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Titel
Initial results of a clinical study with trauma forefoot amputees: Comparison of gait parameters wearing a customized carbon and a silicon prosthesis.

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Zusammenfassung
Kinematic and kinetic data were collected on patients using an eight-camera 3D motion analysis system and an instrumented treadmill. Patients wearing the carbon prosthesis showed an increased walking speed, a reduced step length difference, a lowered CoP-shift and a restored forefoot lever.

Einführung/Grundlagen
Partial forefoot amputations (PFA) are mainly caused by diabetes and cardiovascular diseases, while only a minority is linked to traumatic events (fig. 1). In 2015, the German federal bureau of statistics registered 51 cases of trauma caused amputation affecting the foot or ankle. Existing prostheses and orthoses cover mainly cosmetic aspects, but do not consider the biomechanics necessary for the use of these devices for sports activities. This greatly affects the patient’s daily life. Adequate industrial devices for partial foot amputees are not available. A customized forefoot prosthesis (fig. 2) for trauma patients made of carbon fiber composite was evaluated. The customized prosthesis takes the following individual patient parameter into account: body weight, tibia length, level of amputation, level of mobility. Every supply has the goal of restoring the forefoot lever arm and enabling the patient to be reintegrated into the everyday sport (e.g. walking or running).

Methodik
Trauma patients with partial foot amputation (Lisfranc and Chopart) were recruited based on selection protocol. Anatomical and anthropometric data were collected on five individuals (3 male and 2 female). The mean ± standard deviation (SD) age, stature, and mass were 44.25 ± 6.75 years, 1.72 ± 0.08 m, and 74 ± 9.22 kg. All patients used a standard silicone

prosthesis (SP, fig. 1) and a customized prosthesis (CP, fig. 2). Kinematic data were collected using an eight-camera three-dimensional motion analysis system (Simi Motion, Munich). An instrumented treadmill (zebris GmbH, Isny) was used to generate kinetic parameters (e.g. vertical ground reaction force (vGRF). Data acquisition was performed on the treadmill at a patient-selected walking speed, using a full-body marker setup. Three trials were recorded for each treatment (standard and customized prosthesis).

Durchführung

Temporal and spatial parameters were improved (tab. 1). Four out of five patients showed an increased walking velocity by 0.4 ± 0.1 km/h, while the duration of the gait cycle remained almost consistent for both treatments. Patients showed an average of 50% improved symmetry of the step length between the affected and the sound limb. No changes in the period of swing and stance phase and in the single and double-limb support were detected. The shift of the center of pressure (CoP) towards the center of the body (fig. 3) could be achieved in each patient. While patients with the silicone prosthesis do show a moderate toe off, the forefoot lever in patients treated with the customized prosthesis could be restored in all five patients. Figure 4 shows a representative diagram (blue curve) of the vertical ground reaction force (vGRF). The symmetry of the hip and knee angle of the healthy limb could be improved in the patients treated with the customized carbon prosthesis compared to the affected limb.

Fazit

The purpose of this work was an initial evaluation of a customized forefoot prosthesis for patients with PFA. Patients achieved correspondingly improved gait parameters. No significant abnormalities were observed in the period of stance and swing phase while using the customized, respectively the standard prosthesis. For all patients, the CoP could be shifted closer towards the center of the body. Major differences were recorded during middle and terminal stance (vGRF). Using the customized prosthesis, the forefoot lever arm could be restored. Also, the symmetry in hip and knee angles could be increased while performing different activities. However, the results presented have to be seen as an interim report and require a final evaluation at the end of the study. A Long-term monitoring is also under preparation.

Literaturreferenzen

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Fig. 1 Characteristic PFA (Lisfranc joint line) and silicone prosthesis standard treatment

Fig. 2 Novel customized prosthesis

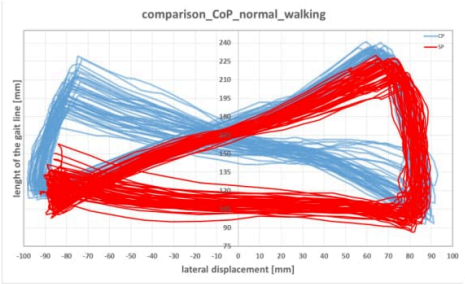

Fig. 3 Representative comparison of the CoP using silicone (SP) and customized prosthesis (CP)

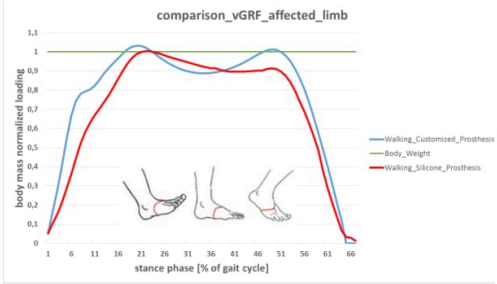

Fig. 4 Normalized vGRF using silicone (red) and customized prosthesis (blue)

Tab. 1 Temporal and spatial values gained during walking, using the silicon (SP) and carbon prosthesis (CP)

Subject	Level	Treat-ment	Cadence (step/min)	Step Length (cm)		Velocity (m/s)
				Affected Limb	Sound Limb	
S1	Cho-part	SP	105,05 ±1,53	63,09 ±1,80	70,08 ±1,60	4,19 ±0,08
		CP	108,63 ±1,51	65,58 ±1,49	71,41 ±1,35	4,51 ±0,07
S2	Lis-franc	SP	111,61 ±1,49	67,47 ±1,13	57,30 ±1,10	4,21 ±0,06
		CP	103,53 ±2,19	61,61 ±1,67	56,20 ±1,74	3,65 ±0,07
S3	Lis-franc	SP	92,9 ±1,59	60,48 ±0,95	68,89 ±1,26	3,10 ±0,06
		CP	101,67 ±1,97	68,08 ±1,76	62,67 ±1,90	4,00 ±0,06
S4	Cho-part	SP	96,7 ±1,86	68,89 ±2,40	66,32 ±2,44	3,9 ±0,07
		CP	97,0 ±2,18	77,11 ±2,38	68,18 ±2,81	4,19 ±0,08
S5	Lis-franc	SP	93,09 ±1,94	57,06 ±1,87	46,16 ±1,38	2,90 ±0,05
		CP	90,40 ±2,59	59,51 ±1,82	48,40 ±1,91	3,00 ±0,05