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Title
Clinical outcome of transfemoral direct socket interface (Part 2)

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Summary
Direct Socket (DS-TF) for transfemoral prosthesis users is a novel interface fabrication process. The study aims to investigate if prosthetic users quality of life, comfort, and mobility with a DS-TF interface is comparable to their experience with their previous prostheses.

Introduction/ basics
Amputation at the transfemoral (TF) level reduces the rate of successful prosthetic fitting, functional outcome, and quality of life (QoL) compared with transtibial amputation. The TF socket interface is considered the most critical part of the prosthesis, but socket discomfort remains the most common user complaint. Traditional socket fitting timelines are comparatively long (1), and prosthetic users would benefit from more expeditious fitting (2). A meager body of published evidence surrounds TF interfaces; therefore, CPs have less evidence to guide their practice. (3) Investigations assessing the advantages and disadvantages of available socket designs are few and lack randomized controls. (3) The DSTF enables a prosthetist to fabricate a custom-made interface directly on the residual limb in a single visit (4). In this way, plaster or foam model intermediates, which only approximate the limb shape, are eliminated.

Material method; implementation/ process
The pre/post design prospective cohort study included 47 (33 male,14 female) prosthesis users representing K-levels 1-4. From this cohort, 36 subjects completed the 6-month follow-up (27 males).

The subject inclusion criteria were as follows: TF amputation >1 year ago, bodyweight 50-166Kg, currently using a prosthesis with a prosthetic liner, cognitive ability to understand all instructions and questionnaires, limb length #20 cm from ischium to the distal end, and limb circumference 40-65cm near the perineum. Data collection included seven outcome measures;

EQ-5D-5L®, PLUS-M™, CLASS, ABC, AMPPRO, OPUS, and TUG. Subjects completed seven baseline outcome measures using their existing interface. Each subject was fitted in a single visit with a custom fabricated DS-TF. On the day of fitting, subjects completed TUG (as an objective measurement) and CLASS (as a subjective measurement) with their new DS-TF interface. Subjects repeated all outcome measures at 6-weeks, and 6-months follow up.

Results

Of the initial 47 subject cohort, 36 participants completed the entire 6-month follow-up (6MFU; 27 men and 9 women: mean age 58.2 years (38-81 years). Nine subjects dropped out of the study or did not return for follow-up. Results showed significant improvement in all outcome measures for the 36 subjects that completed follow-ups (Figure1). In addition, improvement in K-Level and less use of assistive devices were observed with the AMPPRO instrument. The AMPPRO mobility means score at baseline was 38 (SD=6.0). Scores increased to 40 (SD=5.4) at 6WFU and remained at 40 (SD=5.5) at 6MFU (Figure 2).

In addition, QoL increased, as measured in Quality-Adjusted-Life-Years (QALY) from the EQ-5D-5L. The EQ-5D-5L® mean utility score was 0.75 using the existing prosthesis at baseline (SD=0.18). Life quality increased significantly to 0.82 (SD=0.15) at 6WFU and 0.84 (SD=0.12) at 6MFU. The CLASS mean overall score improved significantly from 74% at baseline with the existing interface to 86% on the day of fitting with DS-TF. This improvement was maintained during the follow-up period (Figure 3).

Discussion/ conclusion; conclusion for the practice

Few studies have investigated QoL changes using QALY instruments in the prosthetics field. However, EQ-5D-5L® mean utility scores among DS-TF users in this study cohort show improved QoL, reaching a level similar to the US norm population of 0.85 (5). Results reveal multifaceted improvements in the comparatively large study cohort (n=47), representing a relatively normal transfemoral prosthesis user population, and across a comparatively long investigational period (6 months). The AMPPRO mean scores significantly increase from 38 at baseline to 40 at 6MFU. The cohorts mobility improvements were manifested in K-Level increases, reduced dependency on assistive devices, and the combination thereof. Notice the cohorts distribution on the graphs in Figure 2 shift in a positive direction toward increased

mobility from baseline to 6MFU. That a socket replacement could have a significant impact on K-level was an unexpected but enlightening outcome. The CLASS outcomes after 6-months showed improvement in all subscales indicating increased user satisfaction with interface stability, suspension, and appearance (Figure 3). Evidence from the findings demonstrates that DS-TF can be a good alternative to traditional prosthetic interface delivery. Expediting the fitting timeline is beneficial for patient rehabilitation; however, sacrificing quality to gain speed is unacceptable.

References

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Image: Figure 1 Full Cohort Spider diagram_168.png

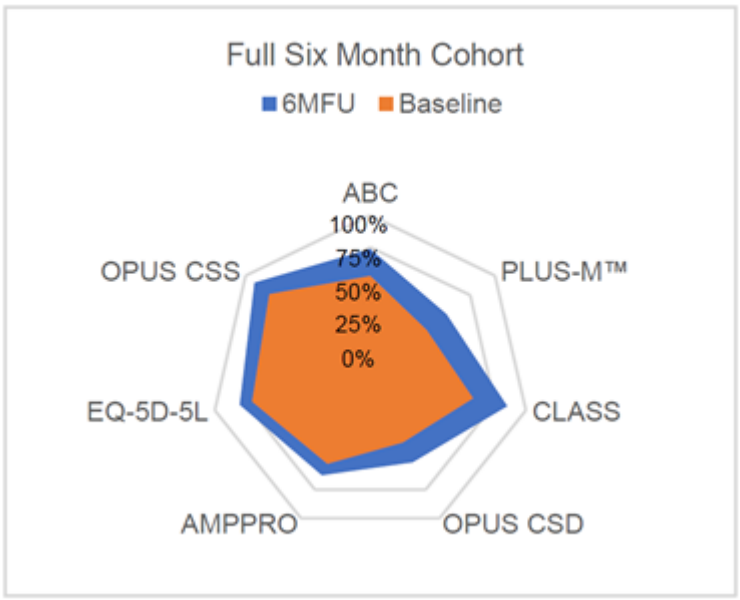

Image: Figure 2 K-Level Bar Graph_169.png

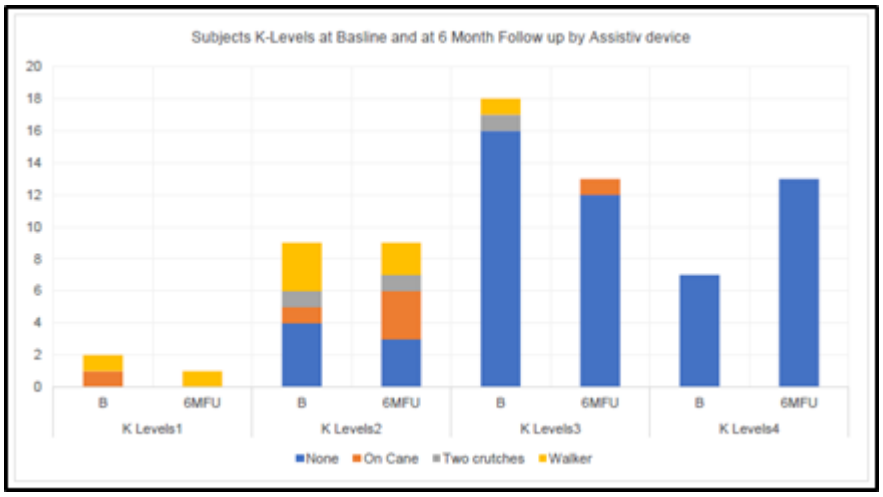

Image: Figure 3 Class score_170.png