A Study of Socket Materials and Clinical Outcomes

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Introduction

As the joke goes, “You will never meet the second best prosthetist in the world because every prosthetist will tell you that they are the best in the world.” Likewise, just about every prosthetist believes that they use the secret recipe of materials for the best socket fabrication. Prosthetists also may use add-on billing codes for materials used in the prosthetic sockets they deliver. However, little research has been done to validate, quantify, or better understand material properties and corresponding clinical results. Regardless of the differences in options, we should be prepared to justify reimbursement for sockets and materials used with material testing data and corresponding outcome measures.

The industry has defaulted to making prosthetic sockets that are very rigid. It is understandable that prosthetists have gravitated toward making rigid sockets, given that sockets need to be exceptionally strong and durable (in both fatigue and peak stress) while also being low profile, adjustable, lightweight, and easy to use in order to meet the needs of prosthetic users.

While these needs are certainly important, we also should consider the fact that we are interfacing with the human body, which is much softer and less rigid than typical socket materials. Fitting rigid sockets on relatively soft and pliable residual limbs may be a large contributor to the high incidence of ulcers, pain, discomfort, and prosthetic abandonment.[1-5]

Logic derived from the laws of physics also would suggest that a more rigid socket would be better at efficiently transferring movements of the residual limb and biomechanical forces between the socket and the residual limb. This logic also would postulate that more rigid shoes, like clogs, would more effectively transfer forces between the foot and the shoe—and yet the vast majority of shoes sold today are considerably less rigid than clogs. The logic of rigid interfaces for improved biomechanical control does not factor the user’s subjective experience into the equation. This may explain why so many users walk with a high degree of symmetry in the clinic but use compensatory movements to dampen forces between the socket and the residual limb outside the clinic.

This is not to say that biomechanical control is not important; rather, that it is one important consideration to be included, along with other important considerations. Other important considerations include elastic modulus of materials and finish construction; durometer; surface area; trim lines; shape; force dampening; force transitions; type of adjustment; cold flow and regionally selective pressure distribution per residual limb length, user weight, user height, and user activity; and other user needs.

There are many factors of prostheses that could affect clinical results. This study aims to better understand the relationship between socket rigidity and clinical results.

Methods

In this study, we used a compression testing machine to test and quantify the rigidity of two different socket types. Hanspal Socket Comfort Scores and functional outcome measures of volunteer participants who were fit with those same two socket types were recorded as outcome measures.

Material Testing Methods

Material properties of four standard-of-care conventional laminated sockets and two Infinite Sockets or dynamic modular sockets were studied and measured.

The four conventional laminated sockets were comprised of two transfemoral suction sockets and two transtibial pin-lock sockets fabricated by two different reputable and independent central fabrication facilities. These sockets included vacuum-formed flexible inner liners and carbon fiber with thermoset acrylic resin composite frames. They were ordered with a request for standard fabrication for a 200-pound user with moderate activity level.

The two dynamic modular sockets tested consisted of one Infinite Socket TF C1 with suction suspension and one Infinite Socket TT with pin-lock suspension from LIM Innovations. These dynamic modular sockets were engineered to have an appropriate modulus of elasticity that was derived from extensive stress testing and user testing. The orders for the Infinite Sockets were requested to accommodate a 200-pound user with moderate activity level. The same CAD file was made to order all of the transfemoral sockets and all of the transtibial sockets, respectively.

Overall socket rigidity or socket compliance was measured with a socket rigidity testing apparatus that included a testing jig, mold, and compression testing machine. The compression testing machine is able to apply forces while measuring and recording resultant forces. The testing jig, which was made to isolate the rigidity of the sockets being tested, included a ½-inch-thick steel plate, a ½-inch steel chain, a steel pulley wheel, and a ½-inch stainless steel cable. The same transfemoral and transtibial molds were used across all different socket types. The molds were made with plaster and reinforced with steel and a 2-inch square steel mandrill. The molds were made such that the roll-on gel liners were included and pin-lock and suction suspension were respectively achieved.

Figure 1
The socket rigidity testing apparatus used to test socket rigidity

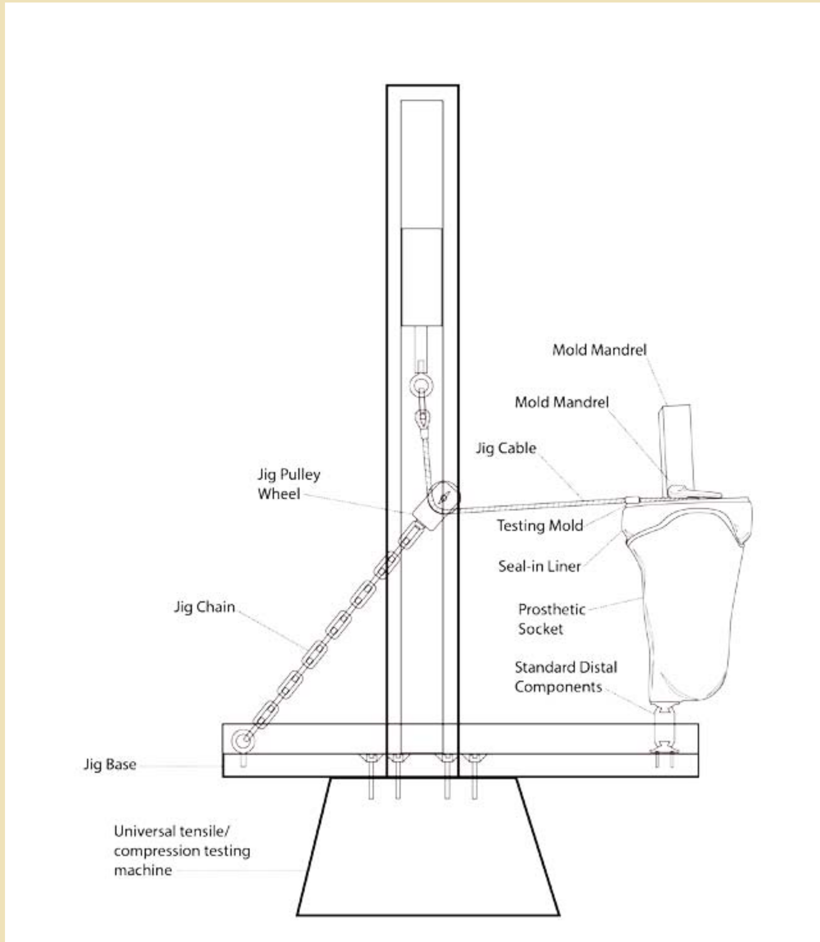


Figure 2

One of the conventional laminated sockets in the socket rigidity testing apparatus

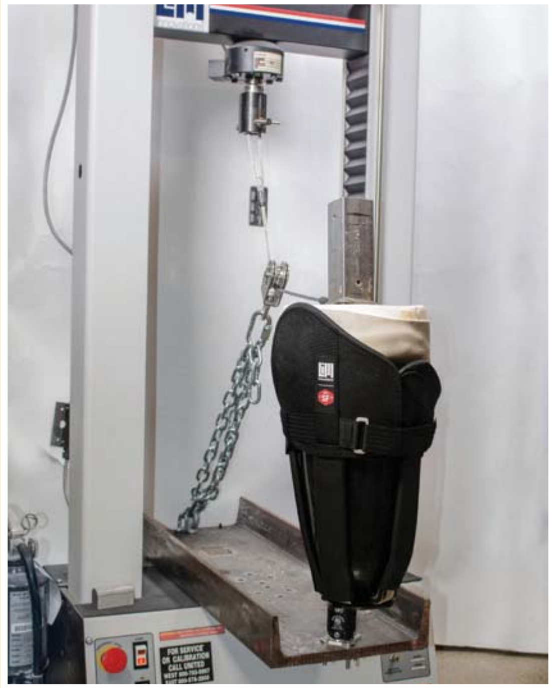


Figure 3

The Infinite Socket TF C1 that was tested in the socket rigidity testing apparatus

Forces were applied to the sockets in four different directions (anterior, posterior, medial, and lateral) and at different maximum loads between 20 pounds and 150 pounds.

Socket materials testing also included testing of individual materials included in the sockets. These materials were tested for their durometer, modulus of elasticity, tensile modulus, and flexural modulus. Tests like the three-point bend test with the compression testing machine were used to measure the results. Materials tested include thermoset composites, thermoplastic composites, thermoplastics, 3-D-printed polyurethane plastic, urethane foams, and various textile materials.

Outcome Measures Methods

Outcome measures were collected from amputees using the same types of prosthetic sockets that were measured in the material testing: Infinite Sockets or dynamic modular sockets compared to conventional laminated sockets. There were 177 amputees who volunteered to participate in this associated study. The volunteer participants were fit at 30 different independent prosthetic service providers. Users included for this study used the same distal components for both socket types. The outcome measures data were statistically analyzed and written up by independent researchers.

Outcome measures were scheduled to be collected immediately after fitting, at two weeks after fitting, and at six months after fitting, but the reporting intervals did vary per user availability and compliance. Participants reported Hanspal Socket Comfort Scores and were tested for functional outcome measures at intervals after being fit with the different socket types. The functional outcome measures used were the L-test, the two-minute walk test, and the four-square step test.

Results

Material Testing Results

Socket compliance results showed the Infinite Socket to be significantly less rigid than the standard-of-care conventionally laminated sockets tested.

Testing for individual materials with the different sockets tested showed a larger variation in elastic modulus or stiffness and a greater number of elastic modulus increments for the Infinite Sockets as compared to the conventionally laminated sockets. The individual materials tested were consistent with the testing results of the entire socket in that the materials in the Infinite Socket were generally less rigid than those of conventional laminated sockets.

The quantities of overall socket rigidity and individual material properties are proprietary to LIM Innovations, but we can see from Figures 4 and 5 that there is a significant difference in rigidity between socket types.

The inherent compliance of the mold with respect to the socket is expected to affect results in the lower portion of the force versus displacement curve. After the mold settles into maximum yield position, the flat portion of the force versus displacement curve demonstrates the socket rigidity.

Outcome Measures Results

Volunteer participants reported significantly better Hanspal Socket Comfort Scores for the less stiff Infinite Socket as compared to conventionally laminated sockets (7.64 ± 2.00 vs. 4.52 ± 2.22, p<0.0001).

Additional Socket Comfort Score results:

- 2.4 percent of participants gave their conventional laminated socket a Hanspal Socket Comfort Score greater or equal to 8 out of 10, compared to 35.4 percent when wearing the Infinite Socket.
- 46.5 percent of participants rated their conventional laminated sockets less than or equal to 4 out of 10 compared to 5.5 percent for the Infinite Socket.

Twenty-six of the volunteer participants performed functional outcome measures in both conventional sockets and the Infinite Socket. For the 26 participants who performed functional outcome measures, results were improved for the two-minute walk test (108.80 ± 31.28 vs. 101.53 ± 33.96, p=0.007) and the four-step square test (17.01 ± 12.14 vs. 21.57 ± 18.52, p=0.005). There was no statistically significant difference in the L-test (30.98 ± 27.51, 36.31 ± 45.64, p=0.246).

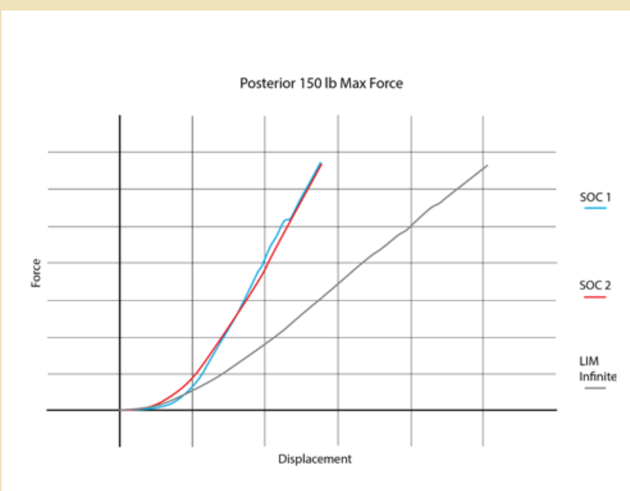
The number of participants who performed functional outcome measures was low relative to the number that reported Socket Comfort Scores. We believe that the relatively low participation in functional outcome measures was due to the added time required to perform these tests and the limited availability of the users and/or prosthetist.

Conclusions

The Infinite Socket is significantly less rigid than the conventionally laminated sockets that were tested. Clinical outcome measures for the Infinite Socket were superior to those of conventionally laminated sockets for the population of amputees that volunteered to participate in the study. More specifically, Hanspal Socket Comfort Scores improved significantly while maintaining or improving functional outcome measures with use of an Infinite Socket as compared to a conventional laminated socket.

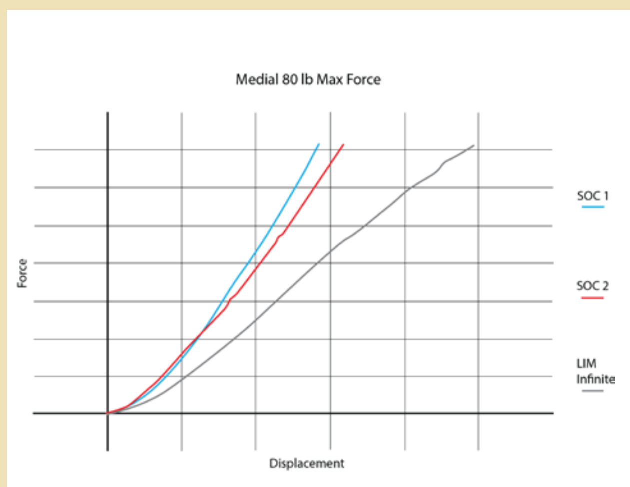
There are many quantifiable differences between the Infinite Socket and the conventional laminated sockets tested, and between other socket types as well. Therefore, these results do not prove that lower rigidity correlated with better clinical outcomes. That being said, we believe that standard-of-care

Figure 4



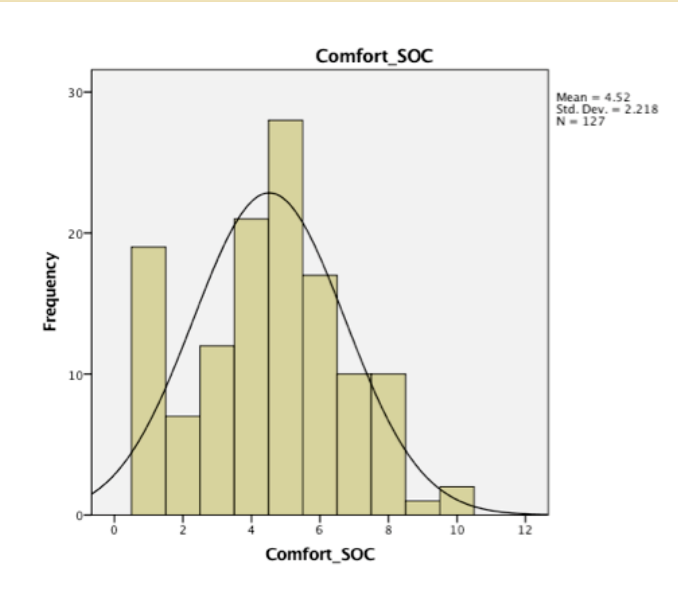
Force versus displacement with a posteriorly directed force on the socket. The two standard-of-care conventionally laminated sockets that were tested are in blue and red. The Infinite Socket tested is in grey. The maximum load in this case was 150 pounds.

Figure 5



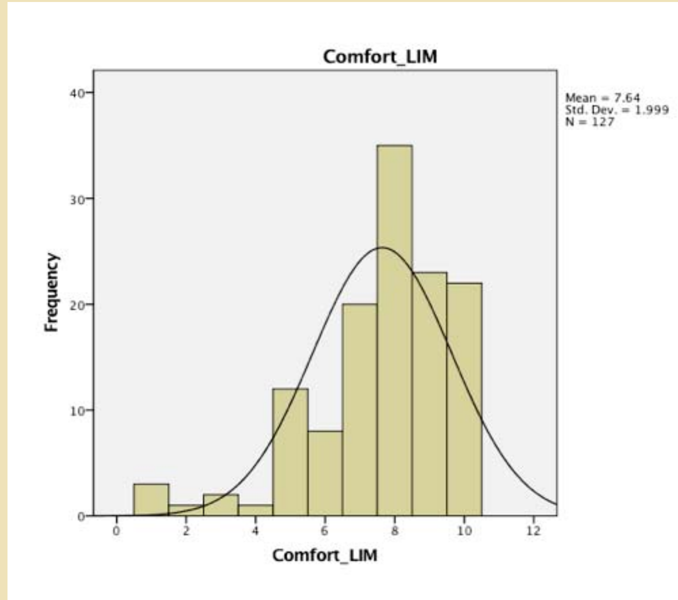
Force versus displacement with a medially directed force on the socket. The two standard-of-care conventionally laminated sockets that were tested are in blue and red. The Infinite Socket tested is in grey. The maximum load in this case was 80 pounds.

Figure 6



Socket comfort scores reported by the volunteer participants for their standard-of-care conventional laminated socket

Figure 7



Socket comfort scores reported by the volunteer participants for their Infinite Socket

conventional laminated sockets are more rigid than they need to be. The results of this study support the possibility that users could benefit from the Infinite Socket or sockets engineered to have more optimized rigidity.

Further research should be conducted by independent researchers to validate or invalidate these findings.

Significance

Whether ordering a socket or fabricating a socket, prosthetists should closely consider and study the optimal materials and amount of rigidity within the prosthetic sockets they make for their patients. Providing prosthetic sockets that are durable (in both fatigue and peak stress), adjustable, low profile, lightweight, and easy to use, and have the optimal amount of rigidity, is certainly not an easy task. Additionally, foot selection and knee programming should take into account socket construction and additional components. It's a good thing that we are all the "best prosthetists" in the world so that we may evolve past the current standard of care. O&P

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