# COMPARATIVE OBSERVATIONAL STUDY – BLIND TEST HYDROSTATIC CASTING VS. OTHER RESIDUAL LIMB IMPRESSION METHODS

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## INTRODUCTION

Hydrostatic casting while bearing full body weight is an alternative to other casting impression methods in providing for transfemoral and transtibial amputees. Previous studies related to the new method have shown positive results in regard to the patient's acceptance, the limited number of necessary corrections and the high amount of successfully produced sockets [2]. For this study, the application and fit of the sockets in relation to kinesic behavior, proprioception, the mastering of a distance and the length of distance, as well as the patient's subjective perception were examined and the results were compared to other residual limb impression methods.

## METHODS

In an observational study during the period of July 8 – 16, 2019, three different residual limb impression casting methods for producing prosthetic sockets were compared.

- **Manual (hand molding)**
  Here, the production of a prosthetic socket is mainly a result of handcraft by the orthopedic technician. By making a plaster impression of the residual limb and its measurement, followed by functional model modification, a positive model of the prosthetic socket is produced. This takes place in a sitting position and the residual limb is in a relaxed and unencumbered state. A thermoplastic test socket is thus produced, by means of a deep-drawing process. After trying on the test socket, it must be modified until an acceptable wearing comfort level is reached and the fit is considered correct from orthopedic, medical and biomechanical points of view.

- **Optical scanning / CAD tracer** (using currently available optical scanning systems)
  Using a 3D scanner, the residual limb is captured by a hand scanner while in a relaxed state and reproduced digitally. The scan result is followed on the monitor in real time. With the aid of CAD software which was especially developed for these tasks, the scanned model is then processed on the monitor. Process steps, as well as modifications, can be reversed and tracked digitally on the monitor, according to need.

- **Hydrostatic cast impression** (using the Symphonie Aqua VC TT, Version 2019)
  For the first time ever, the Symphonie Aqua System enables one to capture the load locus of the residual limb within the prosthetic socket under actual conditions and to produce an accurately fitting plaster impression while bearing full weight. Due to the hydrostatic pressure, the sensitive areas, bony structures, pressure and pain points, as well as scar

tissue on the residual limb are clearly recognized. The plaster impression and the subsequent socket consequently adapt and fit to the anatomy of the residual limb.

As control samples, a total of seven transtibial amputee patients were chosen (2 females, 5 males), aged 20 to 70 years, in varying states of physical condition. Three of the study participants were amputated on the left side, four on the right side. Every day, each patient had three residual limb impressions made, using the three various methods (manual, optical scan and hydrostatic.) In order to avoid distortion, all study participants had differing amputation times and a faultless residual limb situation, without pressure marks or sores. Participants at the so-called K2 level are “limited outside area walkers” and have the ability to overcome lower obstacles, such as curbs, steps or uneven surfaces. Patients at the K3 level are “unlimited outside area walkers” and are also able to move about at varied and faster speeds.

**Table 1: Patients**

| Nr. | Gender | K-Level | Side | Length of residual limb in centimeters<br><br>1 inch = 2.54 cm | Type |
|---|---|---|---|---|---|
| 1 | M | K2 | L | 7,00 | Suction |
| 2 | F | K3 | R | 4,75 | Vacuum |
| 3 | F | K2 | L | 5,00 | Suction |
| 4 | M | K2 | R | 7,50 | Suction |
| 5 | M | K3 | L | 6,25 | Suction |
| 6 | M | K3 | R | 8,50 | Vacuum |
| 7 | M | K3 | R | 6,00 | Suction |

The patients were cared for by three experienced orthopedic technicians. For the subsequent testing of the trial sockets, the subjects underwent a blind test. This means that they did not know which impression method was used for the trial sockets. In producing the trial socket, the manual impression method and the optical scan method were reworked, as is the usual case. However, the impression made by the hydrostatic Symphonie Aqua System was not reworked and the plaster negative was immediately applied for production of the socket.

Following production of the trial sockets with three different impression methods, a comparison was made regarding volume, as well as testing for standing up and walking. Following this, the patients were also asked about the different trial sockets.

## RESULTS

1. The comparison of volume showed that the hydrostatically produced sockets had a larger volume than those produced by both the manual impression method and the optical scanning method. For this measurement, the sockets were filled with a predetermined volume of water. Subsequently, the water level between the central ground mark on the inside and the upper edge was measured. On average, the water level for prosthetic sockets produced by the manual method was 11.05 cm; for sockets produced by the hand scanned method was 11.78 cm; the sockets produced by the hydrostatic method was 10.84 cm. It was further ascertained that the hydrostatically produced sockets did not necessitate the use of residual limb socks for compensation purposes, despite the larger volume. Rather, the fit and adhesion were exactly reproduced, according to the subjects and technicians.

2. In a further (stand up and walk) test, the time was measured for patients to stand up from a sitting position and walk a predetermined distance, followed by returning to the starting position and sitting down. Per patient, this test was conducted twice, consecutively. The results showed that significantly less time was needed for the hydrostatic socket, compared to the sockets produced by the other methods. The hydrostatic socket had an average time measurement of 9.12 seconds, the manual socket – 14.06 seconds, and the scanned socket – 11.55 seconds (see tables 2-4.)

3. Additionally, a walk and distance test was conducted. Each test subject had to cover a distance having the same ground conditions and without obstacles, in order to see how far they could walk in two minutes. This test revealed that the subjects using the hydrostatic socket were able to walk a significantly longer distance in two minutes than with the other sockets. The sockets produced by the hydrostatic method averaged 91.0 m per two minutes, while the compared sockets averaged 85.5 m and 88.3 m, respectively. (See tables 2-4.)

**Table 2: Hydrostatic impression system**

| Stand up and walk test 1 in seconds | Stand up and walk test 2 in seconds | Walk and distance test in meters | Patient |
|---|---|---|---|
| 15.60 | 15.10 | 70.70 | 1 |
| 10.80 | 10.40 | 114.60 | 2 |
| 31.30 | 22.50 | 61.60 | 3 |
| 10.60 | 11.50 | 75.60 | 4 |
| 13.80 | 12.90 | 86.60 | 5 |

| | | | |
|---|---|---|---|
| 7.60 | 7.40 | 137.10 | 6 |
| 12.00 | 9.60 | 90.80 | 7 |

**Table 3: Manual method**

| Stand up and walk test 1 in seconds | Stand up and walk test 2 in seconds | Walk and distance test in meters | Patient |
|---|---|---|---|
| 16.30 | 16.40 | 63.40 | 1 |
| 10.00 | 10.60 | 123.10 | 2 |
| 37.60 | 39.40 | 36.50 | 3 |
| 12.20 | 12.10 | 72.50 | 4 |
| 13.40 | 13.70 | 91.70 | 5 |
| 7.30 | 7.50 | 126.70 | 6 |
| 10.40 | 10.30 | 84.70 | 7 |

**Table 4: CAD optical scanner**

| Stand up and walk test 1 in seconds | Stand up and walk test 2 in seconds | Walk and distance test in meters | Patient |
|---|---|---|---|
| 13.50 | 13.20 | 72.50 | 1 |
| 10.00 | 9.80 | 122.00 | 2 |
| 31.20 | 27.90 | Patient did not participate | 3 |
| 10.50 | 9.80 | 92.00 | 4 |
| 10.20 | 10.40 | 90.20 | 5 |
| 7.20 | 7.20 | 141.40 | 6 |
| 10.50 | 10.80 | 100.50 | 7 |

## CONCLUSION

In a comparative test, the hydrostatically produced sockets exhibited a larger volume, enabled the patients to stand up, walk and sit down faster, as well as to cover a longer distance within a given time period. Patients and orthopedic technicians justified this by referring to the considerably better fit and adhesion of the prosthetic socket. This enables, for example, unhampered standing up due to lack of sensitive pressure and pain points, as well as faster and better motion with the prosthesis. Patients also specified an improved control of movement and increased proprioception. Moreover, the subjects reported that the distance coverage test was felt to be less strenuous with the hydrostatically produced socket and was accompanied with less fatigue. All of the study participants felt distinctly more comfortable in the hydrostatically fitted prosthetic socket and “blindly” voted for this in the results. On the part of orthopedic technicians, it was emphasized that in comparison to other impression taking systems, reworking was not necessary and technicians do not need several years of experience. Additionally, the hydrostatic impression system leads to results that are significantly more reliable and reproducible.


**Image 1: Symphonie Aqua VC TT**

## REFERENCES

1. Motus Research LLC, Jeff Denune, Indianapolis; in cooperation with Indiana University, August 2019

2. Cutti AG et al, Clinical effectiveness of a novel hydrostatic casting method for transfemoral amputees: results from the first 64 patients, O&P News, September-October 2018