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## Evaluation of 3D Printing Technologies and 3D Printed Materials in the use of Orthotic and Prosthetic Devices

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**Evaluation of 3D Printing Technologies and 3D Printed Materials in the use of  
Orthotic and Prosthetic Devices**

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### **Abstract**

Additive Manufacturing (AM) is disrupting fabrication techniques, bringing new design possibilities with associated benefits of less waste, improved design, improved time management, and less cost. The field of Orthotics and Prosthetics (O&P) is investigating how 3D printing, a subset of AM, can be used for fabrication of O&P devices. Before this technology is fully accepted, it needs to go through rigorous testing to ensure the safety of the individuals using the devices and the longevity of the devices themselves to ensure long term-use as a viable option. Research needs to define which type of 3D printing technology and what printed materials practitioners can rely on.

This study will focus on three 3D printing technologies, Fused Deposition Modeling (FDM), Selective Laser Sintering (SLS), and Multi Jet Printing (MJP) along with multiple printable materials. These printed sockets will be identical to each other and undergo 600,000 repetitions on a Tinius Olsen machine. The sockets will be visually assessed, tested with dye to identify any defects, and brought to ultimate failure using the Tinius Olsen machine. Visual and numerical fail points will be recorded which will be compared to the ISO 10328 threshold of 4480N, identifying which 3D printing technologies and printed materials will best be suited for O&P devices. As 3D printing continues to evolve and integrate into the O&P community, this study will serve as a basis to know what 3D printing technologies and materials will keep patients safe while still serving the ultimate purpose of regaining and maintaining their mobility.

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## Chapter 1: Introduction

Additive Manufacturing (AM) is a disruptive technology challenging the aged processes in fabrication of orthotic and prosthetic (O&P) devices. While the field of O&P has developed fabrication processes that are widely used, concerns of excess waste, time management, accuracy, repeatability, and creativity limits are causing the field to see 3D printing (an avenue of AM) to be a possible solution. Before 3D printing is fully accepted into the O&P community, it needs to be thoroughly tested to ensure its reliability and safety as these devices are used by individuals daily.

The field of O&P, “exists for the primary purpose of assisting patients in maintaining functional lives” (American Board for Certification in Orthotics, Prosthetics, and Pedorthics Inc., 2020, p.1). To help maintain or improve function, individuals may need the assistance of an orthotic device to align the joints of their limbs in a biomechanically sound manner. For amputees, a prosthetic device is fabricated to take place of a limb or digit which was lost through trauma, pathology, or one that was not present at birth. While some conditions may allow for the use of an ‘off-the-shelf’ style device, many devices require custom fabrication for efficient alignment. The current fabrication processes of O&P devices include casting a limb or residual limb, filling the cast with plaster to create a positive model, then modifying the positive model by adding or taking away plaster. Thermoplastic materials are then molded over these positive models by use of vacuum for orthotics while prosthetics will generally laminate carbon fiber over the positive model with resin. While this process has proven to be effective, it comes with the cost of excess waste, time, and potential inaccuracies.

The digital workflow attached to AM for O&P devices brings a possible solution to the less desirable attributes of traditional fabrication processes. The digital workflow process replaces casting with scanning the limb or residual limb, modifying the limb in Computer Assisted Design (CAD), and printing the device on a 3D printer. Waste is reduced through scanning which replaces plaster casts,

digital modifications which also reduces excess plaster, and printing only what plastic is needed for the device which prevents excess plaster ending up in the garbage. Time management is improved as clinicians and technicians are not waiting for plaster to set, digital modifications are streamlined making the process very quick, and the 3D printer performing the fabrication of the plastic allowing the practitioner to see more individuals or the technician to work on other projects. Inaccuracies can also be avoided as CAD programs provide real time feedback including precise measurements and 3D models of devices which can be placed over the positive model scan taken from the start. In addition to reducing inaccuracies for the first device, these models can be stored indefinitely, allowing the practitioner to make adjustments as needed to the CAD model and to re-print the same exact device as was initially printed. With all the benefits available, there are barriers AM needs to overcome before being fully accepted into the O&P community for fabrication of their devices.

3D printing is an overarching term with many facets needing to be broken down. Versions of 3D printing include Fused Deposition Modeling (FDM), Selective Laser Sintering (SLS), and binder jetting or droplet based multi-jet printing (MJP). FDM can be compared to a hot glue gun laying melted plastic in a specific pattern with multiple layers. Multiple plastics can be used with this technology, and it can be available at a much lower price range than the other versions of 3D printing. SLS fuses powders together with the use of a CO<sub>2</sub> laser, creating highly accurate devices with higher strength than most FDM printers, however, this comes at a higher cost than FDM technology. MJP is similar to SLS but uses liquid adhesive to bind the powder instead of a CO<sub>2</sub> laser. MJP printing is described by Barrios -Murisel et al. (2020):

In this process, first, a powder layer is spread on the build platform. Second, a liquid binder is deposited selectively through an inkjet printhead by following a patterned layer in the XY plane. Once the 2D pattern is formed, the platform lowers, the next powder layer is spread and so on.

(p.8)

Many printers using this technology will also use a UV light to assist with the curing of the deposited liquid binder without adding much time at all. Layer heights can be as small as 80 microns providing the capability of creating advanced designs without any difficulty. Strong materials such as Nylon can be used in this process creating very strong finished products. While this is an extremely effective technology, it is also much more expensive than the other two printing processes.

With the interest in AM growing for the field of O&P, it needed to undergo rigorous testing to ensure the safety of the individuals using the printed devices. Multiple questions arise about what materials are best suited for these devices for strength and what design parameters are needed to ensure the safety of the individuals wearing the devices. A common theme across many studies is utilizing the International Organization for Standardization (ISO) 10328 to compare the 3D printed devices against traditionally fabricated devices. Nickel et al. (2020) described ISO 10328 as:

Engineered prosthetic components, such as tube clamps, pyramid adaptors, pylons, and feet, are tested to international standards, such as the International Organization for Standardization (ISO) 10328 test standard, to ensure structural strength and durability. The ISO 10328 standard includes strength testing to high loads that simulate an infrequent event with high contact forces and cyclic testing that stimulates daily use during walking. (p. 295)

Using ISO 10328 provides a consistent standard to compare these new devices against fabricated devices. One study performed by Campbell et al. (2018) utilized FDM technology with PLA plastic, 3D printing nine total transtibial sockets with infills (amount of filament between the outer and inner wall of the print) of 30%, 40%, and 50%. All nine sockets exceeded the ISO 10328 threshold of 4480N, noting that it did not seem infill percentages would affect the strength of the socket. It was noted the eventual failures consistently occurred to the lateral mid socket or the mid popliteal area.

A study performed by Sabeti et al. (2018) compared the strength between sockets printed with Nylon, Nylon 12, and PLA utilizing both FDM and SLS printing processes. The sockets were placed under static loads and both Nylon and Nylon 12 were found to exceed the ISO 10328 threshold while PLA did not. All socket failures were noted to be at the distal end of the socket at the adaptor site. Owen and Desjardin (2020) compared traditional carbon fiber laminated sockets and check sockets to a socket printed with PLA through FDM technology. Noting a wall thickness of 7mm with 40% infill and 0.4mm layer height, the sockets were placed under static pressure in the toe-off position. This study found the traditional sockets were able to withstand forces to 6462N, far exceeding the ISO 10328 threshold, while the PLA socket failed at 3836N.

Walker et al. (2020) recruited six unilateral transtibial amputees to wear 3D printed sockets for two weeks at home. Prior to using the 3D printed sockets, they performed a number of tests, including the two-minute walk test, and answered questionnaires in regards to their traditionally fabricated sockets. After wearing the 3D printed sockets for two weeks, they performed the same tests and answered the same questionnaires. Quantitative data showed no difference between the two types of sockets while qualitative data was promising showing only minor concern with the texture of the new sockets and many participants found some flexibility along the proximal brim to be favorable. While this flexibility was seen as a positive, it could cause concern for failure of the socket after some time.

Kerns and Howell (2020) recruited four individuals to use 3D printed sockets for six weeks. Following the six weeks, the sockets were investigated for any signs of stress with a dye penetrant which would reveal any thickness delamination. After evaluating the four sockets, no full thickness intralayer defects were noted with a calculated porosity of 1.8%. This is promising for the 3D printed sockets as the dye penetrant method was proven effective after finding full thickness stress defects on a traditionally fabricated socket that had been used for three years.



Lastly, the Minnesota VA in conjunction with the Department of Bioengineering at Clemson University by Nickel et al. (2020) went through a process of printing twenty-four sockets capable of withstanding the ISO 10328 strength tests and placed one socket that had withstood the ISO 10328 tests to a three million repetitive sinusoidal loading of the socket. Three million cycles was chosen because, “three million cycles is generally presumed by the industry to be representative of up to 3 years of normal usage depending on the activity level of the user” (Nickel, et al., 2020, p.1). This testing was primarily performed to show the reliability of using the ISO 10328 threshold to test the 3D printed sockets, but also showed promise in how a 3D printed socket can become reality for many individuals.

While a vast amount of research has been performed on 3D printed devices for the O&P community, studies focusing on materials and 3D printing technology are needed to ensure reliable safety of these products. If this technology is brought into the O&P community too early without the data resulting in injuries to those wearing the devices, it may be rejected by many O&P clinics and users, leaving them to the old fabrication methods. While many of these studies utilize static loading methods for testing the devices, the human body uses fluid movements to regain and maintain mobility. Further research is needed to investigate the different 3D printing technologies along with the materials and longevity of the devices through use of fluid movements to ensure the safety of the users and the long-term effects their movements will have on their devices.

## Chapter 2: Methodology

### Research Question

The purpose of this study is to identify the reliability of utilizing the different 3D printing technologies along with the materials available for fabrication in the O&P community. While this community fabricates devices for both orthotics and prosthetics, this study will be focused on utilization of 3D printing for a transtibial prosthetic socket which generally withstands much more severe forces than orthotics. The data this study will provide will help reinforce the capabilities of AM within the O&P community for practitioners and users. The data will provide insight as to what methods and materials are best suited to withstand the tri-planar forces prosthetic sockets undergo, guiding practitioners to what technologies may suit their needs best while keeping the user safe. Of note, 3D printing is capable of printing flexible devices which can be used in conjunction with rigid devices. This study will focus on rigid devices.

### Participants

This study will not require involvement of any live subjects. This study is focused on the reliability of the material and AM technology science which can later be used for devices. Further studies following the results of this study may include the involvement of volunteers for both qualitative and quantitative data on the 3D printing technology for their devices.

### Instruments

While 3D printing can produce parts less costly than traditional methods, the technology comes with a great cost while starting up. The 3D printed devices will all be printed through professional printing services. Utilizing professional 3D printing services will eliminate the costs of setup and any potential mistakes that come with learning a new technology that could lead to inaccurate results. The

three types of 3D printers will include FDM, SLS, and MJP. The materials being tested for FDM will include ABS, Nylon, and PETG. Materials for the SLS printed sockets will be made from Nylon, Nylon 12, and Nylon 11 CF (carbon fiber). Materials for the MJP printer will be made from PolyPropylene (PP) and Nylon PA 11.

The device used to test the durability of the sockets will be a Tinius Olsen machine capable of providing forces above the ISO 10328 threshold of 4480N. There will be an adjustment made to this machine causing the foot of the prosthesis to move underneath the socket, anterior to posterior, therefore replicating a gait cycle. If the machine is not able to be modified for this movement, a static block (1") will be placed underneath different parts of the foot for different periods of time as the static loading is repeated to replicate the different positions of the foot during the gait cycle.

The prosthetic socket design will be modeled after a transtibial amputee's residual limb in a total contact fashion. This model will be used for each socket printed and will be designed to attach to a pyramid block which will then be attached to a pylon and prosthetic foot. Alignment, the pylon length, and prosthetic foot will be the same for each test, eliminating any potential adverse forces. The residual limb replacement will consist of a printed tibia and fibula with ballistics gel filled to the same shape as the individual's residual limb. The ballistics gel will allow for tissue displacement in the limb under load as it would naturally occur with a natural residual limb, placing similar forces to all areas of the socket.

### **Procedures**

As mentioned above, each socket will have been printed with the exact same design and set up with the exact same prosthetic foot, pylon length, and alignment. The residual limb replacement will be placed into the Tinius Olsen machine and inserted into the prosthetic socket in the appropriate direction. If the machine is capable of being modified to move the prosthetic foot anterior to posterior while under static load, this will be done under 4480N of force repeatedly for 600,000 repetitions. If this modification

is not able to be performed, a static block (1") will be placed underneath the heel while the device is placed under force for 200,000 cycles to represent heel strike. This block will then be removed and performed again for another 200,000 cycles to represent mid-stance. Once again, the block will be placed underneath the toes of the prosthetic foot for another 200,000 cycles to represent toe-off.

Following the 600,000 repetitions, the sockets will be evaluated for any potential damage that could cause failure of the socket. This will be done through visual inspection as well as the use of dye penetrant which will be applied to both the inside and outside the socket. Once the excess dye penetrant is washed off of the socket, any damage to the socket that may not have been visible to the naked eye should be visible. For any sockets that have reached this stage without significant damage, they will be placed back into the Tinius Olsen machine and will be placed under load until complete failure. If the machine is amenable to the anterior posterior foot slide modification, the static load will be applied for ten repetitions then the force will increase by 44.48N (10 pounds) for another ten repetitions until failure. If the modification was not able to be applied to the machine, the static load will be applied to the socket under mid-stance position without any blocks underneath the prosthetic foot and will go for ten repetitions, adding 44.48N every ten repetitions. Results of the damage will be recorded and analyzed. If possible, this design will be replicated with a second set of prosthetic sockets for each 3D printing technique and material to provide a larger set of data.

### **Design and Analysis**

This is a quantitative design study looking at the structural integrity of the 3D printing techniques and materials available as they apply to the O&P community, specifically transtibial prosthetic sockets. Sockets will be recorded as failed to meet the ISO 10328 threshold of 4480N or will otherwise be recorded at what force the socket failed. There will also be space to note where anatomically the socket failed and if it failed during the initial testing, at what point the socket failed if it was able to be recorded.

These values will be plotted on a bar graph with the ISO 10328 threshold in place to easily discern which sockets passed the ISO 10328 threshold. All data will be recorded on a table (**Appendix A**).

Independent variables of this study include the Tinius Olsen machine, the residual limb and forces applied to the residual limb from the Tinius Olsen machine, the prosthetic foot, the pylon height, and the prosthetic alignment. Dependent variables will include the differing forces causing the prosthetic sockets to fail, the area of the socket that failed, and the amount each socket fails. The alpha value of this study will be 4480N as the threshold each socket needs to meet according to the ISO 10328 standard as a consistent threshold across each socket. The statistical mean of the force causing each socket to fail will be considered this study's measure of central tendency. Replicating this study a second time, if possible, will provide much more accurate data to represent the true results from each of these types of 3D printing techniques and materials.

### **Ethical Considerations**

The ethical considerations of this study are limited due to having little to no live subject involvement. The only involvement will include using the scan or cast of a transtibial amputee. These prosthetic sockets will not be placed on the individual which will prevent any potential harm to their health. Only ethical considerations would include the fabrication of materials that are not being used for a socket that will be used by an individual, the economical considerations of mailing the printed sockets to the facility, and the waste of the sockets after the study is finished.

### Chapter 3: Discussion

As the results of this study come through, they will be of great value to the O&P community as a resource for what type of 3D printing technology and what materials should be used for orthotic and prosthetic devices. While there have been many studies focusing on static loads of 3D printed prosthetic sockets, they mainly focus on static loads and short-term success of their sockets, this study will bring light to the different 3D printing technologies and materials available and what will provide the most stable device for the user. This study will serve as a baseline for further studies utilizing 3D printed sockets on live subjects for long periods of time. For practitioners who do not have access to 3D printing at their clinic, this study will provide them with knowledge to what 3D printing technology and materials will be best to order for their patients while knowing they will not be harmed while using the device.

Limitations of this study include ultimate longevity where a more desirable repetition count would be three million for each socket, but this would extend the project immensely with the large number of sockets. The forces being applied will be in the same direction with each repetition. Humans walk with variability that this study is unable to replicate, lending to the desire for further studies with live subjects. All subjects utilizing a prosthetic socket have unique anatomy so while the material and socket design may work for one individual, it may need to be adjusted for another individual in the thickness of the socket, design, etc.

Recommendations for further research include the use of the sockets of this study which meet the ISO 10328 threshold to be used on live subjects for a long period of time to gain quantitative and qualitative data. Additionally, alternative socket designs should be examined as to what type of adaptor connections may provide the best structural integrity for a prosthetic socket. As AM continues to evolve, further studies into the updated 3D printing technologies and materials should be considered to keep the O&P field up to date.

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**Appendix A**

**FDM - ABS:**

Printing Parameters	
Wall Thickness	
Infill %	
Layer Height	

Visual Observance Following 200,000 Repetitions Heel String (block under heel):

Socket Failure?: **Y / N**

Notes: \_\_\_\_\_  
 \_\_\_\_\_

Visual Observance Following 200,000 Repetitions Mid-Stance (No block)

Socket Failure?: **Y / N**

Notes: \_\_\_\_\_  
 \_\_\_\_\_

Visual Observance Following 200,000 Repetitions Toe-Off (block under toes)

Socket Failure?: **Y / N**

Notes: \_\_\_\_\_  
 \_\_\_\_\_

***Following 600,000 Repetitions:***

Dye Penetration?: **Y / N**

If yes, dye penetration location: \_\_\_\_\_  
 \_\_\_\_\_

Ultimate socket failure force: \_\_\_\_\_

Where did the socket fail? \_\_\_\_\_  
 \_\_\_\_\_

Additional Notes: \_\_\_\_\_

**FDM - PETG:**

Printing Parameters	
Wall Thickness	
Infill %	
Layer Height	

Visual Observance Following 200,000 Repetitions Heel String (block under heel):

Socket Failure?: **Y / N**

Notes: \_\_\_\_\_  
 \_\_\_\_\_

Visual Observance Following 200,000 Repetitions Mid-Stance (No block)

Socket Failure?: **Y / N**

Notes: \_\_\_\_\_  
 \_\_\_\_\_

Visual Observance Following 200,000 Repetitions Toe-Off (block under toes)

Socket Failure?: **Y / N**

Notes: \_\_\_\_\_  
 \_\_\_\_\_

***Following 600,000 Repetitions:***

Dye Penetration?: **Y / N**

If yes, dye penetration location: \_\_\_\_\_  
 \_\_\_\_\_

Ultimate socket failure force: \_\_\_\_\_

Where did the socket fail? \_\_\_\_\_  
 \_\_\_\_\_

Additional Notes: \_\_\_\_\_  
 \_\_\_\_\_

**FDM – Nylon:**

Printing Parameters	
Wall Thickness	
Infill %	
Layer Height	

Visual Observance Following 200,000 Repetitions Heel String (block under heel):

Socket Failure?: **Y / N**

Notes: \_\_\_\_\_  
 \_\_\_\_\_

Visual Observance Following 200,000 Repetitions Mid-Stance (No block)

Socket Failure?: **Y / N**

Notes: \_\_\_\_\_  
 \_\_\_\_\_

Visual Observance Following 200,000 Repetitions Toe-Off (block under toes)

Socket Failure?: **Y / N**

Notes: \_\_\_\_\_  
 \_\_\_\_\_

**Following 600,000 Repetitions:**

Dye Penetration?: **Y / N**

If yes, dye penetration location: \_\_\_\_\_  
 \_\_\_\_\_

Ultimate socket failure force: \_\_\_\_\_

Where did the socket fail? \_\_\_\_\_  
 \_\_\_\_\_

Additional Notes: \_\_\_\_\_  
 \_\_\_\_\_

**SLS – Nylon:**

Printing Parameters	
Wall Thickness	
Layer Height	

Visual Observance Following 200,000 Repetitions Heel String (block under heel):

Socket Failure?: **Y / N**

Notes: \_\_\_\_\_  
 \_\_\_\_\_

Visual Observance Following 200,000 Repetitions Mid-Stance (No block)

Socket Failure?: **Y / N**

Notes: \_\_\_\_\_  
 \_\_\_\_\_

Visual Observance Following 200,000 Repetitions Toe-Off (block under toes)

Socket Failure?: **Y / N**

Notes: \_\_\_\_\_  
 \_\_\_\_\_

**Following 600,000 Repetitions:**

Dye Penetration?: **Y / N**

If yes, dye penetration location: \_\_\_\_\_  
 \_\_\_\_\_

Ultimate socket failure force: \_\_\_\_\_

Where did the socket fail? \_\_\_\_\_  
 \_\_\_\_\_

Additional Notes: \_\_\_\_\_  
 \_\_\_\_\_

**SLS – Nylon 11 CF (carbon fiber)**

Printing Parameters	
Wall Thickness	
Layer Height	

Visual Observance Following 200,000 Repetitions Heel String (block under heel):

Socket Failure?: **Y / N**

Notes: \_\_\_\_\_  
 \_\_\_\_\_

Visual Observance Following 200,000 Repetitions Mid-Stance (No block)

Socket Failure?: **Y / N**

Notes: \_\_\_\_\_  
 \_\_\_\_\_

Visual Observance Following 200,000 Repetitions Toe-Off (block under toes)

Socket Failure?: **Y / N**

Notes: \_\_\_\_\_  
 \_\_\_\_\_

**Following 600,000 Repetitions:**

Dye Penetration?: **Y / N**

If yes, dye penetration location: \_\_\_\_\_  
 \_\_\_\_\_

Ultimate socket failure force: \_\_\_\_\_

Where did the socket fail? \_\_\_\_\_  
 \_\_\_\_\_

Additional Notes: \_\_\_\_\_  
 \_\_\_\_\_

**SLS-Nylon 12:**

Printing Parameters	
Wall Thickness	
Layer Height	

Visual Observance Following 200,000 Repetitions Heel String (block under heel):

Socket Failure?: **Y / N**

Notes: \_\_\_\_\_  
 \_\_\_\_\_

Visual Observance Following 200,000 Repetitions Mid-Stance (No block)

Socket Failure?: **Y / N**

Notes: \_\_\_\_\_  
 \_\_\_\_\_

Visual Observance Following 200,000 Repetitions Toe-Off (block under toes)

Socket Failure?: **Y / N**

Notes: \_\_\_\_\_  
 \_\_\_\_\_

***Following 600,000 Repetitions:***

Dye Penetration?: **Y / N**

If yes, dye penetration location: \_\_\_\_\_  
 \_\_\_\_\_

Ultimate socket failure force: \_\_\_\_\_

Where did the socket fail? \_\_\_\_\_  
 \_\_\_\_\_

Additional Notes: \_\_\_\_\_  
 \_\_\_\_\_

**MJP – Nylon PA11**

Printing Parameters	
Wall Thickness	
Layer Height	

Visual Observance Following 200,000 Repetitions Heel String (block under heel):

Socket Failure?: **Y / N**

Notes: \_\_\_\_\_  
 \_\_\_\_\_

Visual Observance Following 200,000 Repetitions Mid-Stance (No block)

Socket Failure?: **Y / N**

Notes: \_\_\_\_\_  
 \_\_\_\_\_

Visual Observance Following 200,000 Repetitions Toe-Off (block under toes)

Socket Failure?: **Y / N**

Notes: \_\_\_\_\_  
 \_\_\_\_\_

***Following 600,000 Repetitions:***

Dye Penetration?: **Y / N**

If yes, dye penetration location: \_\_\_\_\_  
 \_\_\_\_\_

Ultimate socket failure force: \_\_\_\_\_

Where did the socket fail? \_\_\_\_\_  
 \_\_\_\_\_

Additional Notes: \_\_\_\_\_  
 \_\_\_\_\_

**MJP – Polypropylene**

Printing Parameters	
Wall Thickness	
Layer Height	

Visual Observance Following 200,000 Repetitions Heel String (block under heel):

Socket Failure?: **Y / N**

Notes: \_\_\_\_\_  
 \_\_\_\_\_

Visual Observance Following 200,000 Repetitions Mid-Stance (No block)

Socket Failure?: **Y / N**

Notes: \_\_\_\_\_  
 \_\_\_\_\_

Visual Observance Following 200,000 Repetitions Toe-Off (block under toes)

Socket Failure?: **Y / N**

Notes: \_\_\_\_\_  
 \_\_\_\_\_

***Following 600,000 Repetitions:***

Dye Penetration?: **Y / N**

If yes, dye penetration location: \_\_\_\_\_  
 \_\_\_\_\_

Ultimate socket failure force: \_\_\_\_\_

Where did the socket fail? \_\_\_\_\_  
 \_\_\_\_\_

Additional Notes: \_\_\_\_\_  
 \_\_\_\_\_