones, and 8 male and 8 female bones with unknown ancestry for a total of 118 bones that have been (n=64) or will be imaged (n=54) to be incorporated in Study 2, for implant design parameters, and in the 3-D fit-fill studies. Additionally we borrowed and imaged 42 black males bones, 12 black female bones, and 15 Hispanic male bones (total of 69 bones) from the William M. Bass Donated Skeletal Collection to be used in Study 2 and for implant design parameters. Unfortunately, the William M. Bass Donated Skeletal Collection does not include any Hispanic females and we have not been able to find any Hispanic females for purchase or loan to date. We are continuing with the data collection as planned while continuing to search for Hispanic female bones to included in Study 2 as originally intended.

The exhaustive search for cadaveric femora to purchase and then the arrangement of a loan of the Bass Collection femora unfortunately delayed the acquisition of data for Study 2 and put that study behind schedule. To date we have 60 femora (all the femora required for Study 2 except for Hispanic females) imaged, and the radiographic data collection and 3-D analyses of the bones are underway and scheduled to be completed by the end the first quarter of year 2. The complete data analyses for Study 2 are scheduled to be concluded by the middle of the second quarter of year 2.

F. Design human implant trials. (**YEAR 1, QUARTER 1 – 4, YEAR 2, QUARTER 1-2):**

On August 28, 2007 the implant design team will meet with Mr. Richelsoph to begin the preparation for establishing the design parameters for the human femoral osseointegrated implant based on our osteometric studies on age, gender, and ethnicity. The CT and radiographic data appears to dictate that the implant design will be modular in order to fit and fill the medullary canal of the amputee warriors to accommodate the different residual bone lengths in each individual. The 3-D cadeveric imaging results to date support that, despite the absence of data on the Hispanic females, the implant designs will likely be custom and modular in principle. These designs features will accommodate the possible broad anatomical variations that will be presented the implant manufacturer.

Research Components Ahead of Schedule:
Kinematics and ground reaction force analyses:

We have been designing a suitable analysis system to measure the kinematics and ground reaction forces of the sheep planned for Year 2. In Study 7, we proposed to place sheep on a treadmill every 30 days and using a forceplate system, confirm weight bearing on the implant as well to compare their progress over time. While, we have obtained a 6-axis load cell (AMTI MC3-6-1000) that we will be using to measure the ground reaction forces, and are constructing the platform, we have developed a new strategy to overcome unforeseen difficulties as well as to add additional information to our analyses.

Our initial concept of Study 7 was primarily directed at measuring the reaction force normal to the ground. We intended to measure the pre-amputated ground reaction forces of both the forelimbs. Once that was accomplished, we would amputate the right forelimb, implant the metal endoprostheses, and attach the exoprosthesis. However, we have had two set-backs with this plan. First, since the artificial hoof of the exoprostheses could not be identical in shape and material to the biologic hoof that was amputated, the ground reaction forces between the pre-amputated and the post-amputated time points would be artificially altered. Second, after some preliminary work, we determined that the ground reaction forces of all four limbs should be measured to keep any confusion of the weight distribution of the quadrupedal sheep out of the data. However, it would be nearly impossible to get clean and accurate readings on all four limbs of a quadruped simultaneously.

We believe that we have solved both of these initial setbacks by using a Forceboot, a device that we are currently designing and will be testing over the next month. The Forceboot is made of multiple thin force sensors embedded into a rubber boot that can be quickly put on and taken off from the sheep. These force sensors will be wired to a quick connector. As the sheep are booted and standing on the treadmill, the quick connectors are attached to a computer system monitoring and recording from the force sensors. The treadmill is turned on, set to a predefined walking velocity, and the ground reaction forces are measured on all four limbs. Prior to implantation, calibration studies will be performed on the exprostheses with the Forceboot to confirm known loading parameters following amputation. Once the endoprosthesis is implanted and the exoprosthesis is installed, the animal will be allowed to recover for a week, and allowed to ambulate with the rest of the flock (observation from previous pilot study). The animals will resume treadmill and kinematics and ground reaction force will be gathered starting at week 1 and thereafter every 30 days until scheduled sacrifice (3 months, 6 months, 9 months, and 12 months).

Overload Protection Device (Years 2, 3):

We have indicated that we had a pre-existing design for a safety release mechanism to protect the osseointegrated implant from overloaded stresses. We were fortunate to complete the prototyping phase (Figure 17, see Appendix A also) of the device for Study 6 of the proposal.

Our initial torque testing indicated that we were on the right path, but not completed with our design. Torque rotation curves of the device (Figure 18), indicated that large torques could be applied to the system, then at a predefined maximum torque, would release and not allow additional torques to affect the osseointegrated interface.

However, there were some materials problems with this prototype device. Following testing, visual inspection of several components indicated that some deformation was occurring in the metals (Figure 19). We are currently modifying our design and will be on schedule for testing in Study 6.

Key Research Accomplishments

- Obtained 24 sheep metacarpal III bones, 22 lower sheep forelimbs, and 26 complete sheep forelimbs for morphometric studies and cadaveric piloting for sheep weight bearing model.
- Conducted sheep morphometric and implant design studies to design and manufacture an osseointegrated implant for the weight bearing animal model.
- Conducted cadaveric fit-fill analyses of initial sheep implant design.
- Re-designed sheep implant for weight bearing animal model.
- Established implant design principles.
- Accelerated implant manufacturing.
- Improved manufacturer response time and collaboration.
- Maintained access to state of the art implant materials.
- Established X-Ray, CT, and MRI scanning protocols for 3-D reconstruction (see Appendices).
- Purchased 118 cadaveric human femora and borrowed 69 skeletal femora to image for studies.
- Radiographed and CT imaged 133 bones and MRI imaged 26 bones to date.
- Developed custom-written soft-wear for CT and MRI image analysis.
- Conducted comparative analyses of imaging modalities for 3-D reconstruction studies.
- System to measure kinematics and ground reaction forces of the sheep under development.
- Development of overload protection device for implants.

Reportable Outcomes

The first year of research has positioned our team to produce 2-3 abstracts for the Orthropaedic Research Society and the American Association of Physical Anthropologists to be submitted in September 2007. We will also be submitting 2-3 peer reviewed manuscripts during the 2007-2008 funding cycle based on the first year of research.

This research supports 1 PhD who will receive her doctorate in October 2007, a volunteer medical student, 2 volunteer undergraduate students, and 4 volunteer premedical students. Two (2) of the premedical students gained entrance to medical school in 2007.

We received $145, 000 in private donations to support the program. We are currently working with a senior executive at Boston Scientific to explore the possibilities of receiving a multi-million dollar donation to support the amputation program. Because of this program and the historical research accomplishments of Dr. Bloebaum, he was awarded the Clemson Award for Applied Research in Basic Science in 2007 by the Society of Biomaterials. Dr. Bachus has developed the overload protection device, which

he has applied for patent protection (see Appendix A). This branch of the program remains ahead of schedule.

Conclusion

It has been a productive and challenging year. The challenge of obtaining human cadaver specimens delayed our timeline but we will complete the task within the first quarter of the second year. We believe we have established the imaging principles for developing customized implants for our warrior amputees. The imaging principles developed are also applicable to the final design work to assure implant fit and fill to be used in the second year sheep amputation study.

We are confident that MRI imaging will not be as accurate as CT imaging or radiographic analysis. Comments made a recent meeting where Dr. Chuck Scolville mentioned MRI could be harmful to the warriors because of the residual metal shrapnel that may be present in their limbs altered us to that very important aspect of our future patients that we had not considered when writing the research proposal. That comment makes sense and we have since (based also on data from Study 1) decided not to pursue further research avenues to refine or improve the MRI image capturing or 3-D reconstruction techniques.

Further and additional research on different CT imaging protocols needs to be perused to determine if protocols that limit radiation exposure by shortening scan time and increasing scan slice thickness (i.e. 3mm or 5mm thick slices) will provide as accurate data as the 1mm scans, which have higher radiation exposure and scan times. Kopp and Bloebaum have recently submitted a research proposal to address this question using the human humerus to the Otto Bock Corporation, who appear interested.

The ability to assess differences in femoral medullary canal morphology with respect to age, gender, and ancestry will be accomplished by the mid-second quarter of year 2. The data provided by Study 2 will help to determine the design criteria for the human osseointegrated implants.

In conclusion we have prepared this report to the best of our abilities and can provide all the images, raw data, and analysis methods if requested. We are confident that we will be able to keep on deadline and continue to reach agreed upon milestones.

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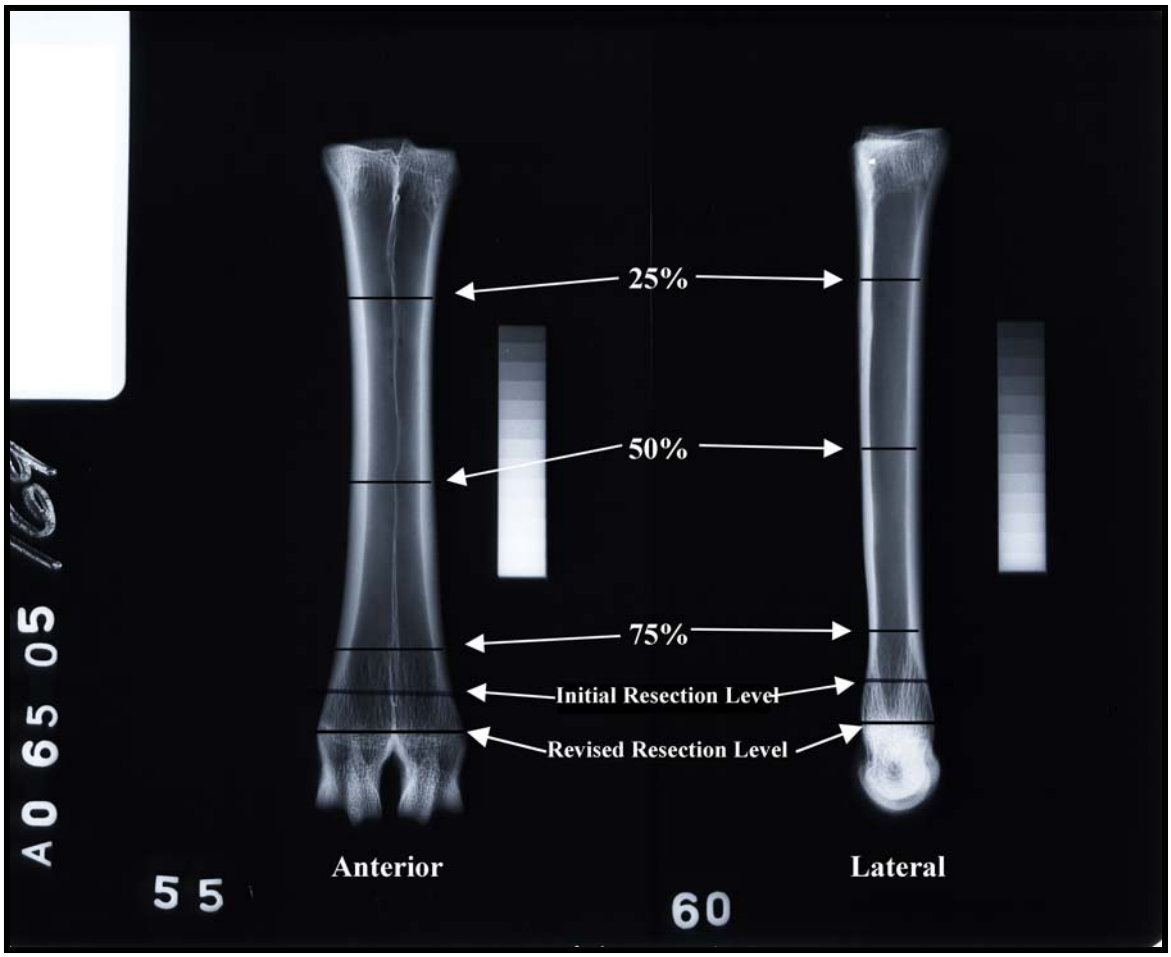

Figure 1. Anterior and Lateral radiographs of a sheep metacarpal III with initial and revised resection levels and percent lengths noted.

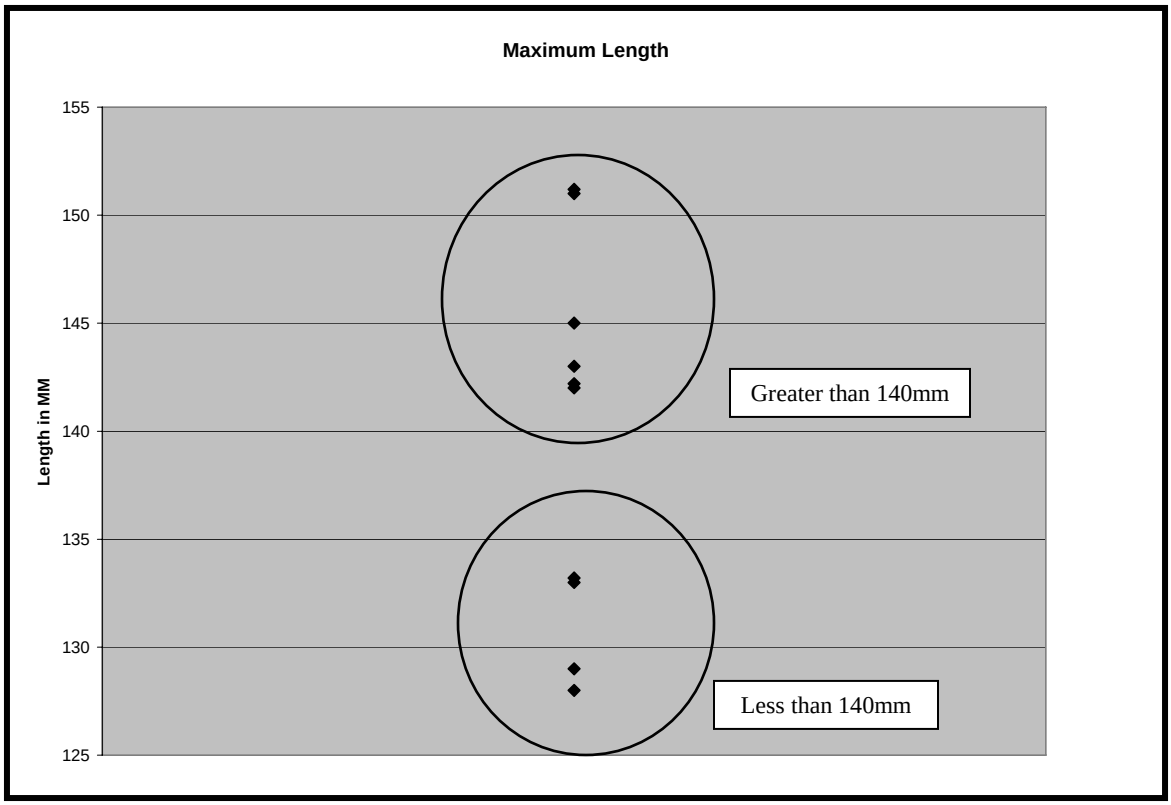

Figure 2. Graph of maximum length of the metacarpal III bones, showing two main size groups. Note that there is quite a bit of variation between each animal represented by the diamonds on the graph (see Table 1).

Table 1. Means and standard deviations (in mm) of geometric measurements of the sheep metacarpal III bone showing the variation that is present along the length of the metacarpal III bone (N=9).

	75%		50%		25%	
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**
ML Canal	11.67	1.28	10.73	1.38	17.28	2.30
AP Canal	7.90	1.18	7.12	1.28	7.16	1.70
Med CT	3.53	0.58	3.96	0.52	3.49	0.64
Lat CT	3.26	0.45	3.82	0.58	3.47	0.70
Ant CT	3.89	0.55	3.73	0.57	3.35	0.95
Post CT	3.73	0.78	2.90	0.47	1.96	0.36

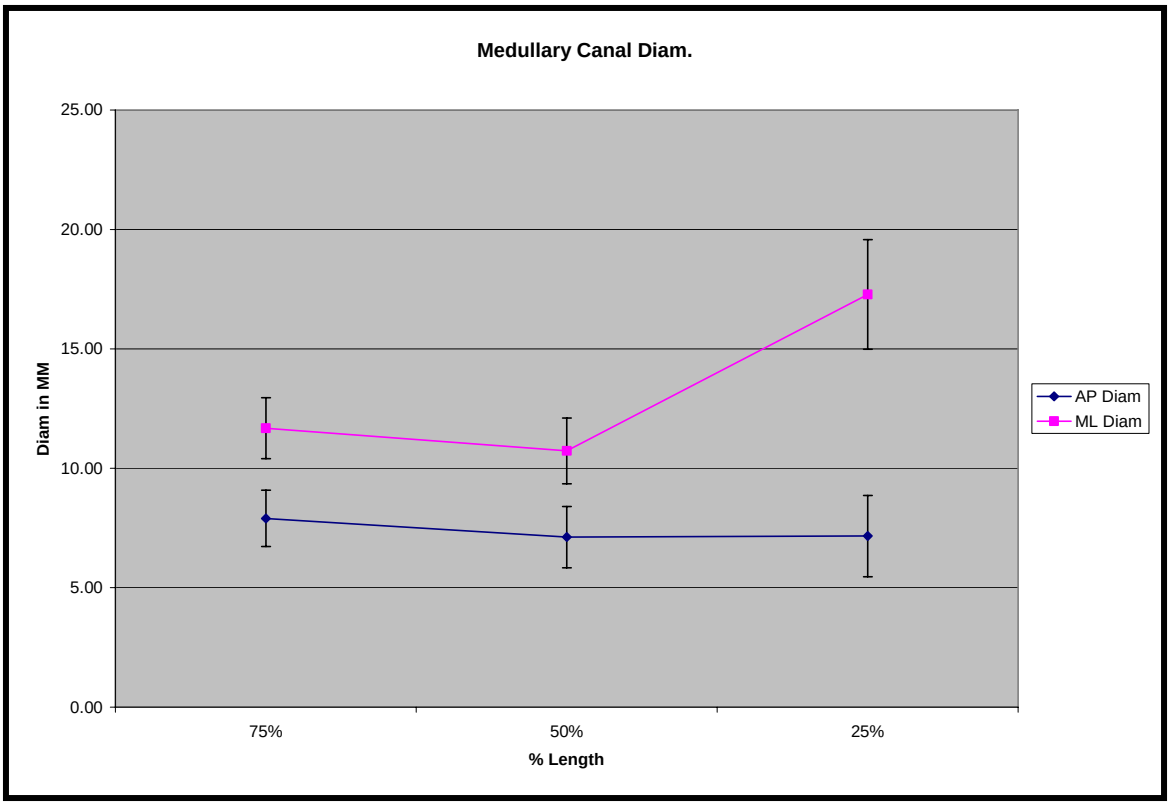

Figure 3. Graph of average (with standard deviation bars) anterior-posterior (AP) and medial-lateral (ML) medullary canal diameters along the length of the sheep metacarpal III bone showing the variation in medullary canal along the length of the bone.

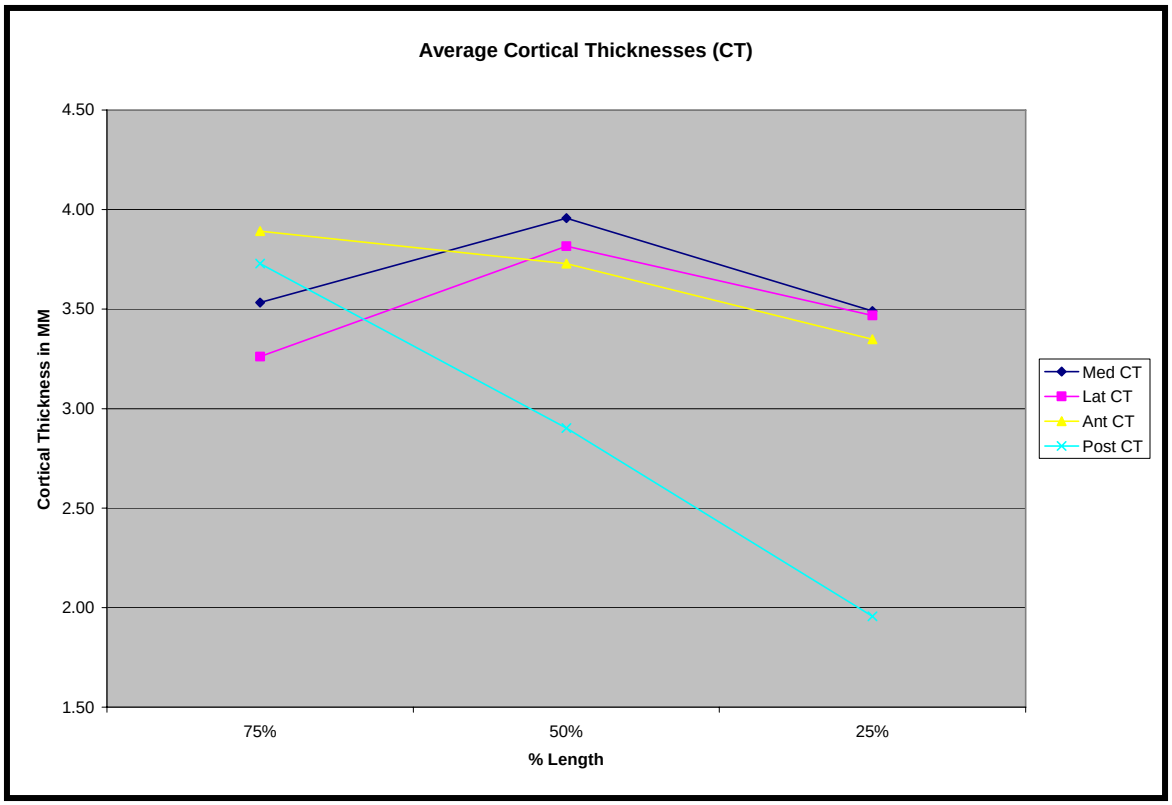

Figure 4. Graph of average cortical bone thicknesses for medial (MedCT), lateral (LatCT), anterior (AntCT), and posterior (PostCT) showing the variation of cortical bone thickness along the length of the sheep metacarpal III bone for each aspect.

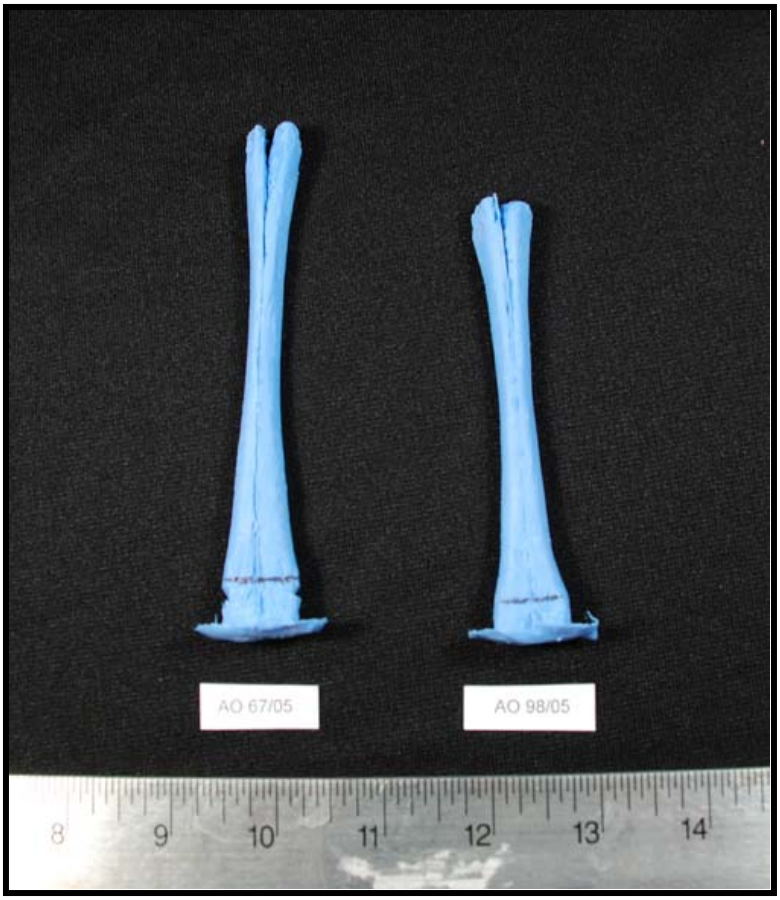

Figure5. Image of molds of the medullary canal of the sheep Metacarpal III bone showing anatomical variation.

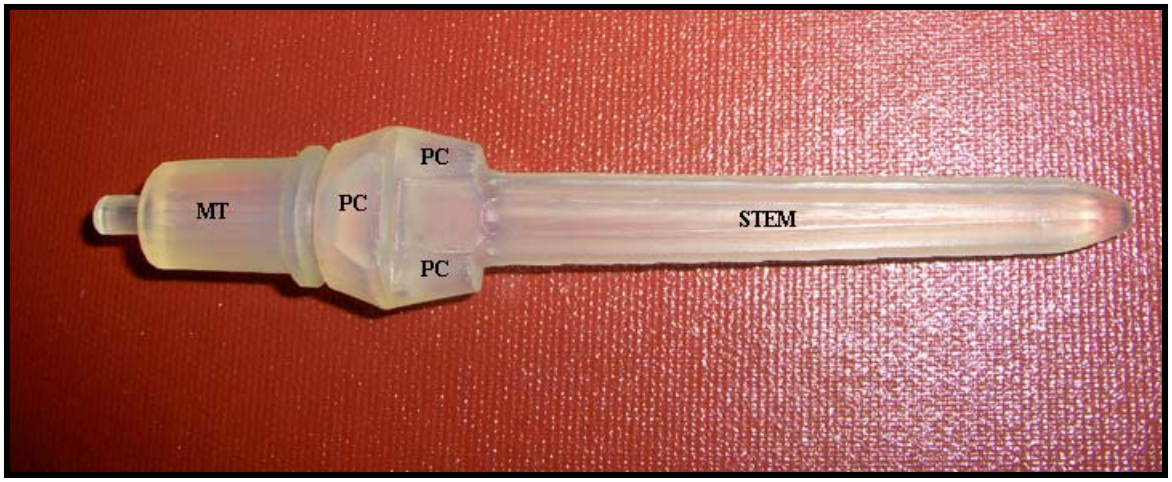

Figure 6. Image of Delrin trial implant. Design features include a Morse Taper (MT) where the prosthesis will attach, a region of porous coating (PC) where bone ingrowth is to occur, and a fluted and grit blasted stem for endosteal attachment and rotational stability.

Figure 7. Anterior and lateral radiographs of metatarsal III with Delrin trial implant inserted. The Delrin implants have been outlined in white for easier viewing. MT = Morse Tapered post for prosthetic attachment.

Figure 8. Image of titanium (Ti) and tantalum (Ta) implant. Design features include a Morse Taper (MT) where the prosthesis will attach, a region of porous coating (Ta) where bone ingrowth is to occur, and a fluted and grit blasted titanium stem (Ti) for endosteal attachment and rotational stability.

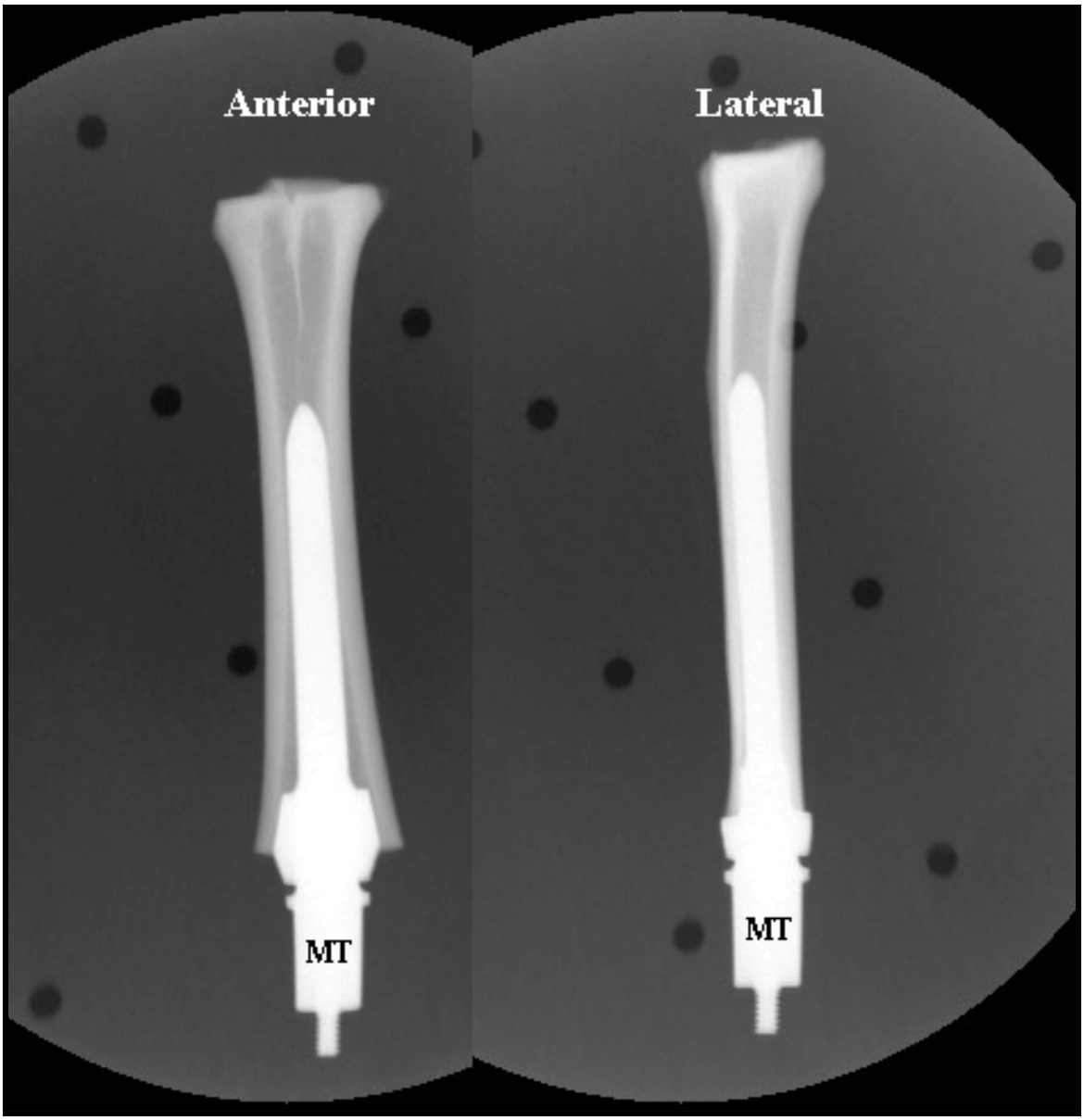

Figure 9. Anterior and Lateral radiographs of metacarpal III with metal implants inserted. MT = Morse Tapered post for prosthetic attachment.

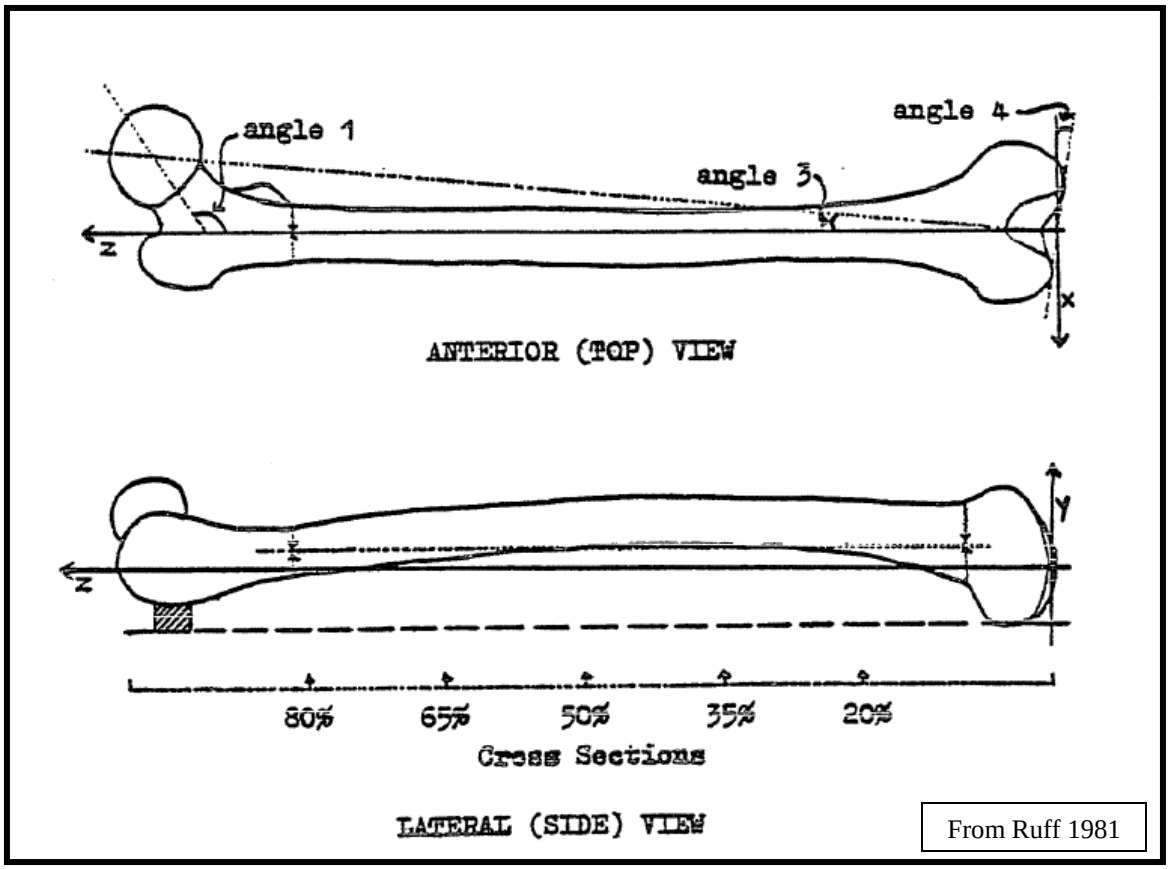

Figure 10. Schematic showing the orientation and percent biomechanical length locations used in the study.

Figure 11. Lateral (top) and superior (bottom) views of a femur in standardized anatomic position for anterior view radiography and CT/MRI imaging.

Figure 12. Lateral (top) and superior (bottom) views of femur in standardized anatomic position for lateral view radiography.

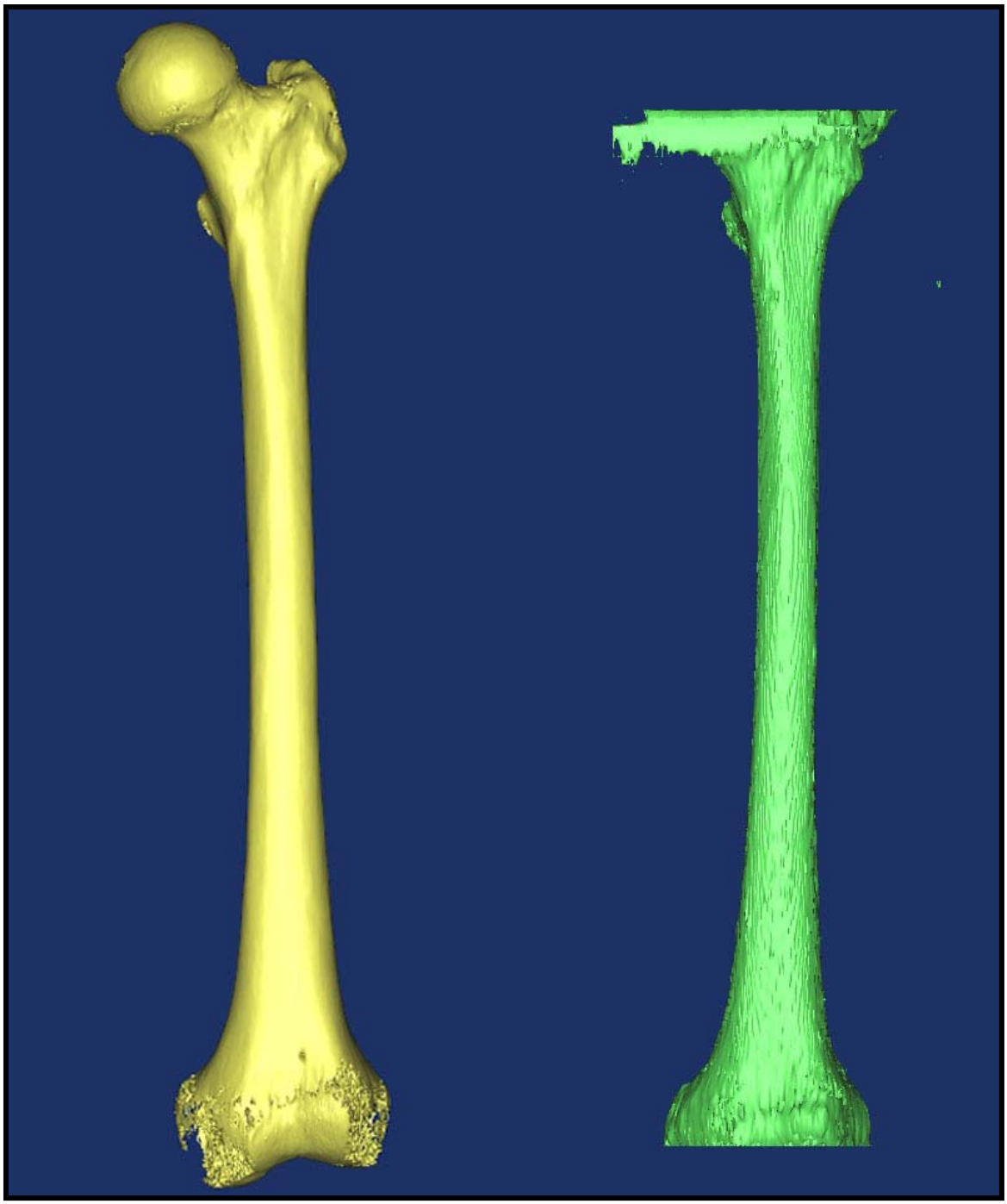

Figure 13. Anterior views of Mimics 3-D reconstructions of the same bone from CT (Left) and MRI (Right) data. Notice the incomplete and distorted proximal and distal ends and incomplete cortices of the cortical bone of the MRI reconstruction compared to the CT reconstruction. It is also apparent that the diaphysis of the MRI image is smaller than the CT image.

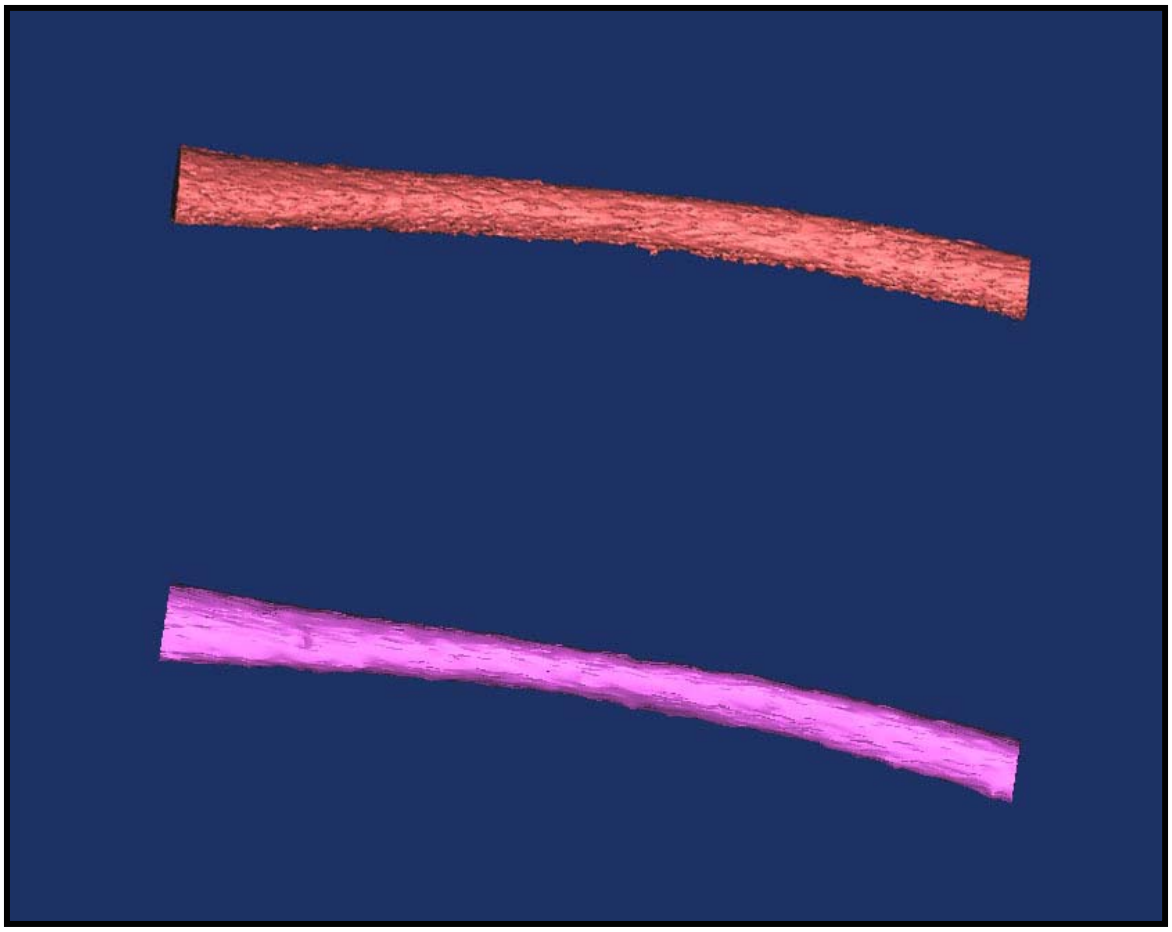

Figure 14. Lateral views of Mimics 3-D reconstructions of the endosteal surface of the medullary canal of the same bone from CT (Top) and MRI (Bottom) data. Notice the high definition of the endosteal surface provided by CT data (Top) compared to MRI data (Bottom).

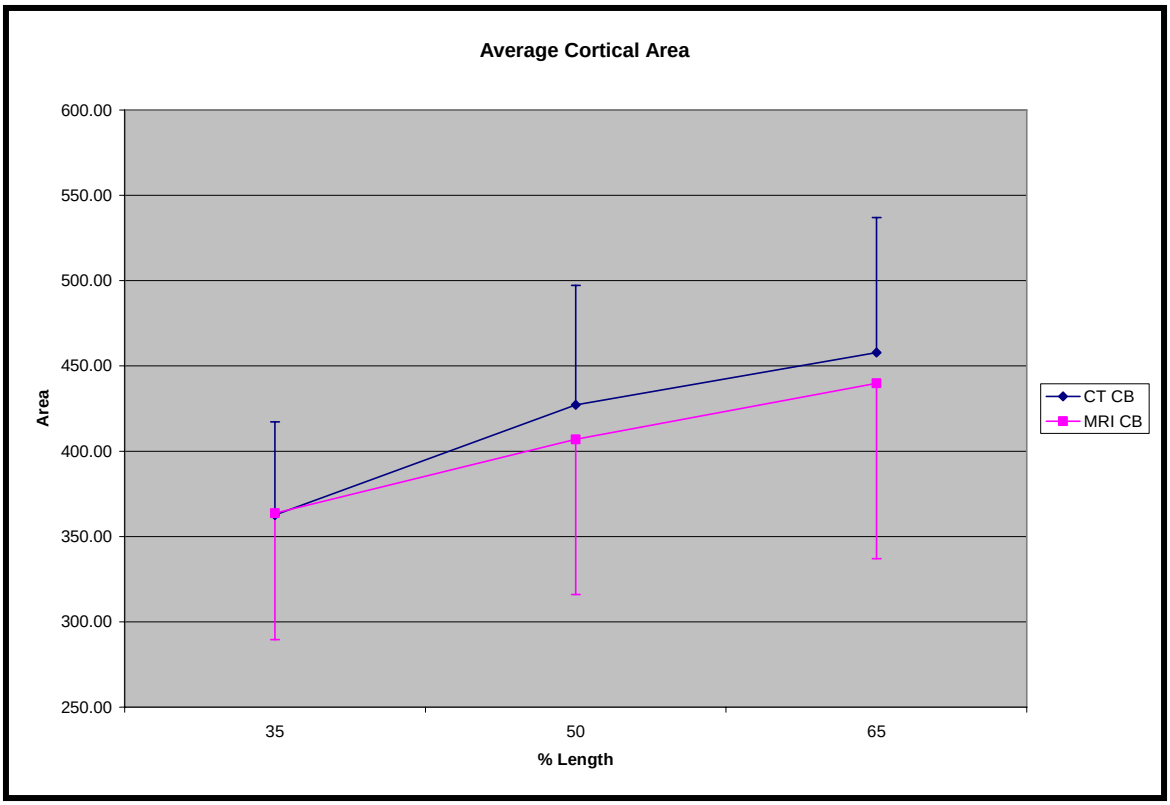

Figure 15. Graph of the average cortical area (with associated standard deviations) calculated from CT and MRI scans. MRI scans underestimated cortical area and had greater standard deviations in the data.

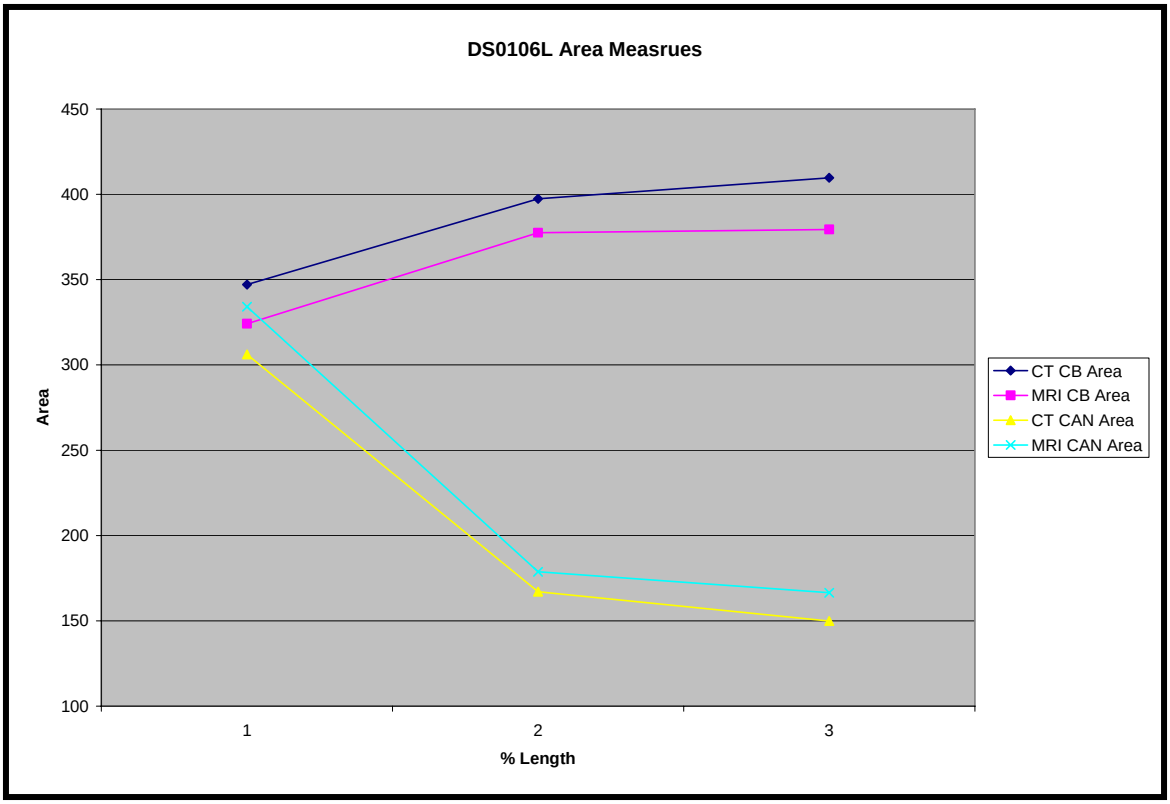

Figure 16. Graph of CT and MRI estimated cortical bone area (CB Area) and medullary canal area (CAN Area) for Study 1 bone DS0106L. Differences between CT and MRI data are statically different for each measurement location (see Table 2 and 3).

Table 2. CT and MRI cortical bone area data for bone DS0106L. All MRI data was significantly different from the CT data ($p \leq 0.05$).

	CT			MRI		
	Mean	**StDev**	**Var**	**Mean**	**StDev**	**Var**
35%	***347.05***	***54.67***	***8.58***	***324.13***	***73.99***	***14.81***
50%	***397.40***	***69.95***	***9.49***	***377.44***	***91.01***	***42.29***
65%	***409.61***	***79.11***	***5.57***	***379.43***	***102.85***	***43.83***

Table 3. CT and MRI medullary canal area data for bone DS0106L. All MRI data was significantly different from the CT data ($p \leq 0.05$).

	CT			MRI		
	Mean	**StDev**	**Var**	**Mean**	**StDev**	**Var**
35%	***306.11***	***76.98***	***79.23***	***334.08***	***82.23***	***55.40***
50%	***167.08***	***38.85***	***19.06***	***178.73***	***44.87***	***69.17***
65%	***149.94***	***40.48***	***1.55***	***166.49***	***46.00***	***24.30***

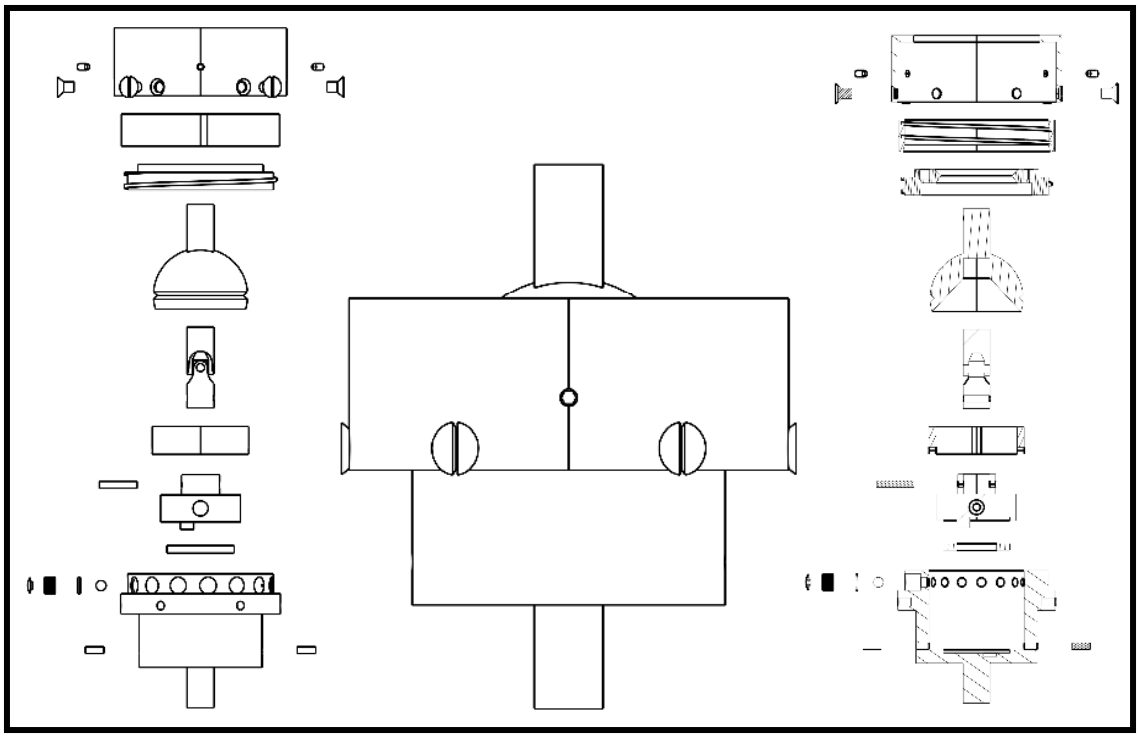

Figure 17: Exploded views of the prototype of Overload Protection Device designed and evaluated this past year.

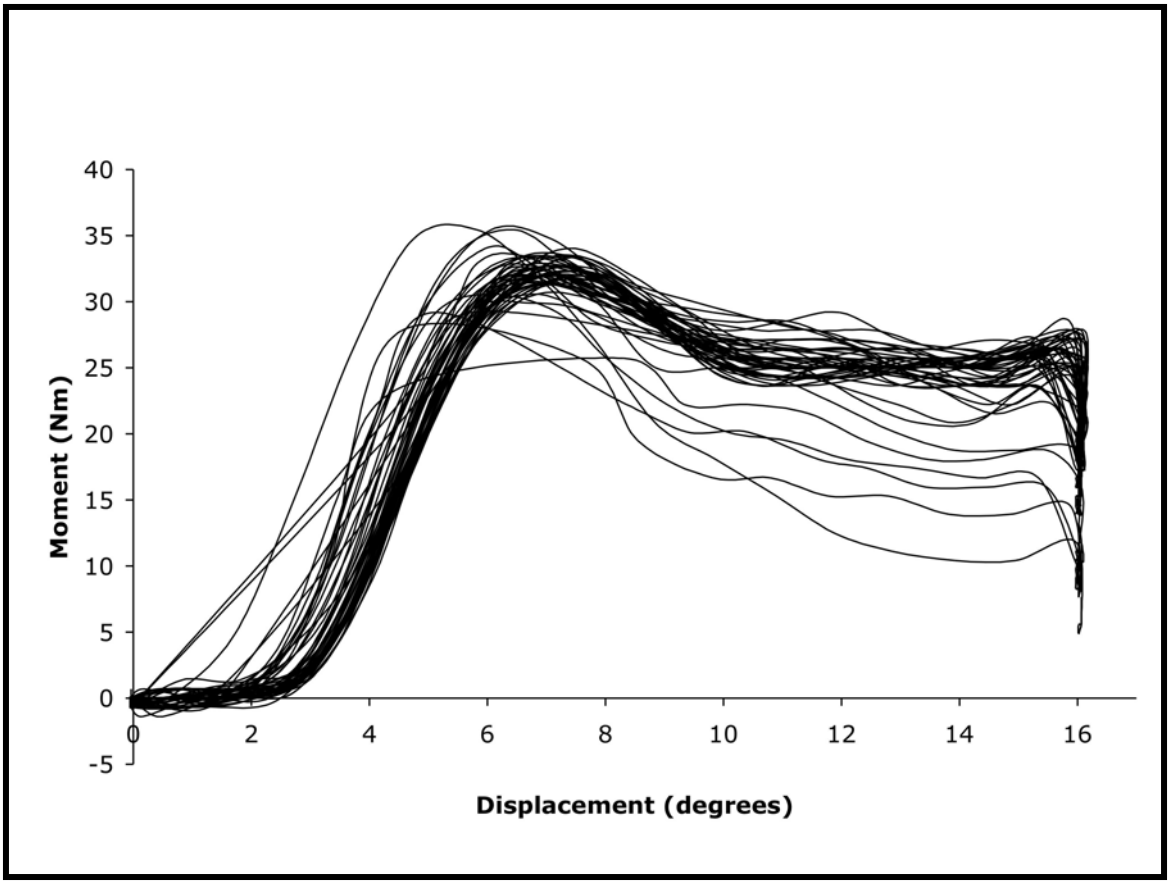

Figure 18: Torque-rotation curves resulting from numerous mechanical tests of the Overload Protection Device. Note that the specific design criteria that predefined maximum load were obtained fairly well throughout the testing.

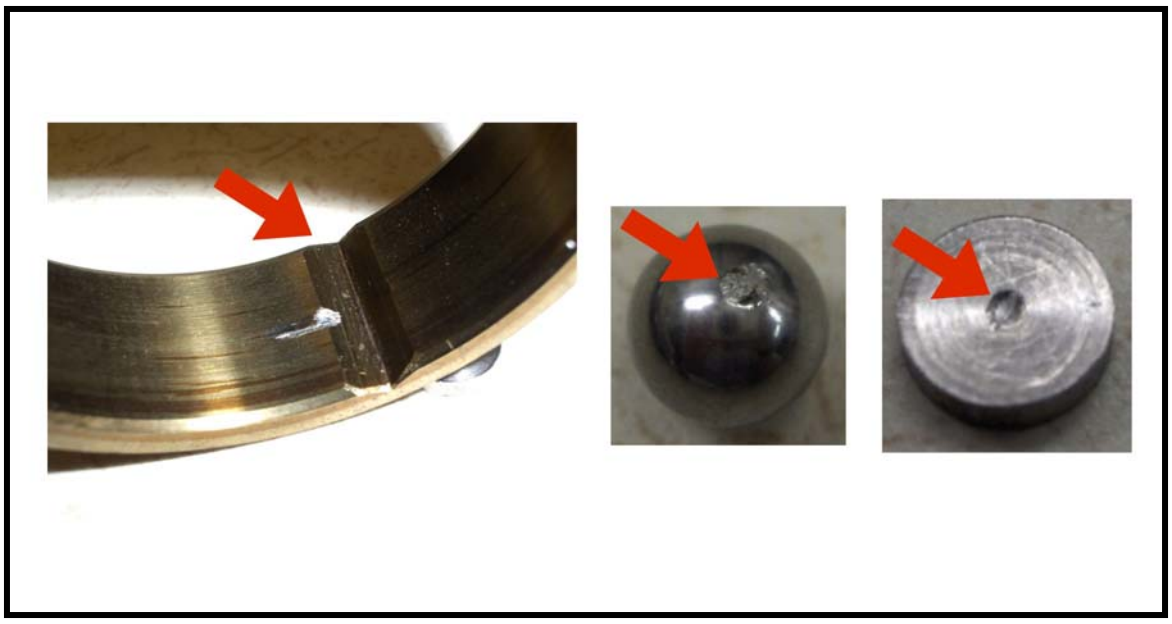

Figure 19: Photographs of material failures with the Prototype Overload Protection Device. Arrows indicate plastic deformation in the materials that can be eliminated with alternative designs and material choices.

Appendix A: Patent application for Overload Protection Device.

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(71) Applicant *(for all designated States except US)*: **UNIVERSITY OF UTAH RESEARCH FOUNDATION** [US/US]; 615 Arapeen Drive, Suite 310, Salt Lake City, UT 84108 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **BACHUS, Kent, N.** [US/US]; 4638 South Stockburdige Lane, Salt Lake City, UT 84117 (US). **BORCHERT, Jeremy, D.** [US/US]; 1349 East 4750 South, Apt. #G4, Holladay, UT 84117 (US).

(74) Agents: **LOWRY, Stuart, O.** et al.; Kelly Lowry & Kelley LLP, 6320 Canoga Avenue, Suite 1650, Woodland Hills, CA 91367 (US).

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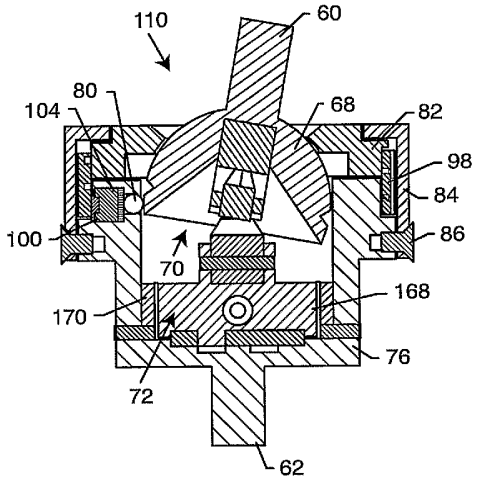
[Continued on next page]

(54) **Title:** RELEASIBLE ATTACHMENT SYSTEM FOR A PROSTHETIC LIMB



(57) **Abstract:** A releasible attachment system is provided for use with a bone anchored post and related external prosthesis such as a prosthetic limb or the like, wherein the attachment system includes a safety release mechanism designed to release or break away when encountering an excess mechanical load. The bone anchored mounting post is implanted for direct affixation to patient bone, and carries or is connected to a fixator structure protruding through soft skin tissue and the like at the end or stump of an amputated limb for mechanical connection to the external prosthesis. The safety release mechanism accommodates substantially normal patient movement throughout a corresponding range of substantially normal mechanical loads, but releases in the presence of an excess load to prevent undesirable fracture failures.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

RELEASIBLE ATTACHMENT SYSTEM FOR A PROSTHETIC LIMB

BACKGROUND OF THE INVENTION

This invention relates generally to improvements in external or exoskeletal prosthetic devices and systems of the type utilizing an implanted, bone anchored mounting post having or carrying an externally protruding or externally exposed fixator structure for removable attachment to a prosthesis such as a prosthetic limb or the like. More particularly, this invention relates to an improved attachment system for coupling the external fixator structure to the prosthesis, wherein the attachment system includes a safety release mechanism adapted to release in response to an excess mechanical load applied to the prosthesis.

Socket type prosthetic limbs such as prosthetic arm and leg structures for use by amputees are generally well known in the art, wherein a prosthesis is constructed with an open-ended and typically padded socket structure for receiving and supporting the post-surgical stump of an amputated limb. By way of example, a socket type prosthetic leg includes such open-ended socket structure at an upper end thereof for receiving and supporting the post-surgical upper leg of a transfemoral amputee. Various straps and/or other fasteners are provided for securing the prosthetic leg to the amputated limb to accommodate walking mobility at least on a limited basis. Such prosthetic limbs can be an important factor in both physical and mental rehabilitation of an amputee.

However, socket type prosthetic limbs are associated with a number of recognized limitations and disadvantages. In particular, the socket style prosthesis inherently couples mechanical loads associated with normal ambulatory activity through a soft tissue interface defined by the soft tissue covering the end or stump of the amputated limb, but wherein this soft tissue interface is structurally unsuited for this purpose. While many different arrangements and configurations for the requisite straps and other fasteners have been proposed for improved transmission and distribution of these

mechanical loads to bone structures to achieve an improved secure and stable prosthesis attachment, to correspondingly accommodate a more natural ambulatory movement, such arrangements have achieved only limited success. In addition, compressive loading of the soft stump tissue interface often results in blisters, sores, chafing and other undesirable skin irritation problems which have been addressed primarily by adding soft padding material within the socket structure. But such soft padding material undesirably increases the extent of the soft or non-rigid interface between the amputated limb and prosthesis, all in a manner that is incompatible with an optimally secure and stable prosthesis connection. As a result, particularly in the case of a prosthetic leg, traditional socket style connection structures and methods have generally failed to accommodate a normal walking motion.

In recent years, improved external or exoskeletal prosthetic devices have been proposed, wherein the external prosthesis is structurally linked by means of a bone anchored mounting system directly to patient bone. In such devices, a rigid mounting post is surgically implanted and attached securely to patient bone as by means of osseointegration or the like. This implanted bone anchored mounting post extends from the bone attachment site and includes or is attached to a fixator pin or post structure that protrudes through the overlying soft stump tissue at the end of the amputated limb. Thus, one end of the fixator structure is externally exposed for secure and direct mechanical attachment to a prosthetic limb or the like by means of a rigid linkage.

In such bone anchored mounting systems, mechanical loads on the prosthetic limb during ambulation are thus transmitted by the rigid linkage and through the external fixator structure and implanted mounting post directly to patient bone. As a result, conventional and undesirable mechanical loading of the soft tissue interface is avoided, and substantially improved and/or substantially normal patient movements are accommodated. In addition, the requirement for compressive loading of the soft tissue at the end of the amputated limb is significantly reduced, to correspondingly reduce

incidence of blisters and other associated skin irritation problems. Moreover, by mechanically linking and supporting the prosthesis directly from patient bone, amputees have reported a significant increase in perception of the prosthesis as an actual and natural body part – a highly desirable factor referred to as "osseoperception".

Although use of a bone anchored mounting system offers potentially dramatic improvements in secure and stable prosthetic limb attachment, and corresponding improvements in amputee lifestyle, major complications can arise when the prosthetic structure encounters a mechanical load that exceeds normal design parameters. More particularly, in the event of a tensile, bending, or torsion load exceeding structural design limitations, fracture-failure can occur. Breakage of prosthesis structures such as the implanted bone anchored mounting post often requires repair by surgery. Breakage of the patient bone at or near the interface with the implanted mounting post also requires surgical repair, and reseating or replacement of the implanted mounting post may not be possible. Both of these failure modes represent traumatic and highly undesirable complications.

There exists, therefore, a significant need for further improvements in and to external or exoskeletal prosthetic devices of the type utilizing a bone anchored mounting post, wherein an improved attachment system couples the prosthetic device to an externally protruding fixator structure in a manner accommodating substantially normal patient movement and a corresponding range of normal mechanical loads, but wherein the improved attachment system includes a safety release mechanism adapted to release in response to an excess mechanical load thereby preventing undesirable fracture failures. The present invention fulfills these needs and provides further related advantages.

SUMMARY OF THE INVENTION

In accordance with the invention, an improved releasible attachment system is provided for use in combination with a bone anchored post and related external prosthesis such as a prosthetic limb or the like adapted for connection thereto. The bone anchored mounting post comprises an implant component adapted for secure and stable affixation to patient bone. This bone anchored mounting post carries or is connected to a fixator structure such as an elongated pin which protrudes through soft skin tissue and the like covering the end or stump of an amputated limb, and is adapted for secure and stable attachment to the external or exoskeletal prosthesis. The improved attachment system incorporates a safety release mechanism designed to accommodate substantially normal patient movement and a corresponding range of substantially normal mechanical loads. However, in the event of an excess mechanical load applied to the prosthetic structures and/or to the implant interface of the mounting post with patient bone, the safety release mechanism is designed to release or break away thereby preventing undesirable fracture failure modes. The safety release mechanism is designed for response to excessive bending, tensile, and/or torsion loads.

In a preferred form, the releasible attachment system is interposed between the prosthesis and the fixator structure, and is adapted for mechanical connection with a radially enlarged mounting flange on the fixator structure. The safety release mechanism includes an upper socket member lined by a plurality of spring-loaded jaw elements for releasible clamp-on, substantially snap-fit engagement with the fixator structure mounting flange. The socket member is coupled by a resilient tension band to a lower release clutch including a plurality of downwardly presented, radially open detent seats having a sawtooth geometry or the like for respectively receiving a plurality of radially projecting detent pins. The tension band normally draws and retains the detent pins securely within the detent seats.

Upon encountering a bending force exceeding a predetermined limit, the tension band accommodates relative movement between the upper socket member and the lower release clutch, while the spring-loaded jaw elements accommodate relative movement between the socket member and the fixator structure mounting flange. When the bending force exceeds a predetermined limit, the jaw elements will accommodate separation of the socket member from the fixator structure. Similarly, upon encountering a tensile force load exceeding a predetermined limit, the tensile band will elongate and/or the spring-loaded jaw elements will displace to accommodate similar relative motions between components of the attachment system. Upon encountering a torsion force load exceeding a predetermined limit, the tensile band will elongate sufficiently to accommodate relative rotational displacement between the detent pins and the detent seats.

In an alternative preferred form of the invention, the attachment system or unit comprises a bending force clutch for adjustably responding to a bending force overload condition, and a torsion force clutch for adjustably responding to a torsion force overload condition. The bending force clutch comprises a relatively large ball-shaped member having a peripheral groove for normally seated reception of an array of spring-loaded clutch balls. This ball member is coupled by means of a universal joint linkage with the torsion force clutch comprising a torque cartridge including spring-loaded detent balls carried within a generally cup-shaped unit housing. The ball member and the unit housing are adapted for connection between the bone anchored fixator structure and the prosthesis. The ball member is designed for angular movement relative to the housing in response to a bending force overload condition, whereas the torque cartridge is designed for rotational movement relative to the housing in response to a torsion force overload condition.

Other features and advantages of the present invention will become apparent from the following more detailed description, taken in connection

with the accompanying drawing which illustrate, by way of example, the principals of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings illustrate the invention. In such drawings:

FIGURE 1 is a somewhat schematic diagram showing the releasible attachment system of the present invention in combination with a bone anchored prosthesis mounting post for use in releasible external attachment to an exoskeletal prosthesis;

FIGURE 2 is a somewhat schematic diagram illustrating an amputated upper leg portion of a transfemoral amputee, prior to implanted installation of a bone anchored mounting post;

FIGURE 3 is a somewhat schematic diagram similar to FIG. 2, but showing the amputated upper leg portion following implantation of the bone anchored mounting post;

FIGURE 4 is a fragmented perspective view showing the lower or stump end of the amputated upper leg portion, and illustrating a fixator structure protruding externally from the amputated limb;

FIGURE 5 is a somewhat schematic diagram similar to FIG. 1, but depicting initial release and displacement of the attachment system in response to a bending force overload condition;

FIGURES 6 through 8 are diagrams similar to FIG. 5, and showing successively further release and displacement of the attachment system in response to a bending force overload condition;

FIGURE 9 is another schematic diagram similar to FIGS. 1 and 5-8, illustrating initial release and displacement of the attachment system in response to a tensile force overload condition;

FIGURE 10 is a somewhat schematic diagram similar to FIGS. 1 and 5-9, and showing initial release and displacement of the attachment system in response to a torsion force overload condition;

FIGURE 11 is a perspective view showing the top, front and left sides of a releasible attachment unit constructed in accordance with one alternative preferred form of the invention;

FIGURE 12 is a front elevation view of the releasible attachment unit of FIG. 11;

FIGURE 13 is a left side elevation view of the releasible attachment unit of FIG. 11;

FIGURE 14 is an exploded top perspective view of the releasible attachment unit of FIG. 11;

FIGURE 15 is an exploded bottom perspective view of the releasible attachment unit of FIG. 11;

FIGURE 16 is an exploded front view of the releasible attachment unit of FIG. 11;

FIGURE 17 is an exploded saggital or medial-lateral sectional view of the releasible attachment unit shown in FIG. 16;

FIGURE 18 is an enlarged top plan view of a cup-shaped housing forming a portion of the releasible attachment unit, taken generally on the line 18-18 of FIG. 17;

FIGURE 19 is an exploded left side elevation view of the releasible attachment unit of FIG. 11;

FIGURE 20 is an exploded anterior-posterior sectional view of the releasible attachment unit shown in FIG. 19;

FIGURE 21 is an enlarged saggital or medial-lateral sectional view of the assembled releasible attachment unit shown in FIG. 17;

FIGURE 22 is an enlarged anterior-posterior sectional view of the assembled releasible attachment unit shown in FIG. 20;

FIGURE 23 is an enlarged anterior-posterior sectional view similar to FIG. 22, but showing a ball member displaced to a released position in response to a force overload condition;

FIGURE 24 is an enlarged anterior-posterior sectional view similar to FIG. 23, but illustrating threaded retraction of an inner adjustment ring to

relieve spring-loaded retention forces acting on the ball member, thereby facilitating return movement of the ball member to a normal operating position; and

FIGURE 25 is an enlarged anterior-posterior sectional view similar to FIG. 24, and depicting return displacement of the ball member to the normal operating position.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in the exemplary drawings, an attachment system referred to generally by the reference numeral 10 in FIGURES 1 and 5-10 is provided for releasibly connecting an external or exoskeletal prosthesis 12 in a bone anchored mounting system of the type having an implanted bone anchored mounting post 14. The attachment system 10 is designed for secure and stable attachment of the bone anchored mounting post 14 to the external prosthesis 12, such as a prosthetic limb or the like for an amputee. In accordance with the invention, the attachment system 10 includes a safety release means or mechanism which provides a substantially rigid and direct-coupled attachment of the prosthesis 12 to an externally protruding fixator structure 16 formed on or carried by the implanted mounting post 14, to accommodate a substantially normal range of force loads encountered during substantially normal movement and/or use of the prosthesis 12. However, the safety release mechanism is also designed for displacement and ultimately for breakaway separation in response to an applied force load exceeding a predetermined design limit, thereby safeguarding the prosthesis and the bone-mounting post attachment interface against undesired fracture failure.

The releasible attachment system 10 of the present invention is particularly designed for use with external or exoskeletal prosthetic fixation or mounting systems of the type having the internal, implanted bone anchored mounting post 14 which is surgically attached to and securely

supported by patient bone, as by means of osseointegration or the like. For example, with reference to FIGS. 2-4, an amputated patient limb 18 such as the upper leg in the case of a transfemoral amputee includes a portion of a long patient bone 20 such as the femur which, prior to amputation, anatomically supports a range of loads encountered during normal ambulatory movements. When amputated, as viewed in FIG. 2, the femur 20 is surgically severed, and upon healing is covered by soft stump tissue 22 including skin and the like.

FIG. 3 shows the bone anchored mounting post 14 in the form of an elongated tube or rod constructed typically from a high strength and biocompatible metal or the like and adapted for secure affixation within the intramedullary canal 24 of the long patient bone 20. In this regard, mounting post affixation can be obtained by a threaded post construction (not shown) adapted for thread-in placement into the medullary canal 24, or by alternative affixation means (also not shown) such as press-fitting, and/or by the provision of a bone ingrowth surface or surfaces on the mounting post 14. The fixator structure 16 comprises an elongated post or pin carried by or formed integrally with the implanted bone anchored mounting post 14, and protrudes therefrom through the overlying soft stump tissue 22 to an externally positioned lower or distal end. As shown in FIGS. 3-4, the lower or distal end of the fixator structure 16 includes or carries a mounting element 26 such as the illustrative radially enlarged mounting flange for releasible connection to the prosthesis 12. This releasible connection is provided by the attachment system 10 of the present invention.

FIG. 1 shows the attachment system 10 in accordance with one preferred form of the invention. As shown, the system 10 including the safety release mechanism comprises a first component in the form of an upper socket member 28 for spring-loaded clamp-on and substantially snap-fit releasible reception and retention of the mounting flange 26 on the fixator structure 16. This upper socket member 28 comprises a generally cup-shaped structure having a sturdy and rigid base plate 30 in combination with

an upstanding sturdy and rigid peripheral wall 32 which cooperates with the base plate 30 to define an upwardly open, generally cup-shaped receptacle. A plurality of at least two jaw elements 34 are pivotally mounted at or near an upper margin of the peripheral wall 32 in a radially inwardly projecting orientation. Springs 36 urge these jaw elements 34 toward a normal position pivoted downwardly relative to the peripheral wall 32.

With this construction, the spring-loaded jaw elements 36 cooperate with the base wall 30 and associated peripheral wall 32 to define a pocket 38 (FIG. 8) having a size and shape for clamped, substantially snap-fit reception of the mounting flange 26 on the fixator structure 16. The downwardly loaded jaw elements 36 springably support and retain the mating flange 26 in an essentially fixed position relative to the socket member 28, throughout a normal range of mechanical loads. However, as will be described in more detail, the spring-loaded jaw elements 36 are designed to accommodate movement of the mounting flange 26 relative to the socket member 28 when a force overload condition occurs.

A relatively short tension member or tension band 40 (shown in FIG. 5) is suitably connected to the underside of the socket member base plate 30, and extends downwardly therefrom for suitable connection to an upper face of a lower base link 42. This lower base link 42 comprises a second component and is shown connected to the prosthesis 12 which may include one or more mechanical links secured to each other by appropriate fasteners 13 or the like. A plurality of radially outwardly and downwardly open detent seats 44 are defined between a sawtooth array 46 protruding downwardly from the underside of the base plate 30. A corresponding plurality of radially projecting detent pins 48 are carried by or formed on the lower base link 42 for respective seated engagement within the detent seats 44 of the sawtooth array 46. In a normal position, the tension band 40 (which may be formed from a strong and longitudinally resilient material such as metals, plastics, wood and composites) draws the lower base link 42 upwardly for secure and stable, substantially rigid seated engagement of the detent pins 48 within the

sawtooth detent seats 44. However, and as will be described herein in more detail, the tension band 40 accommodates relative movement between the upper socket member 28 and the lower base link 42 when a force overload condition occurs.

FIGS. 5-8 illustrate safety release operation of the attachment system 10 in response to a bending force overload condition, wherein a bending force illustrated by arrow 50 is encountered with a magnitude exceeding a predetermined maximum limit. Upon such bending force overload, the tension band 40 in initially stretched (FIG. 5) to accommodate pivoting motion of the lower base link 42 away from the sawtooth array 46 at the underside of the upper socket member 28. Accordingly, in the presence of a relatively minor bending force overload, the tension band 40 springably or elastically permits a limited amount of relative movement between the socket member 28 and base link 42 to protect the prosthetic components including the attachment interface of the implanted mounting post 14 with patient bone 20 against risk of fracture failure.

Upon encountering a larger magnitude bending force overload, as viewed in FIG. 6, the spring-loaded jaw elements 36 are designed to displace. That is, the mounting flange 26 at the lower end of the fixator structure 16 bears against the underside surfaces of the jaw elements 36 and forces them to pivot upwardly in a manner permitting limited relative movement therebetween. If the bending force overload condition is severe enough, the jaw elements 36 will continue to pivot upwardly as viewed in FIG. 7 to accommodate complete release or separation of the socket member 28 from the mounting flange 26 (FIG. 8). Such socket member separation is, of course, accompanied by complete release or separation of the prosthesis 12 from the amputated limb 18. While such prosthesis separation renders the prosthesis temporarily ineffective (until re-attached to the fixator structure 16) and may cause the patient to fall, *e.g.*, when the prosthesis comprises an artificial leg, the prosthetic components and the patient bone 20 are protected against fracture failure.

FIG. 9 shows response of the attachment system 10 to a tensile force overload acting in the direction of arrow 52. In particular, upon encountering a tension force overload, the tension band 40 elongates to accommodate relative motion between the upper socket member 28 and the lower base link 42. In the event of a tension overload of substantial degree, further downward force on the tension band 40 will eventually exceed the retention force applied to the fixture structure mounting flange 26 by the spring-loaded jaw elements 36, resulting in separation and release of the mounting flange 26 from the socket member 28 as depicted generally in FIG. 8. Once again, such component separation beneficially protects the prosthesis components and the patient bone 20 against fracture failure.

FIG. 10 illustrates response of the attachment system 10 to a torsion force overload condition represented by arrow 54. As shown, in the event of torsion force overload, the detent pins 48 on the lower base link 42 ride downwardly within the individual detent seats 44 defined by the sawtooth array 46, for accommodating rotation of the lower base link 42 relative to the sawtooth array in the direction of the applied torque. The tension band 40 stretch-elongates sufficiently to accommodate this relative rotation, and then draws the detent pins 48 back upwardly into adjacent seats 44 defined by the sawtooth array. Accordingly, the sawtooth array 46 cooperates with the detent pins 48 and the tension band 40 to provide a spring-loaded torsion clutch that accommodates relative rotation in either direction upon encountering a torsion force overload.

In actual use, forces applied to the prosthesis 12 and the related attachment system 10 typically comprise a combination of bending, tensile, and/or torsion forces. The attachment system 10 of the present invention responds cooperatively to these applied forces to provide a sturdy and essentially rigid interconnection between the prosthesis 12 and patient bone 20, provided that these forces do not exceed a predetermined safe design limit in any direction. If and when the applied forces do exceed such predetermined safe design limit in any or in a combination of directions, the

attachment system 10 responds to permit an appropriate degree of relative movement between components sufficient to prevent fracture failures. If the applied force overload is sufficiently high, the permitted relative movement involves separation of the prosthesis from the fixator structure 16 of the bone anchored mounting post 14.

FIGS. 11-25 depict an alternative preferred form of the invention, wherein a modified releasible attachment unit 110 is provided for connection between an external fixator structure 116 (FIGS. 12-13) formed on or carried by a bone anchored mounting post (not shown) or the like and an exoskeletal prosthesis 112 such as a prosthetic limb. This modified releasible attachment unit 110 includes a first component in the form of an upwardly projecting mounting stud 60 having a non-circular cross sectional shape such as the illustrative square cross section for quick and easy attachment to the fixator structure 116 in any suitable manner, as by means of one or more set screws (not shown). Similarly, the attachment unit 110 further includes a second component in the form of a downwardly projecting mounting stud 62 which also has a non-circular cross sectional shape such as the illustrative square shape for quick and easy attachment in a secure and stable manner to the prosthesis 112, as by means of one or more set screws (also not shown).

In operation, the releasible attachment unit 110 normally provides a rigid, substantially motion-free interface connection between the fixator structure 116 and the prosthesis 112 for normal patient movements, such as normal walking movements in the case of a prosthetic leg. However, upon encountering a force overload condition attributable, for example, to an excessive bending force or an excessive torsion force, the attachment unit 110 is designed to release quickly and substantially completely to prevent transmission of said excessive force via the fixator structure 116 to the patient bone. Accordingly, the releasible attachment unit 110 comprises a safety release mechanism of alternative design for safeguarding against highly undesirable fracture failures.

In general terms, the modified releasible attachment unit 110 comprises an upper bending force clutch 64 for adjustably responding to a bending force overload condition, and a lower torsion force clutch 66 for adjustably responding to a torsion force overload condition. The upper clutch 64 includes a relatively large ball member 68 having the upwardly projecting mounting stud 60 carried thereon as by integral formation therewith. This ball member 68 is coupled by means of a universal joint linkage 70 with the lower torsion force clutch comprising an underlying torque cartridge 72 including spring-loaded detent balls 74. The ball member 68 and the torque cartridge 72 are carried within a lower, generally cup-shaped unit housing 76. The downwardly projecting mounting stud 62 is carried on the underside of this housing 76 as by integral formation thereon.

More specifically, the ball member 68 comprises a relatively large part-spherical or ball-shaped component of generally hemispherical configuration. The ball member 68 has a diametric size for slide-fit reception into the upwardly open unit housing 76, as viewed best in FIGS. 21-25. In this position, the upper mounting stud 60 projects upwardly from the ball member 68. In a normal operating position, the ball member 68 is oriented within the unit housing 76 so that the upper mounting stud 60 projects generally coaxially with respect to the unit housing 76 (FIGS. 21-22 and 25), for suitable connection of the stud 60 to the fixator structure 116 (FIGS. 12-13) as previously described.

A peripheral groove 78 is formed in the ball member 68 generally near a lower margin thereof, for spring-loaded partial reception of a circumferential array of clutch balls 80 carried within a respective plurality of radially outwardly open ports 81 formed in the housing 76 near the open upper end thereof. Each clutch ball 80 is adapted for radially inward biasing with a selected spring force for partial reception into the ball member groove 78, for purposes of releasibly locking the ball member 68 in the upright normal operating position. Importantly, the spring locking force is adjustably selectable for custom setting of a release force or release point in response

to a bending force exceeding a predetermined selected threshold value. When the unit 110 is subjected to a bending release force exceeding the selected set point, the clutch balls 80 retract radially outwardly from the ball member groove 78 sufficiently to permit ball rotation or displacement from the normally locked operating position to an unlocked angular position as viewed in FIGS. 23-24.

The spring locking/release force is adjustably set by means of an inner adjustment ring 82 rotatably carried within a generally annular cover 84 fastened onto the upper end of the unit housing 76 as by means of a plurality of short screws 86 or the like. This annular cover 84 has a radially in-turned upper flange 88 which overlies and engages an annular shoulder 90 on the inner adjustment ring 82 to retain said ring 82 in a position with an inner diameter surface 92 thereof pressed against the part-spherical outer surface of the ball member 68. The inner adjustment ring 82 has an externally threaded segment 94 engaged with an internally threaded segment 96 of an outer adjustment ring 98. This internally threaded segment 96 of the outer adjustment ring 98 merges with a tapered-edge bearing seat 100 positioned for bearing against an outboard spacer 102 of a clutch spring assembly including a disk spring 104 or the like interposed between the outboard spacer 102 and an inboard spacer 106 engaged in turn with an associated one of the clutch balls 80.

Rotation of the inner adjustment ring 82, as by means of engagement of a pair of upwardly open drive ports 108 (FIG. 1) by a spanner wrench (not shown) or the like, causes upward or downward translation of the outer adjustment ring 98, in accordance with the direction of rotational displacement. In this regard, the outer adjustment ring 98 has as least one axially or vertically elongated slot 97 formed therein for slide-guided reception of an associated set screw 99 on the cover 84 to limit the outer adjustment ring 98 to axial or up/down displacement in response to rotation of the inner adjustment ring 82. Downward displacement of the outer adjustment ring 98 moves the tapered-edge bearing seat 100 thereon into progressively further

radially overlying engagement with the outboard spacers 102 of the clutch spring assemblies, and thereby progressively increases the inward spring force applied to the associated clutch balls 80. Accordingly, such downward displacement of the outer adjustment ring 98 is accompanied by increased inward spring force applied to the clutch balls 80, and thereby adjustably increases bending release force required to displace the ball member 68 from the upright normal operating position. However, as viewed in FIG. 23, when this adjustably set bending release force limit is reached, as represented by an adjustably set bending force overload condition, the clutch balls 80 retract radially outwardly from the ball member groove 78 sufficiently to permit rapid shifting of the ball member 68 to an angularly oriented release position.

Following such release in response to a bending force overload condition, the ball member 68 is returnable to the upright normal operating position in a manner that does not require application of substantial force or effort. In this regard, the inner adjustment ring 82 can be rotationally displaced to retract the outer adjustment ring 98 upwardly and thereby retract the tapered-edge bearing seat 100 upwardly relative to the clutch spring assemblies. This results in a substantial relieving of the spring forces urging the clutch balls 80 in a radially inwardly direction, and thereby permits relatively quick and easy return of the ball member 68 to the upright normal operating position. When this upright normal position is achieved, the inner adjustment ring 82 can be reverse-rotated in a manner increasing the bending force release point to the desired higher level, as previously described.

The universal joint linkage 70 interconnects the ball member 68 with the lower torsion force clutch 66 mounted within a lower end of the cup-shaped unit housing 76. In this regard, the U-joint linkage comprises an upper drive member 160 of non-circular cross sectional shape, such as a square-drive key or the like, seated within a matingly shaped socket 162 formed within a hollow underside of the ball member 68. The U-joint linkage

70 additionally includes a lower drive member 164 which is also formed with a non-circular shape, such as a square-drive key or the like, seated within a matingly shaped socket 166 formed on the upper side of a torque member or torque plate 168. These upper and lower drive members 160 and 164 of the U-joint linkage 70 are rotatably interconnected as by means of a pair of pivotally joined link components conventionally provided in a so-called universal joint. Accordingly, further description of U-joint construction details are not included herein, such details being known to persons skilled in the art. One preferred and exemplary U-joint linkage is available from Lovejoy, Inc., of Downers Grove, IL, under the product designation D-2 Solid U-Joint.

The torque plate 168 comprises a portion of the torque cartridge 72, and has a generally disk-shaped profile sized for slide-fit reception into a cylindrical lower region of the cup-shaped unit housing 76, preferably within an annular torque or spacer ring 170 which is slidably seated in turn within the housing 76 and locked against rotation therein as by radially extending set pins 172 (FIG. 22). The torque plate 168 is diametrically sized for relatively free rotation within the torque spacer ring 170, and includes an axially downwardly projecting tab 174 extending into a part-annular channel 176 formed in a base wall 178 of the unit housing 76. As shown best in FIG. 18, this part-annular channel 176 extends on a common radius through an arcuate length dimension of less than 360°, such as an arcuate length on the order of about 340-350°.

A diametrically extending bore 180 is formed in the body of the torque plate 168. This bore 180 is sized and shaped to receive and support a spring unit 182 including, *e.g.*, a set of disk springs 184 sandwiched between a pair of spacers 186. The spacers 186 bear in turn against a pair of detent balls 74 to urge those balls 74 radially outwardly beyond the perimeter of the torque plate 168 with a predetermined force setting. As shown best in FIG. 21, the detent balls 74 are urged radially outwardly into a matingly shaped and diametrically aligned pair of shallow detent seats 190 formed in the inner diameter surface of the torque spacer ring 170. Accordingly, the spring unit

182 normally engages and locks with the torque spacer ring 170 for releasibly maintaining the torque plate 168 in a predetermined rotational position relative to the torque spacer ring 170 and the associated unit housing 76. In this normally locked and normal operating position, the tab 174 on the torque plate 168 is positioned within the underlying channel 176 generally mid-way between the opposed channel ends.

Upon encountering a torsion force overload condition, wherein the applied torsion force exceeds the spring forces holding the detent balls 74 within the detent seats 190, the detent balls 74 retract against the springs 184 sufficiently to permit relative rotation between the torque plate 168 and the torque spacer ring 170 within the unit housing 76. Such relative rotation corresponds with safety release of the attachment unit 110 to prevent undesired fracture failure. The prosthesis 112 is thus permitted to rotate with the housing 76, relative to the torque plate 168 and ball member 68 coupled thereto wherein the ball member 68 is coupled in turn to the patient bone interface. Importantly, the tab 174 accommodates such rotation through an angular increment of nearly but less than 180°, such as an increment of about 160°. Such rotational increment is normally sufficient to relieve the torsion force overload, and also precludes re-engagement of the detent balls 74 with the opposed detent seats 190. Accordingly, with the detent balls 74 disengaged from the detent seats 190, the unit 110 can be returned quickly and easily to the desired normal operating position by merely back-rotating the prosthesis 112 and/or housing 76 until the detent balls 74 re-engage in a snap-fit manner with the associated detent seats 190.

Accordingly, the attachment unit 110 provides a safety release mechanism for securely interconnecting the prosthesis 112 with the associated bone-supported fixator structure 116 in a substantially motion-free secure and stable manner during normal operating conditions. However, upon encountering a bending force overload condition, or a torsion force overload condition, or a combination thereof, the attachment unit 110 provides the requisite safety release mechanism for quickly and substantially

completely de-coupling in a manner to safeguard the bone-supported interface against fracture failures. Following a force overload incident, the attachment unit 110 can be returned quickly and easily to a normal operation position for resumed patient use.

Although various embodiments and alternatives have been described in detail for purposes of illustration, various further modifications may be made without departing from the scope and spirit of the invention. For example, persons skilled in the art will recognize and appreciate that the safety release mechanism as shown and described herein may be constructed in alternative configurations adapted to accommodate relative component movements in response to force overloads applied in different directions. Accordingly, no limitation on the invention is intended by way of the foregoing description and accompanying drawings, except as set forth in the appended claims.

WHAT IS CLAIMED IS:

1. A releasible attachment system for coupling an exoskeletal prosthesis to a patient limb having a bone anchored mounting post with an external fixator structure, said releasible attachment system comprising:

a first component adapted for connection to the fixator structure;

a second component adapted for connection to the prosthesis; and

a safety release mechanism normally retaining the prosthesis in a rigid substantially motion-free interconnected relation to the fixator structure, said safety release mechanism responding to a force overload condition to permit relative movement between the prosthesis and the fixator structure.

2. The releasible attachment system of claim 1 wherein said force overload condition comprises a bending force exceeding a predetermined magnitude.

3. The releasible attachment system of claim 1 wherein said force overload condition comprises a tensile force exceeding a predetermined magnitude.

4. The releasible attachment system of claim 1 wherein said force overload condition comprises a torsion force exceeding a predetermined magnitude.

5. The releasible attachment system of claim 1 wherein said safety release mechanism responds to said force overload condition to permit relative movement between said first and second components.

6. The releasible attachment system of claim 1 wherein said safety release mechanism responds to said force overload condition to permit detachment of said first component from the fixator structure.

7. The releasible attachment system of claim 1 wherein said safety release mechanism comprises a bending force clutch responsive to a bending force overload condition to permit relative angular displacement of said second component relative to said first component, and a torsion force clutch responsive to a torsion force overload condition to permit relative rotational displacement of said second component relative to said first component.

8. The releasible attachment system of claim 7 further including a universal joint interconnecting said bending and torsion force clutches.

9. The releasible attachment system of claim 7 wherein said bending force clutch comprises a ball member movably mounted within a unit housing, and spring-loaded detent means engageable between said unit housing and said ball member for releasibly retaining said ball member in a normal position within said unit housing, said detent means responding to a bending force overload condition to permit angular displacement of said ball member relative to said unit housing.

10. The releasible attachment system of claim 9 wherein said first component is carried by said ball member, and wherein said second component is carried by said unit housing.

11. The releasible attachment system of claim 9 wherein said spring-loaded detent means comprises an array of detent balls, and spring means for urging said detent balls with a selected spring force into engagement with a peripheral groove formed in said ball member.

12. The releasible attachment system of claim 11 wherein said spring-loaded detent means further comprises adjustment means for adjustably

setting a detent spring force applied to said detent balls by said spring means for releasibly retaining said ball member in said normal position.

13. The releasible attachment system of claim 12 wherein said adjustment means comprises a rotatable adjustment ring carried by said unit housing.

14. The releasible attachment system of claim 7 wherein said torsion force clutch comprises a torque member rotatably mounted within said unit housing, and spring-loaded detent means reacting between said torque member and said unit housing for releasibly retaining said torque member in a normal position fixed against rotation within said unit housing, said detent means responding to a torsion force overload condition to permit rotational displacement of said torque member relative to said unit housing.

15. The releasible attachment system of claim 14 wherein said torsion force clutch further includes means for preventing full revolution rotational displacement of said torque member relative to said unit housing.

16. The releasible attachment system of claim 15 wherein said unit housing has a generally cup-shaped configuration defining a base wall at one end thereof, said means for preventing full revolution displacement of said torque member relative to said unit housing comprising a part-annular channel formed in said base wall and a tab carried by said torque member and protruding into said channel, said tab being generally centered within said channel when said torque member is in said normal position.

17. The releasible attachment system of claim 14 further including a torque ring mounted within said unit housing and fixed against rotation therein, said detent means being engageable between said torque ring and said torque member.

18. The releasible attachment system of claim 1 wherein first component comprises a socket member including at least one spring-loaded jaw element for releasibly engaging the fixator structure in response to a bending and/or tensile force overload condition, and wherein said safety release mechanism comprises a torsion clutch coupled between said socket member and the prosthesis.

19. The releasible attachment system of claim 18 wherein said torsion clutch comprises a base plate carried by said socket member, a base link comprising said second component, a tension member coupled between said base plate and said base link, and cooperatively engageable detent means carried by said base plate and said base link.

20. The releasible attachment system of claim 19 wherein said cooperatively engageable detent means comprises a plurality of radially outwardly extending detent pins on one of said base plate and said base link, and a plurality of radially open detent seats defined by the other of said base plate and said base link.

21. A releasible attachment system for coupling an exoskeletal prosthesis to a patient limb having a bone anchored mounting post with an external fixator structure, said releasible attachment system comprising:

a first component adapted for connection to the fixator structure;

a second component adapted for connection to the prosthesis; and

a safety release mechanism normally retaining the prosthesis in a rigid substantially motion-free interconnected relation to the fixator structure, said safety release mechanism responding to a force overload condition to permit relative movement between the prosthesis and the fixator structure;

said safety release mechanism comprising a bending force clutch responsive to a bending force overload condition to permit relative angular displacement of said second component relative to said first component, a

torsion force clutch responsive to a torsion force overload condition to permit relative rotational displacement of said second component relative to said first component, and a universal joint interconnecting said bending and torsion force clutches.

22. The releasible attachment system of claim 21 wherein said bending force clutch comprises a ball member movably mounted within a unit housing, and first spring-loaded detent means engageable between said unit housing and said ball member for releasibly retaining said ball member in a normal position within said unit housing, said first detent means responding to a bending force overload condition to permit angular displacement of said ball member relative to said unit housing; and

wherein said torsion force clutch comprises a torque member rotatably mounted within said unit housing, and second spring-loaded detent means reacting between said torque member and said unit housing for releasibly retaining said torque member in a normal position fixed against rotation within said unit housing, said second detent means responding to a torsion force overload condition to permit rotational displacement of said torque member relative to said unit housing.

23. The releasible attachment system of claim 21 wherein said first component is carried by said ball member, and wherein said second component is carried by said unit housing.

24. The releasible attachment system of claim 21 wherein said bending force clutch further includes adjustment means for adjustably setting a spring force associated for releasibly retaining said ball member in said normal position.

25. The releasible attachment system of claim 21 wherein said torsion force clutch further includes means for preventing full revolution rotational displacement of said torque member relative to said unit housing.

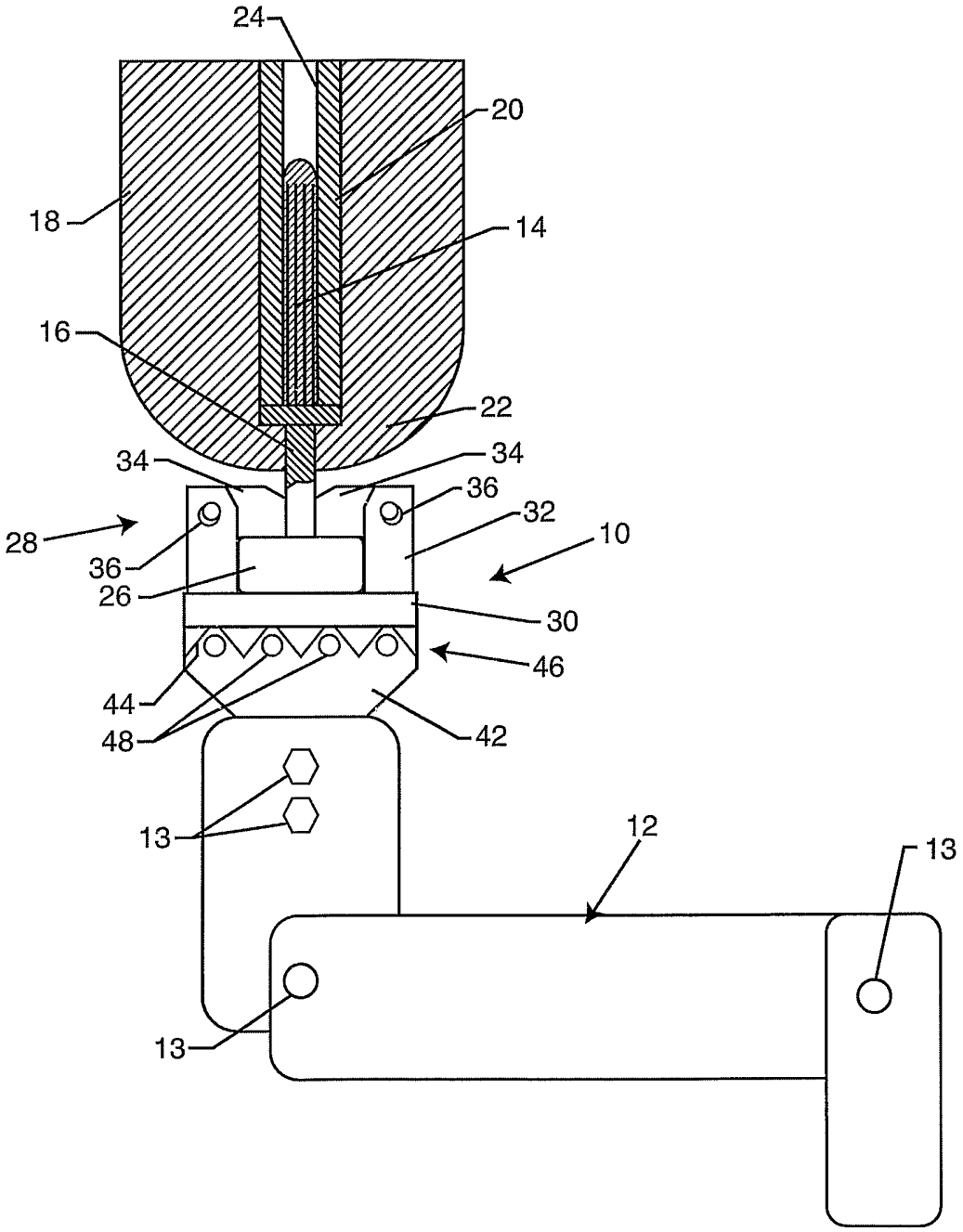

FIG. 1

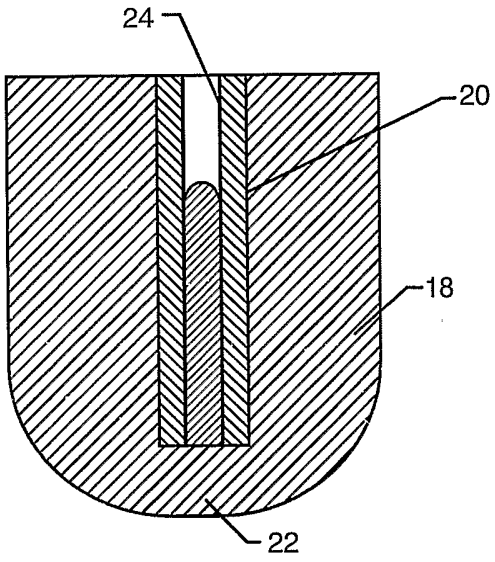

FIG. 2

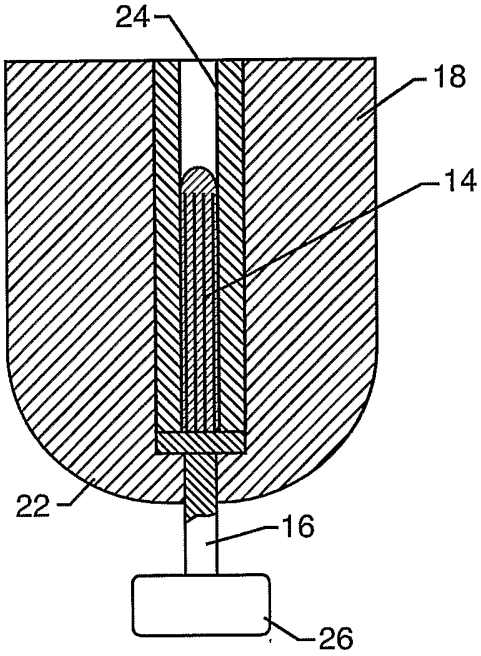

FIG. 3

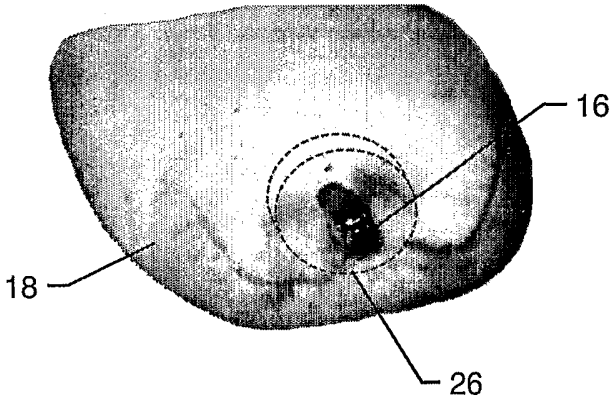

FIG. 4

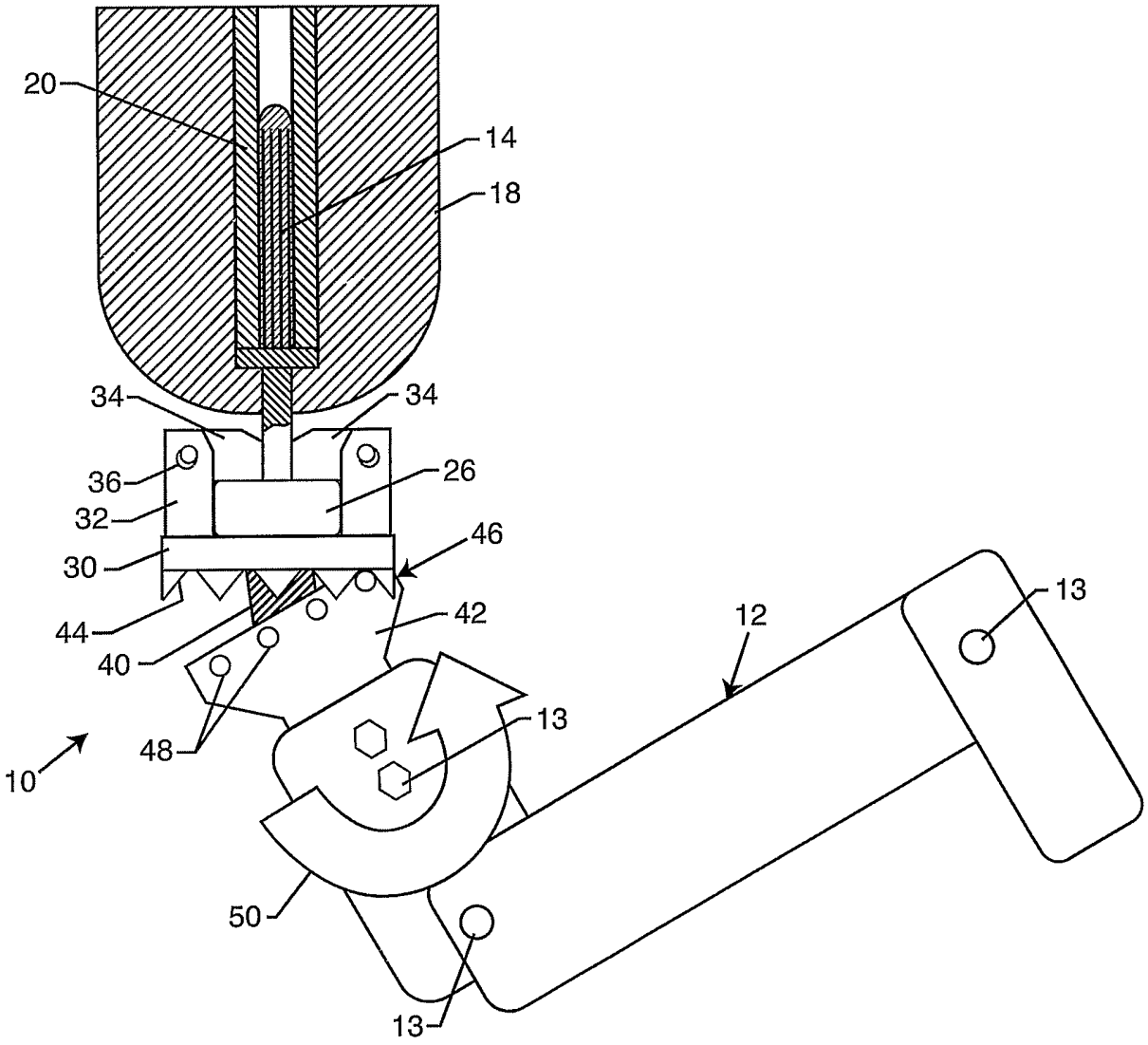

FIG. 5

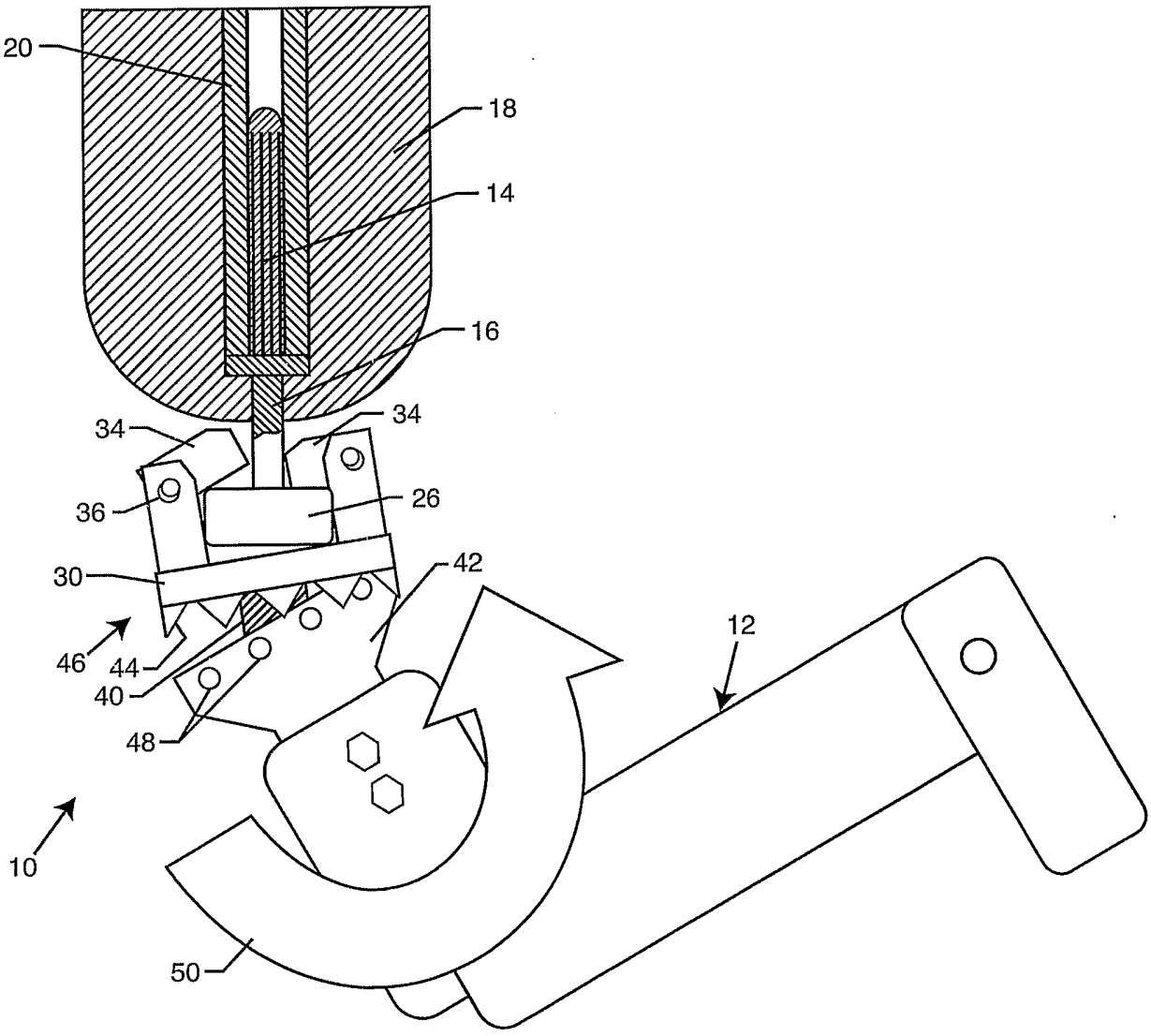

FIG. 6

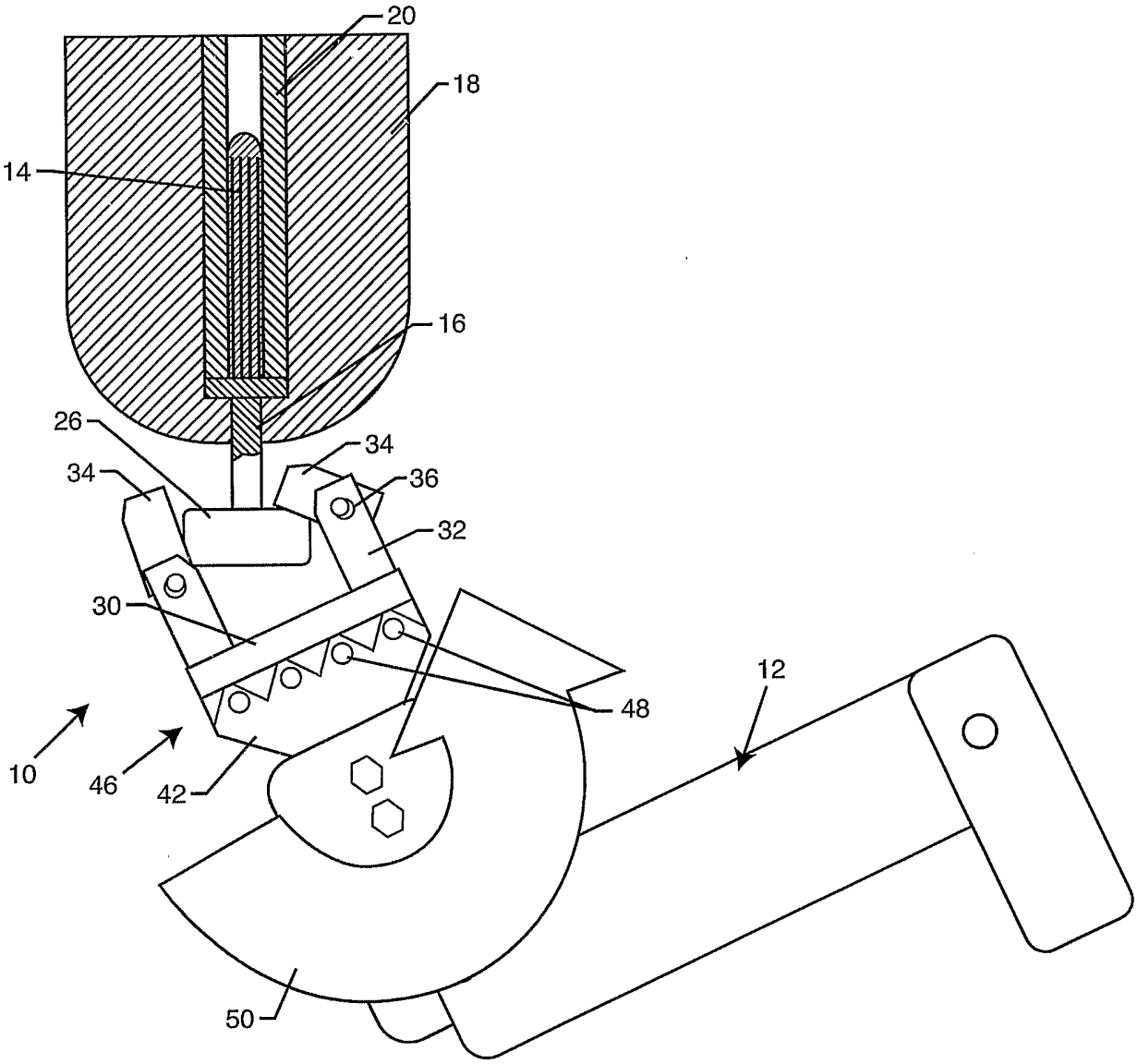

FIG. 7

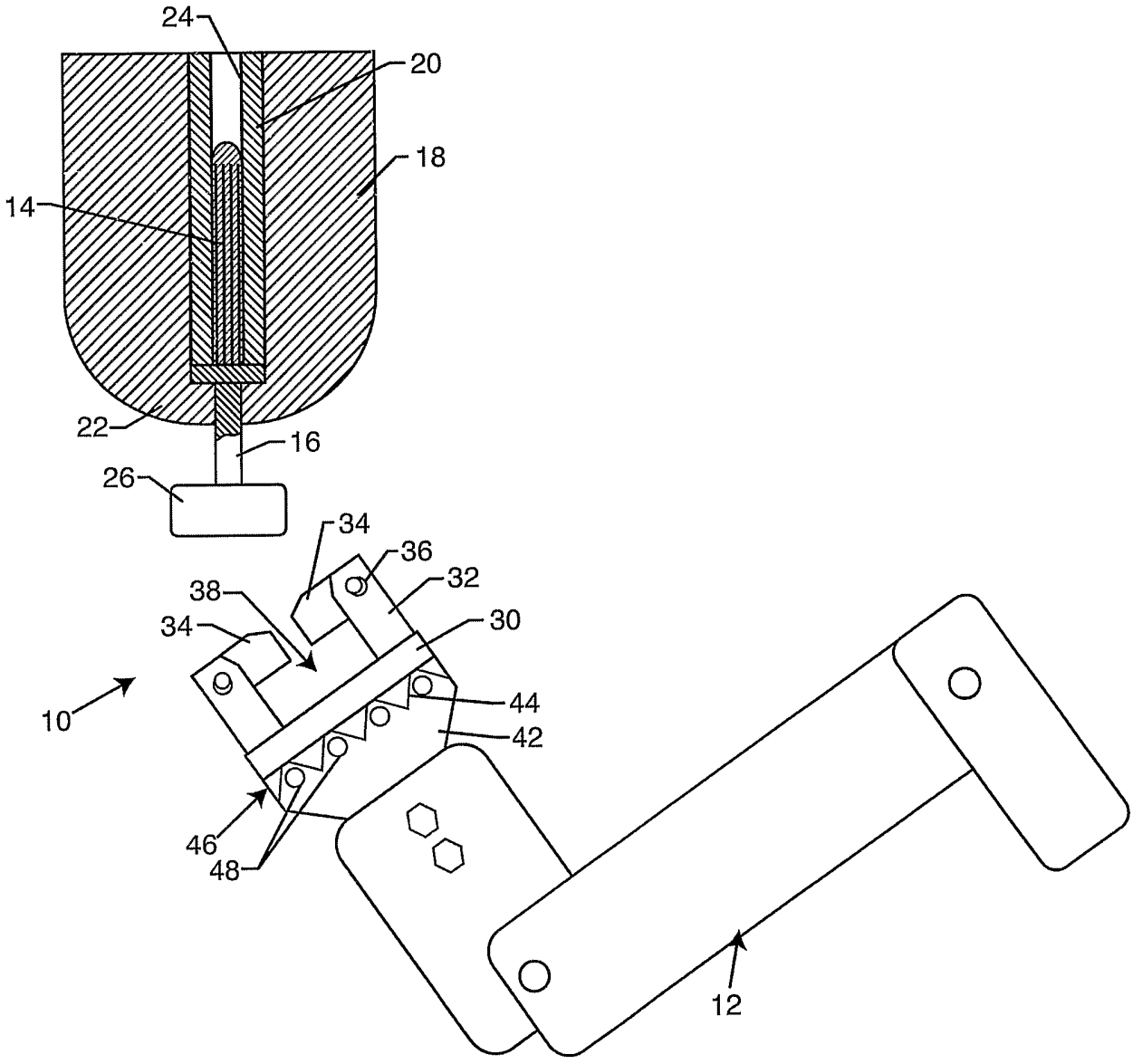

FIG. 8

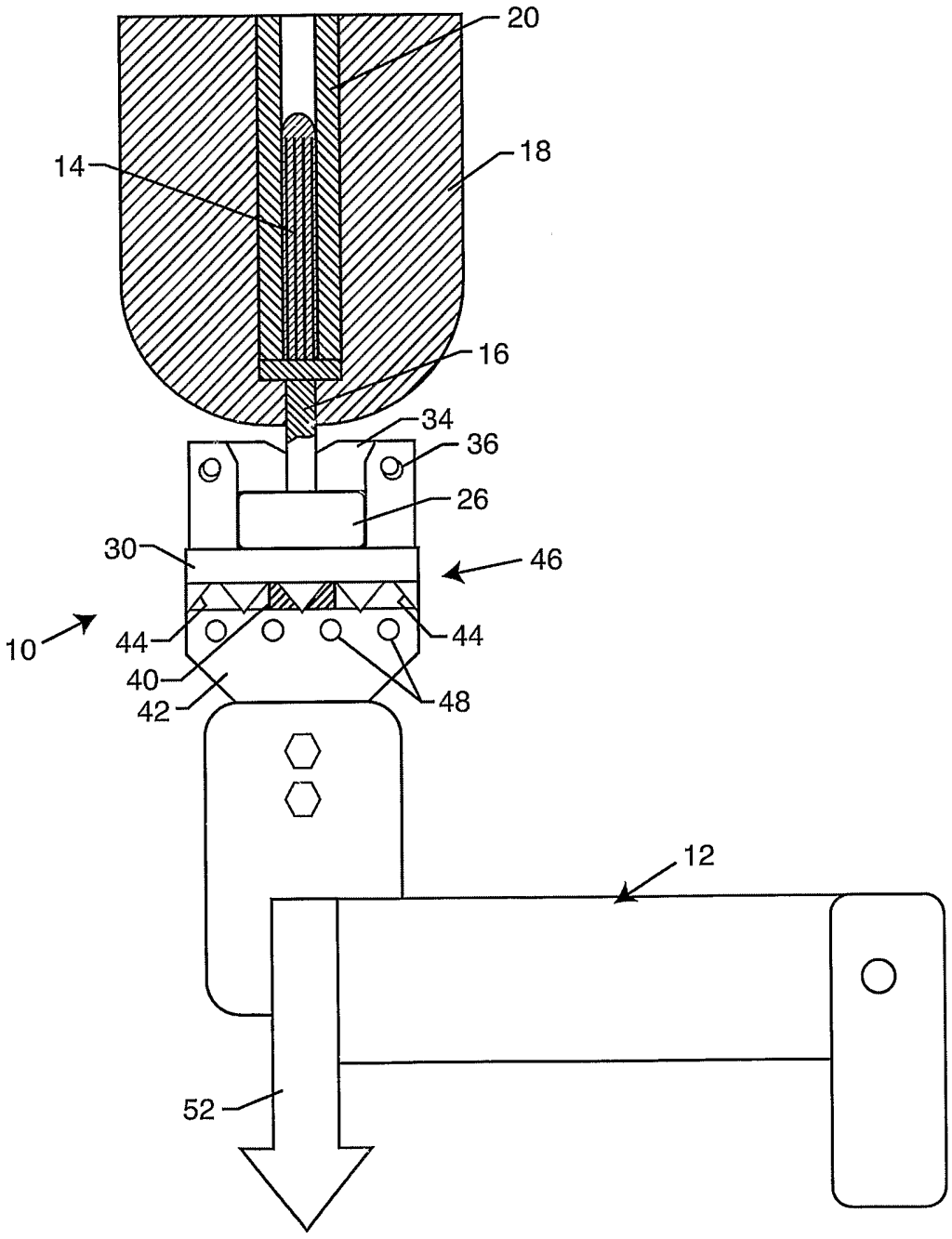

FIG. 9

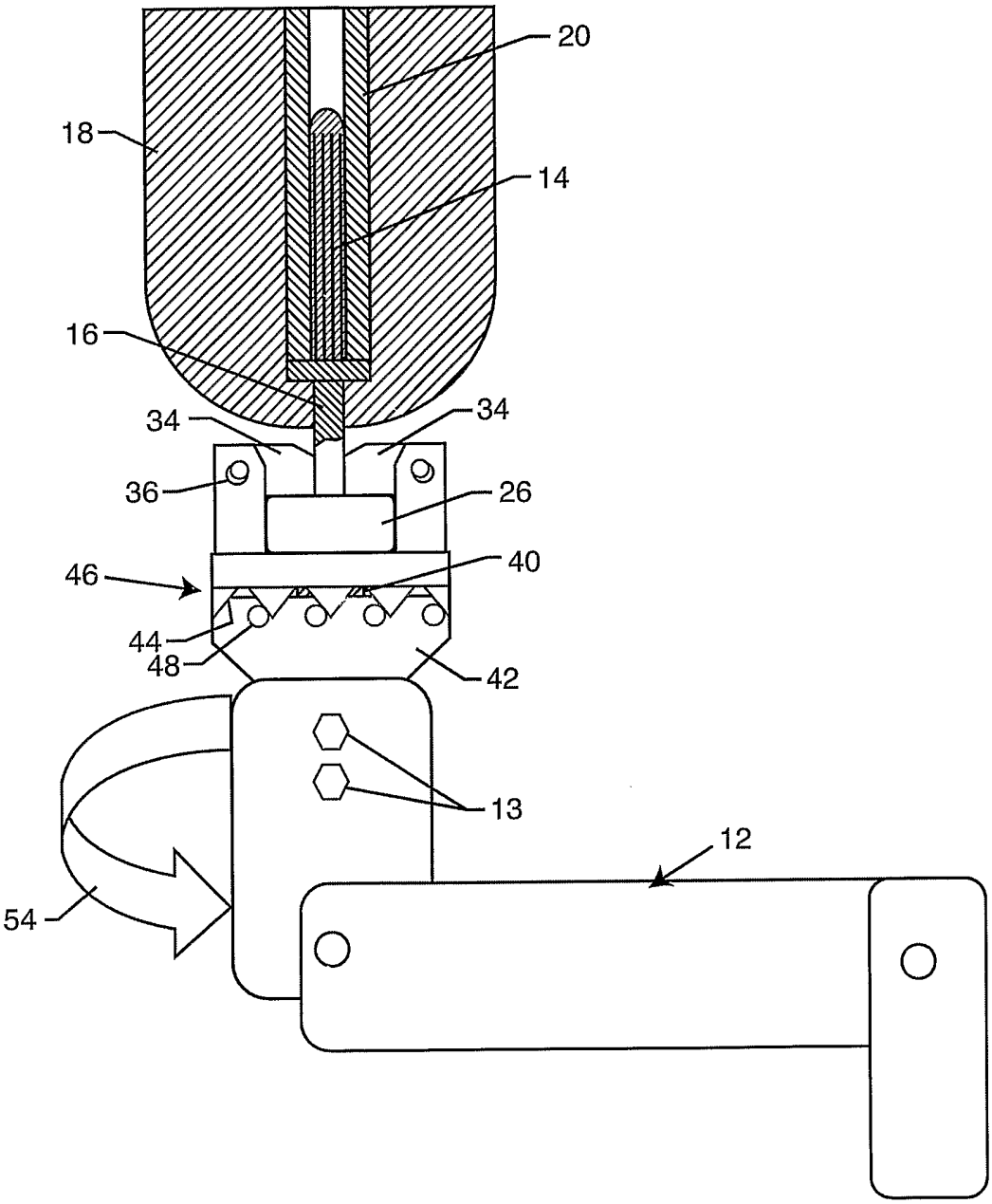

FIG. 10

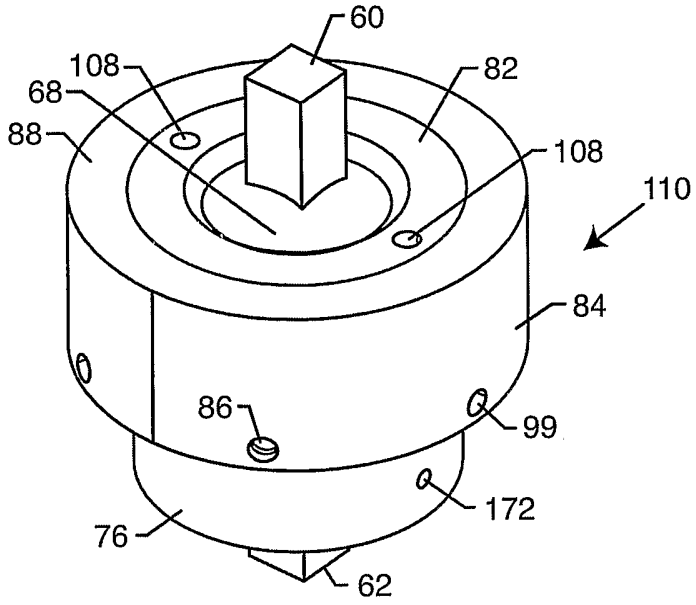

FIG. 11

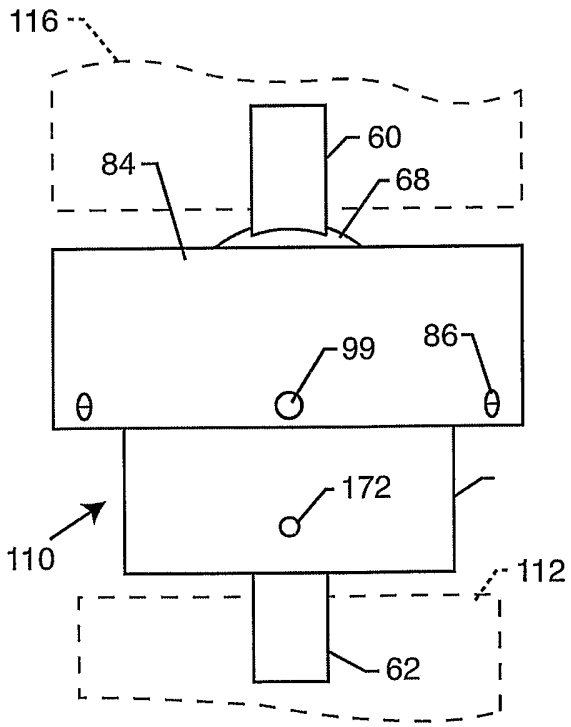

FIG. 12

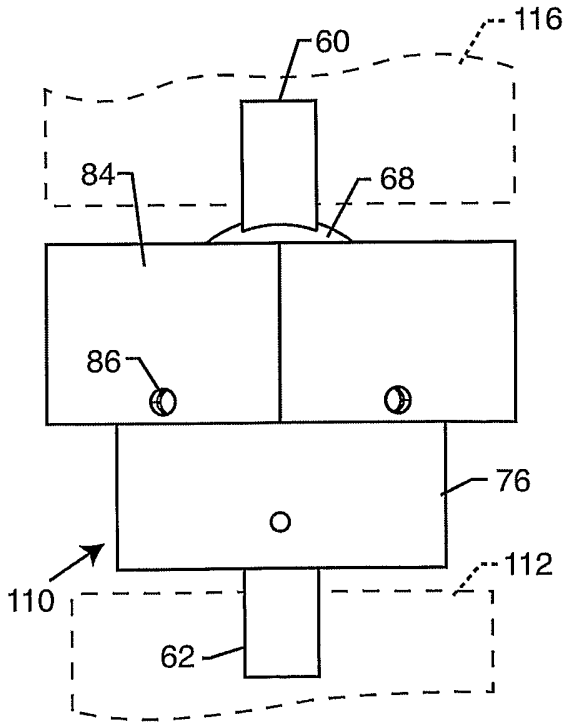

FIG. 13

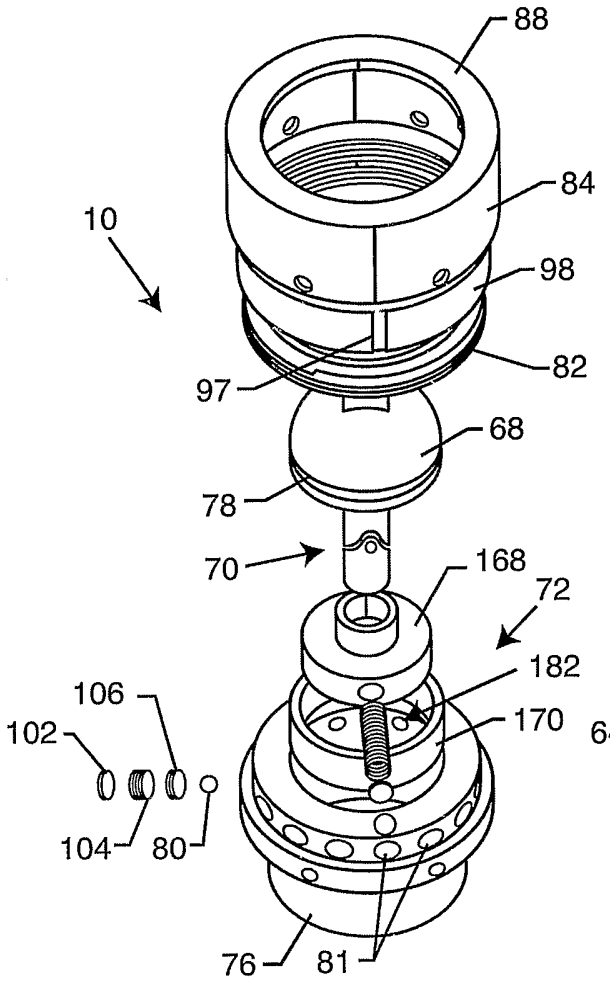
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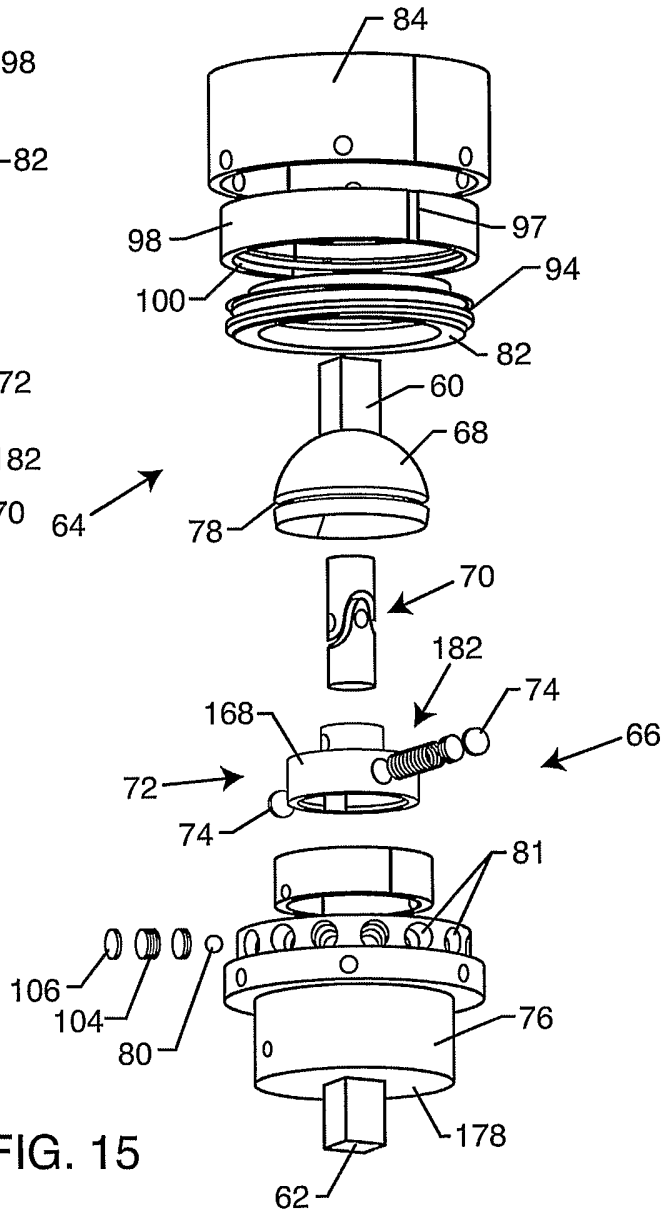
FIG. 14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62

FIG. 15

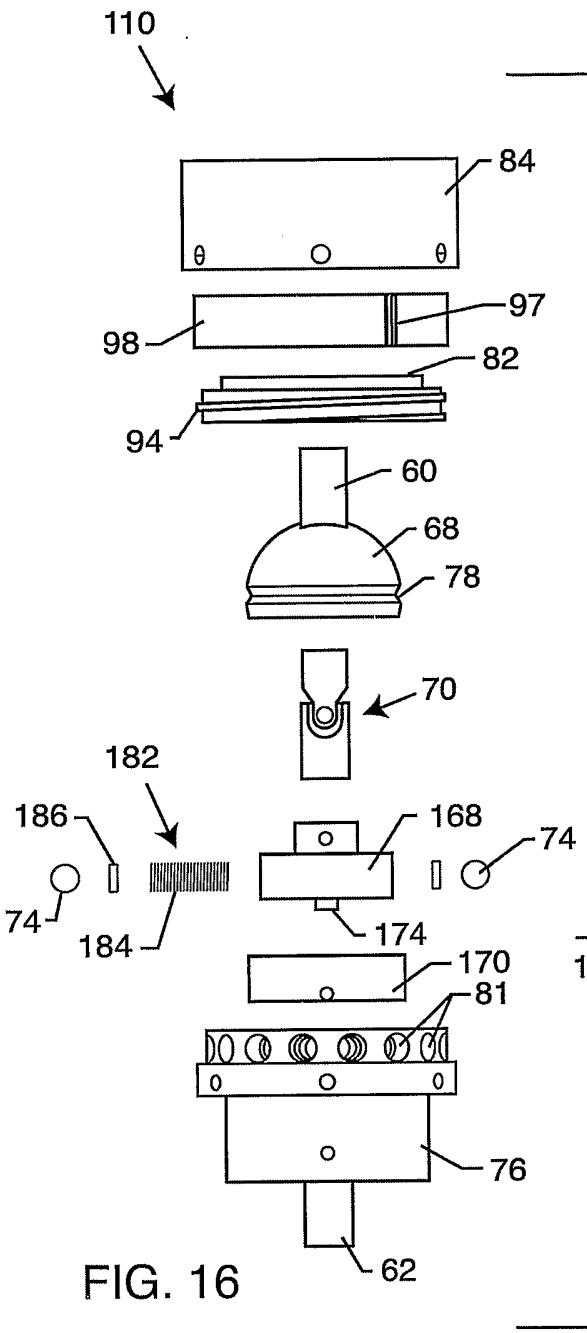


FIG. 16

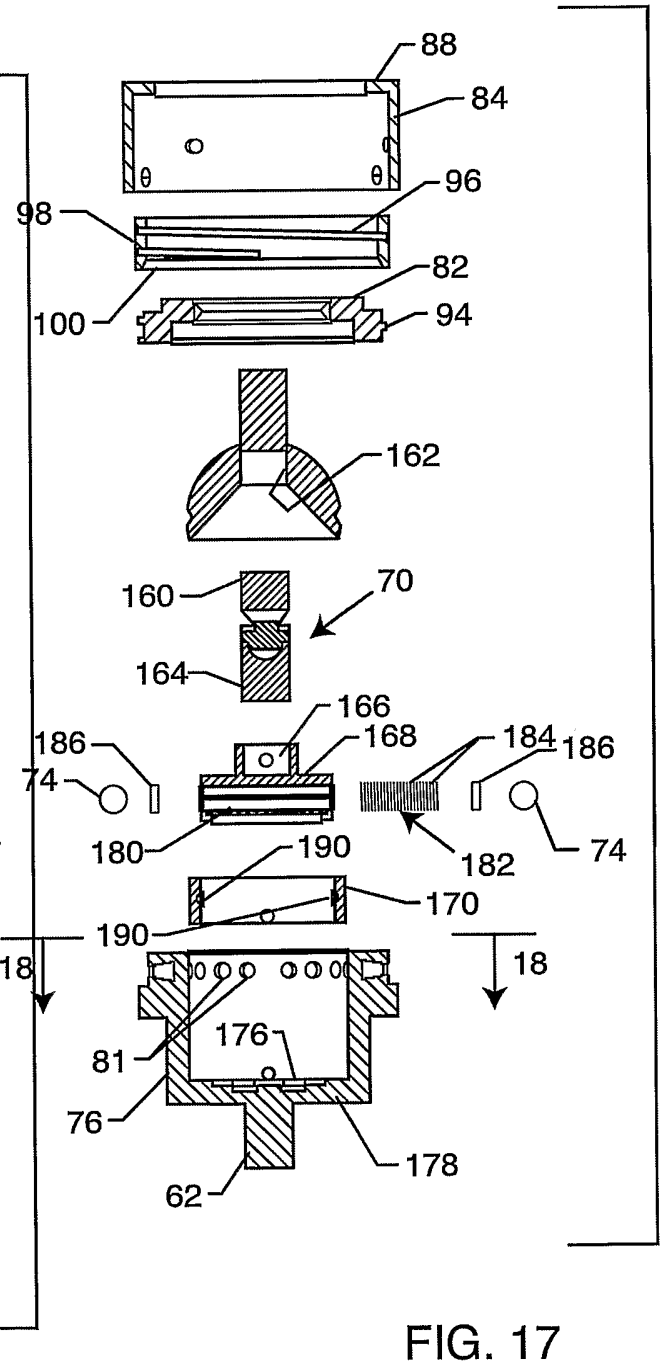


FIG. 17

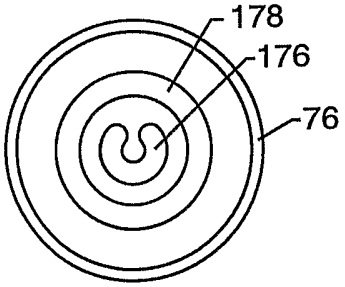
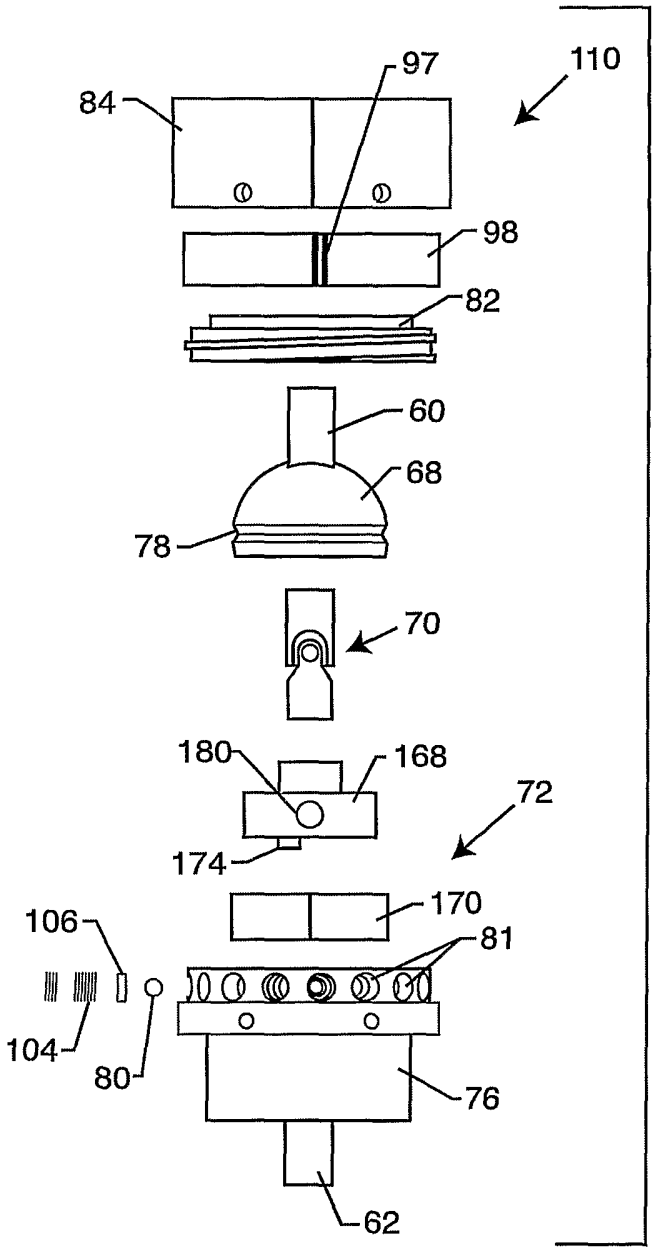


FIG. 18


110
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180
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FIG. 19

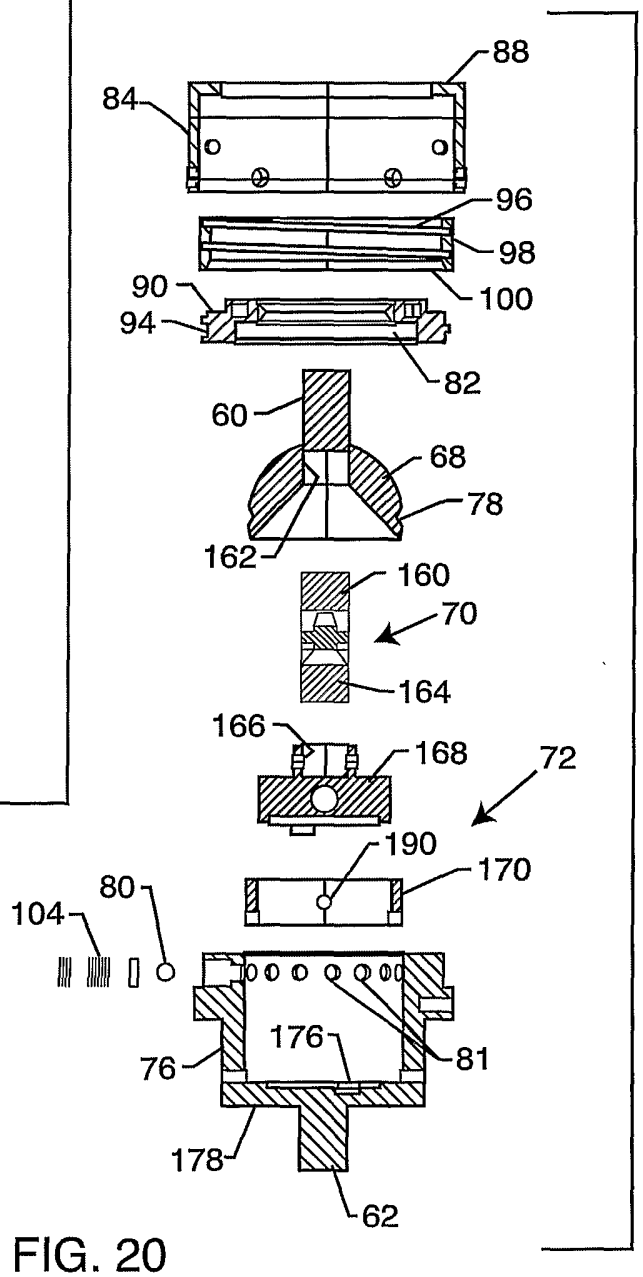
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FIG. 20

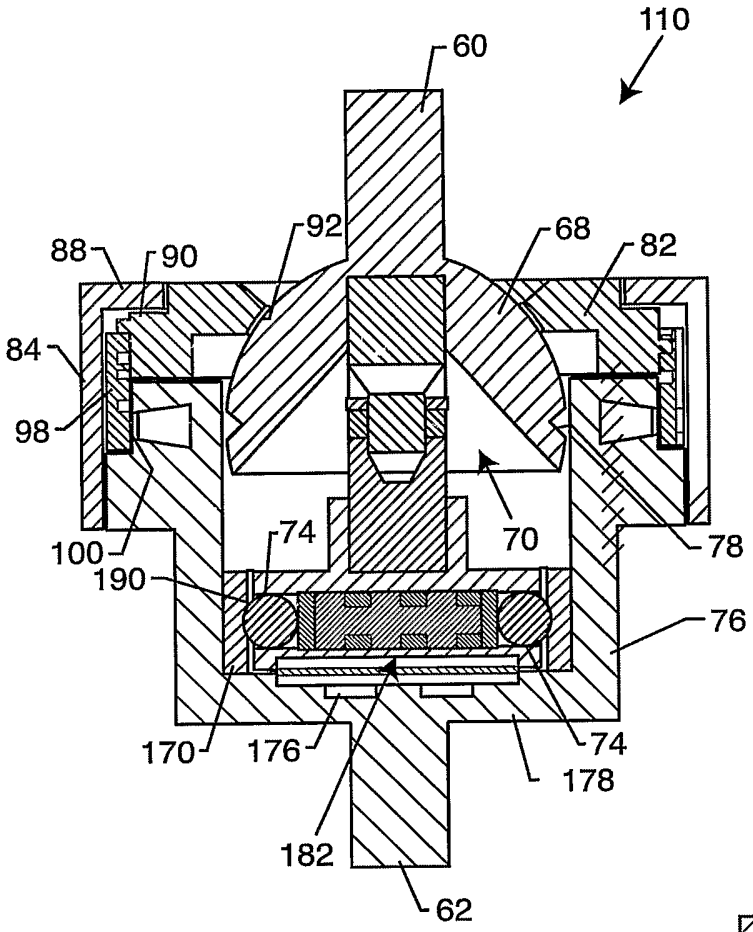
110
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FIG. 21

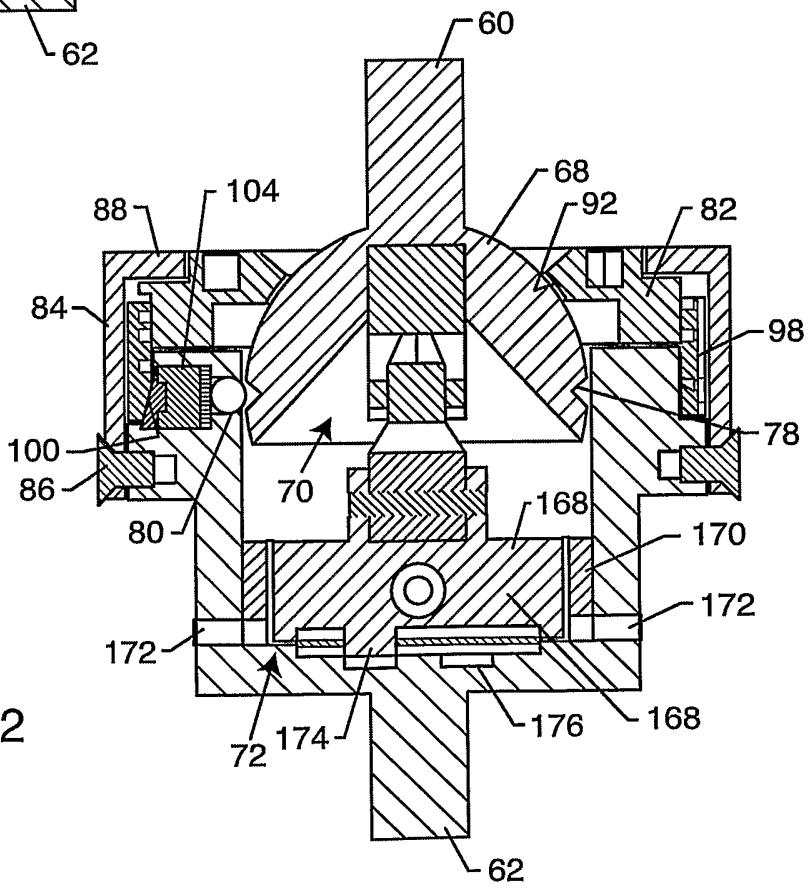
60
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FIG. 22

FIG. 23

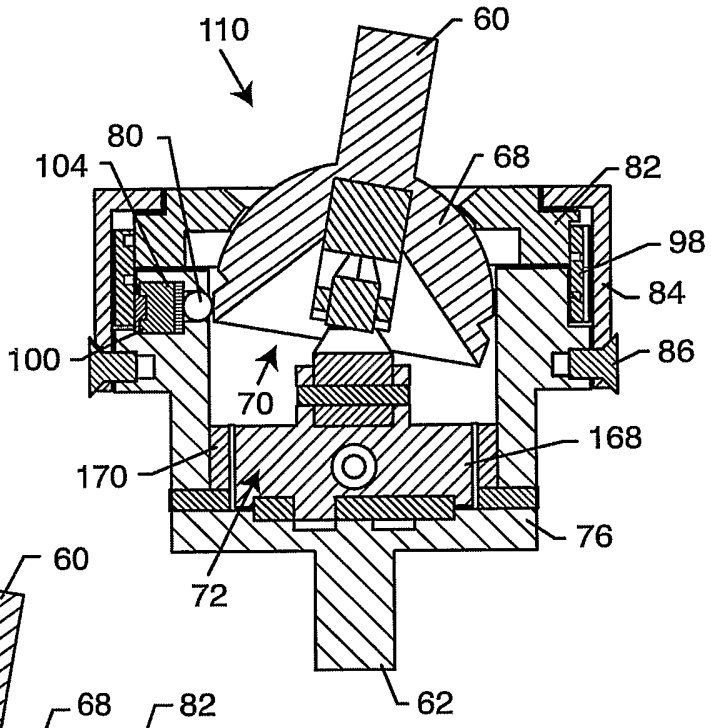

FIG. 24

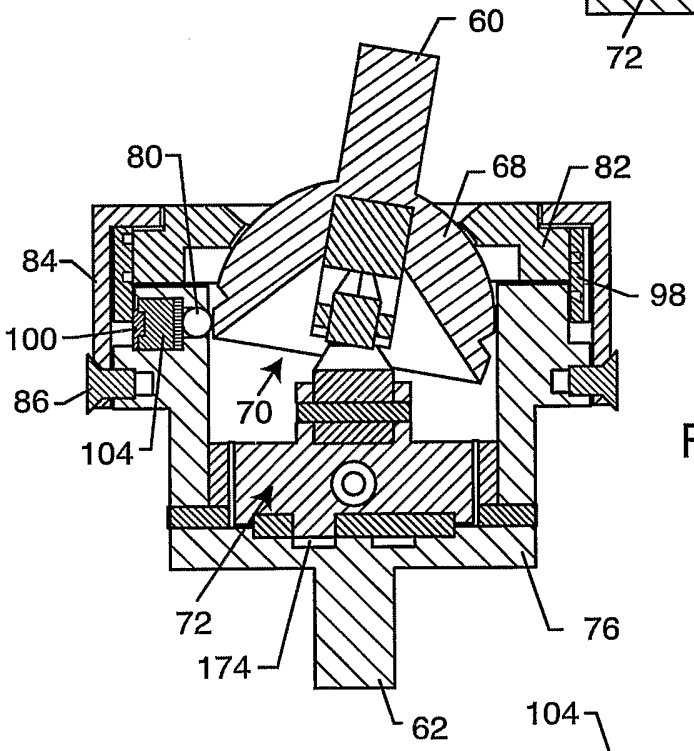

FIG. 25