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Title

Transfemoral Socket Fabrication Method Using Direct Casting: Outcomes Regarding Patient Satisfaction With Device and Service

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Summary

Direct Socket prosthetic socket is a unique, efficient and effective method of providing a prosthetic interface. This interface is fabricated directly on the residuum thus requiring specific training to understand and effectively fabricate the interface directly on the residuum.

Introduction/ basics

Direct Socket for transfemoral (DS-TF) prosthetic interface system is a unique, efficient and effective method of fabricating a laminated interface directly on the residuum.

Specialized training is required to understand the clinical requirements, concepts and process to effectively and safely use this system. The service model is significantly different and more efficient than most traditional prosthetic processes and may improve patient satisfaction by enabling interface fabrication and delivery in one visit.

This study was conducted to evaluate patient satisfaction of the interface and the service associated with the TF-DS system as compared to more traditional methods.

Material method; implementation/ process

: In this longitudinal study (from July 2018 to April 2020), the DS-TF was implemented in six prosthetic clinics across the United States. Certified prosthetists (CP) and assistants were trained using a standard protocol. 47 prosthetic users participated, both those in need of a new socket and those without need. Two modules from the Orthotics and Prosthetics Users' Survey (OPUS), involving questions related to satisfaction with the Device and Services, was used to evaluate each DS-TF user outcome vs. baseline. The only part of the prosthesis that was replaced was the interface, except in 2 cases.

Results

. Each DS-TF interface was fabricated, fit and delivered in a single clinic visit. At 6-months follow-up, 38 users reported an average of 29.8% increase in satisfaction with their new interface compared with original, and a 14.8% increase in satisfaction with the services they received from the clinic in providing of the new prosthesis vs. their original prosthesis. The main outcome increases were between baseline (initial fitting) and 6-week follow-up and remained consistent after 6 months. This improvement was consistent irrespective if the user needed a new socket for clinical reasons or not.

Discussion/ conclusion; conclusion for the practice

OPUS CSD questions related to the function of the interface for all subjects indicate a significant improvement in user satisfaction with their DS-TF interface over their previous interface in terms of weight, comfort, donning, appearance, durability, and reduced clothing wear and tear. Results also showed significantly improved satisfaction regarding skin abrasions and irritation, as well “pain free to wear”. All improvements were consistent between the 6-week and 6-month study periods. At 6MFU the average CSS score was 93, or 14.8% higher, a significant improvement compared with baseline.

One might think that amputees who need a new socket for clinical reasons may be more dissatisfied with their existing socket than amputees who do not need a new socket for clinical reasons and might therefore be more inclined to show greater satisfaction improvement with a new prosthesis than the subjects who did not need a new interface. To identify this potential influence, all completed subject data was analyzed together, as well as broken into two separate cohorts- “with clinical need of new interface” and “without clinical need of new interface

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Image: TD DS Material Kit and socket_203_203.jpg



Image: TF DS IRB outcome article 1_204_204.jpg

| | Baseline | 6 Week Follow Up | 6 Month Follow Up |
|---|------------------------------------|------------------------------------|------------------------------------|
| Number of subjects | 47 | 40 | 38 |
| Average age (years) | 59 | 58 | 58 |
| K-levels | 4 K1, 11 K2, 21 K3, 11 K4 | | |
| Needed new interface for clinical reasons | 34 | 29 | 28 |
| Outcome measure | OPUS Device & Service Satisfaction | OPUS Device & Service Satisfaction | OPUS Device & Service Satisfaction |

Image: TF Ds Irb Outcome graph pic 2_205_205.jpg

| | Baseline Previous Socket | 6 Week Follow Up On DS-TF | 6 Month Follow Up On DS-TF | Change Baseline to 6 MFU |
|---------------------------|--------------------------|---------------------------|----------------------------|--------------------------|
| OPUS Device Satisfaction | 46 +/-1.9 | 60 +/-2.2 | 61 +/-2.5 | 33% +/-3.8 (p<0.001) |
| OPUS Service Satisfaction | 82 +/-3.0 | 90 +/-2.2 | Similar to 6WFU | 10% +/-2.9 (p=0.018) |