Comparison of Pressure Profiles Between Hand Casted Patellar-Tendon Bearing Sockets and Pressure Casted Hydrostatic Sockets in Persons with Unilateral Transtibial Amputation

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Clinical Question: Do pressure casted hydrostatic sockets improve pressure profiles compared to hand casted patellar-tendon bearing (PTB) sockets in patients with unilateral transtibial amputation?

Background: In 2005, it was estimated that 623,000 people in the United States live with a major lower limb amputation.[1] For patients with unilateral transtibial amputations, successful outcomes are highly dependent upon the fit and comfort of the prosthetic socket.[2] With over half of all users experiencing moderate to severe pain while wearing a prosthesis, users report socket comfort as the most important feature of their prosthesis.[2] The prosthetic socket acts as the interface between the patient's limb and the prosthesis, thus, achieving optimal socket fit can be challenging due to the uniqueness of each person's limb and variability of traditional hand casted socket methods.[3] It is known that the successful fit of a prosthetic socket is highly contingent on the skill and experience of the prosthetic practitioner.[4] This is particularly true in developing counties where access to trained practitioners is limited.[4] Pressure casting systems are less dependent on practitioner training and have been advocated to offer improved socket shape consistency[5] leading to increased quality control, reduced production time and reduced costs.[6] To evaluate the fit of sockets made with pressure casting systems, multiple studies have compared the interface pressure profiles of hand casted PTB sockets to pressure casted hydrostatic sockets.[7-10] The purpose of this CAT is to evaluate the existing literature on pressure profiles of hydrostatic sockets compared to PTB sockets in patients with unilateral transtibial amputations.

Search Strategy:
Databases Searched: PubMed, Google Scholar
Search Terms: (artificial limb [Mesh Major Topic] OR "prosthetic socket" OR "hydrostatic socket") AND (cast OR "casting" OR "impression" OR "pressure casting" OR "socket shape" OR fabricat*) AND (pressure)
Inclusions/Exclusion Criteria: 1999- Present, English

Synthesis of Results: Four studies compared pressure profiles of hand casted PTB style sockets and hydrostatic sockets using pressure data from a total of 63 individuals with unilateral transtibial amputations.[7-10] The studies included an interrupted time series trial,[7] a before and after trial,[8] a case control trial[9] and a secondary analysis using Finite Element Analysis (FEA).[10] Small sample sizes[7-10] and variability in testing procedures [7-10] make it difficult to draw clinical conclusions from the results. Three studies[7,8,10] used water-based pressure systems with full[7] or partial[8] weight bearing and one study[9] used a non-weight bearing air-pressure based system. In-built pressure transducers[8] in-situ transducers[7,9] and FEA[10] were used for measuring and predicting pressures at the limb/socket interface. Two[7,10] of the four studies found consistently lower overall pressure magnitudes in hydrostatic sockets during ambulation with one[9] study showing slightly higher magnitudes and one[8] study showing mixed results during ambulation, but lower pressure magnitudes during static testing. All four[7-10] studies found more uniform distribution, with less variation of pressure values in the hydrostatic sockets compared to PTB sockets. Three[7-9] of the studies were human subject design with low sample sizes which make it difficult to generalize any of the results to the overall transtibial amputee population. All of the studies used different methods to analyze pressure distributions and three[8-10] of the studies did not account for differences in alignment, which can greatly influence the results.

Clinical Message: Preliminary research shows that pressure casted sockets provide generally more uniform pressure profiles than hand-casted sockets with lower peak pressure values during ambulation. The results indicate that pressure casting techniques may be a viable alternative to traditional hand casting and have the potential to produce more comfortable sockets for patients with unilateral transtibial amputations. Further studies are needed involving larger sample sizes to determine the clinical viability of pressure casted sockets.

Evidence Table:

	Convey and Buis, 1999 [7]	Goh et al., 2004 [8]	Dumbleton et al., 2009 [9]	Moo et al., 2009 [10]
Population	Number of subjects: 1 Demographics: Male Cause: Trauma Age: 37 Limb length: not specified	Number of subjects: 4 Demographics: Male (4) Cause: PVD (1), Trauma (3) Mean Age: 40 Mean limb length: 13.1 cm	Number of subjects: 48 Demographics: Male (40); Female (8) Cause: PVD (12), other (36) Mean Age: 50.04 Mean limb length: 14.1 cm	Number of subjects: 10[11] Demographics: Male (10) Cause: PVD (5), Trauma (4), Other (1) Mean Age: 56.90 Mean limb length: 13.9 cm
Location	National Centre for Training and Education in Prosthetics and Orthotics, University of Strathclyde, Glasgow, Scotland, UK	Department of Orthopedic Surgery, National University of Singapore, Singapore	National Centre for Training and Education in Prosthetics and Orthotics, University of Strathclyde, Glasgow, Scotland, UK	Department of Biomedical Engineering, University of Malaya, Kuala Lumpur, Malaysia
Intervention	Hydrostatic socket casted with modified Ice-Cast Pressure Cylinder. Water- pressure Weight bearing with 100% of body weight.	Hydrostatic socket casted with PCast System Water-pressure Weight bearing with 50% of body weight.	Hydrostatic socket casted with Ice-Cast Compact casting system Air-pressure Non-weight bearing	Scanned model of hydrostatic socket casted with PCast System Water-pressure Weight bearing not specified
Comparison	Hand casted PTB style socket with single-ply sock[12]	Hand casted PTB style socket with unique number of socks for each subject; The same number of socks were worn for both socket types	Hand casted PTB style socket with Pelite liner.	Scanned model of hand casted PTB style “hard” socket with unspecified number of socks, suspension sleeve and no liner
Study Design	Interrupted Time Series Trial	Before and after trial	Case control trial	Secondary data analysis using Finite Element Analysis.
Inclusion Criteria	Not specified	Unilateral transtibial amputation for at least 5 years prior to study	Unilateral transtibial amputation for at least 1 year prior to study and have been wearing current prosthesis for at least 6 months	Not specified
Relevant Outcome	Dynamic interface pressures	Static and dynamic interface pressures	Dynamic interface pressures	Dynamic interface pressures.
Outcome Measures	4 in-situ Tekscan FSR transducer arrays with 350 individual sensing points placed at anterior, posterior and medial walls; Pressure data and walking velocity recorded simultaneously with force plate outputs	16 in-built strain-gauge type pressure transducers connected to a 3D motion analysis system and force platforms	4 in-situ Tekscan transducer array with 350 individual sensing points with synchronized video recording	Finite Element Analysis applied to secondary data collected from four types of transducers: patellar tendon transducer, bioengineering sheer transducer, pressure load cell device and electrohydraulic

				transducer; 14 transducers in the PTB socket and 15 in the pressure cast socket; Pressure data applied to Finite element analysis socket model
Key Findings	Dynamic pressures were more evenly distributed and lower in hydrostatic socket; Higher localized pressures recorded in hand casted socket.	Hydrostatic socket exhibited similar or lower pressure values to PTB during static testing. During dynamic testing, only one subject exhibited similar pressure profiles between both sockets; Hydrostatic sockets exhibited lower pressure ranges except for one subject; Static ML pressure profiles were similar	Dynamic pressure distributions slightly higher for hydrostatic sockets with less variation in pressure than PTB socket; Distribution of pressure is consistent between PTB sockets and hydrostatic sockets; No significant differences found during stance phase between two groups	Pressure distribution is relatively uniform in hydrostatic socket without drastic changes throughout stance phase; Pressure magnitudes are lower in the hydrostatic socket; PTB socket showed higher peak values
Key Limitations	Single subject; low statistical power; In-situ transducers do not account for shear stress	Small sample size; all male subjects; in-situ transducers do not account for shear stress; Did not account for differences in alignment	Pressure casting method is non-weight bearing and considerably different than other casting systems compared; Foot type and differences in alignment not considered in the analysis	Data was pooled from secondary analysis; methods unclear; In-built transducers may have altered socket shape and pressure measurements; Source data represent average of 10 trials using a PTB socket, these data were then applied to PTB and hydrostatic models.
Study Quality	Low	Medium	Medium	Low
Conclusion	Both the socket types demonstrated distinct and different pressure profiles when compared on a single subject.	Each of the four subjects experienced unique pressure profiles when testing both socket types. Other factors such as alignment, residual limb shape, muscle strength and foot type should be considered when evaluating pressure profiles.	Pressure distributions were similar between both socket types. Higher overall pressures but smaller variations in interface pressures recorded for the hydrostatic sockets	Hydrostatic socket model was found to exhibit more uniform pressure profile and lower pressure magnitudes than hand casted socket model

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