ÖSSUR®
LIFE WITHOUT LIMITATIONS

DIRECT SOCKET TF

Comfort & confidence

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Functional outcome and quality of life are the main challenges with regards to successful prosthetic socket fitting. The socket interface is considered the most critical part of the prosthesis, with socket discomfort still being the most common prosthetic user complaint. Direct Socket is a novel interface fabrication process where the socket is shaped and laminated directly on the residual limb, aimed at maximizing the patient outcome and quality of life.

Direct Socket is a standardised, amputee-centric socket solution for amputees of all activity levels. It enables prosthetists, O&P Clinics and their business owners to consistently provide end users with a high quality, correctly fitting, tailored prosthesis.

The process and socket solution are designed to **increase user satisfaction** through improved outcomes such as **improved comfort, function and confidence**.

During the fabrication process, a specific casting liner is rolled onto the residual limb, followed by application of a protective silicone sheath. Next, the prosthetist places a size-specific silicone brim at the proximal part of the limb. A fiberglass or basalt fabric with a pre-attached 4-hole distal adapter is then rolled on the length of the limb.

An additional protective sheath is applied on the outside of the fabric, and a two-part resin is injected through the distal adapter. The resin saturates the fiber, and then it hardens and cures. After 10-15 minutes it has cured enough to be removed. Finally, the socket is prepared to be connected to the knee and foot.

The brim is made of flexible silicone and laminated to the socket during this process, making the socket flexible proximally, while most of the socket is rigid.

The flexible silicone brim **encompasses and compresses the proximal thigh muscles** when contracted, thereby stabilising the hip at **initial contact, loading response, mid-stance, and terminal-stance** while creating axial and transverse stabilisation.

During swing phase, the brim only follows the hip movement.

See page 7 for a visual representation of the process.

View more videos and tutorials on our YouTube channel:
www.youtube.com/ossuracademy

STUDY OUTLINE

In 2020 and 2021 two research articles* were published. The aim of the prospective cohort studies, conducted by seven Certified Prosthetist (CP) at six different sites, was to investigate prosthetic users' satisfaction with device and services, quality of life (QoL), comfort, and mobility with a Direct Socket TF interface.

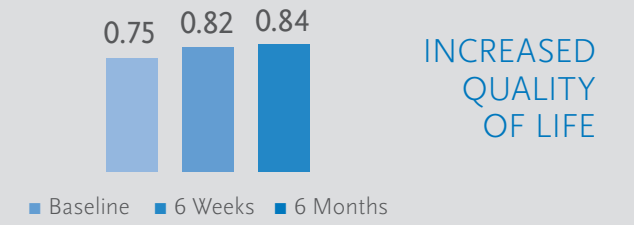
Methodology

The pre/post design prospective cohort study included 47 subjects. From this cohort, 36 subjects completed the 6-months follow-up (mean age 58 years, 27 males). Outcomes at baseline included EQ-5D-5L®, PLUS-M™, CLASS, ABC, AMPPRO, and TUG. At 6-weeks and 6-months, subjects repeated all measures. Seven Certified Prosthetist (CP) investigators performed observations and data collection at six different sites (from July 2018 to April 2020).

STUDY RESULTS*

Quality of life

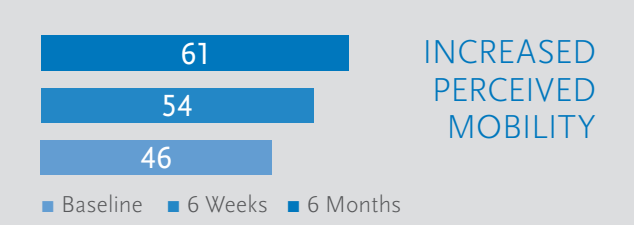
With the EQ-5D-5L® questionnaire, the quality of life of an amputee can be measured. Based on 5 dimensions - mobility, self-care, usual activities, pain/discomfort and anxiety/depression - an indicator for the health state of the amputee is calculated. This test was done 6 weeks and 6 months after the amputees being fitted with a Direct Socket TF.



This indicates that the average Direct Socket TF users in this study cohort significantly improved their quality of life and reached a level similar to the US norm population of 0.85.

Mobility

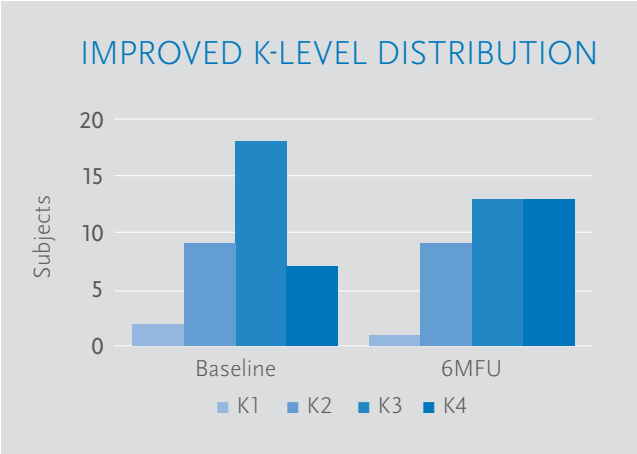
To measure the perceived mobility of the prosthetic user with a Direct Socket TF, the PLUS-M™ test was performed. 12 questions about mobility and the ability to do certain activities with or without any difficulty, indicate the perceived mobility of the prosthetic user.



"Patient satisfaction and the outcomes are so valuable for me as a prosthetic user. It's very nice to see that my clinic acts upon that. It requires a **good relationship between the patient and the CPO**, good communication and a clean, tidy and up to date facility which offers the best possible solutions.

I'm very happy with the result and I can now move freely without pain or discomfort. When I don't have to deal with that, **I can focus on what is really important; doing my daily activities and living a normal life.**" – Asa, female, Direct Socket TF user

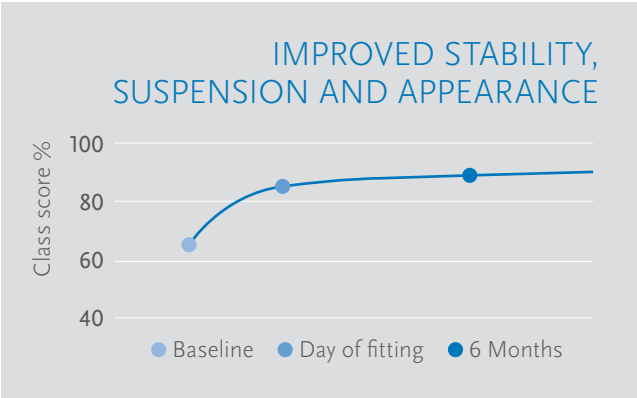
To assess the amputee's mobility and existing or potential functional ambulation an AMPPRO test was conducted. The test consists of 21 tasks, classified into four categories: sitting balance, simple mobility, standing balance, and gait and functional activities. The total score ranges from 0 to 47 points and higher scores indicate better mobility. **K1 = 15-26 points, K2 = 27-36 points, K3 = 37-42 points and K4 = 43-47 points.**



Stability, suspension and appearance

The Comprehensive Lower-limb Amputee Socket Survey is an outcome measurement tool that reports the function of the prosthetic interface. The CLASS score is represented on a 0-100% scale with 100% indicating excellent satisfaction.

The outcomes after 6 months showed improvement in all subscales indicating increased user satisfaction with interface stability, suspension, and appearance, which means that the improvement was maintained during the follow-up period.



Satisfaction

The Orthotics and Prosthetics User's Survey (OPUS), a set of 21 self-reported outcome measures, was used for the assessment of functional status, quality of life, and client satisfaction. From the five independent modules, two of which were used in this study: Client Satisfaction with Device (CSD) and Client Satisfaction with Services (CSS).

29.8% INCREASE IN SATISFACTION WITH INTERFACE AFTER 6 MONTHS

The study also showed that clinical need did not affect the measure, meaning that regardless of the user needing a new socket, there was a significant increase in satisfaction with the new socket.

14.8% INCREASE IN SATISFACTION WITH SERVICE

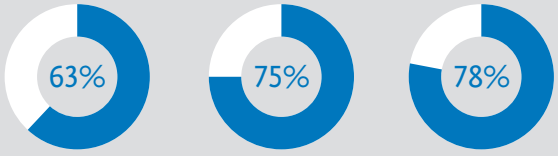
The main outcome increases were between the initial fitting and the 6-week follow-up and remained consistent after 6 months. This improvement was consistent irrespective if the user needed a new socket for clinical reasons or not.

To summarise, this study shows that after a standardised training and implementation, the Direct Socket TF fabrication process including a new interface improves the user's satisfaction with their prosthetic device and services.

Balance confidence

The Activities Based Confidence indicator quantifies 'individuals' confidence in their ability to perform 16 activities of daily living by rating confidence from 0% (no confidence) to 100% (complete confidence) for each activity.

BALANCE CONFIDENCE



Existing prosthesis | Direct Socket 6 Weeks | Direct Socket 6 Months

STUDY RESULTS*

Risk of falling

The TUG test measures a number of tasks that are essential for an amputee's mobility, such as standing up from a seated position, walking, turning, and sitting down on the chair. A lower limb prosthetic user who takes more than 19 seconds to complete the TUG indicates an increased risk of falling.

The results from the TUG test showed that Direct Socket TF significantly improved the time it took to perform the test.

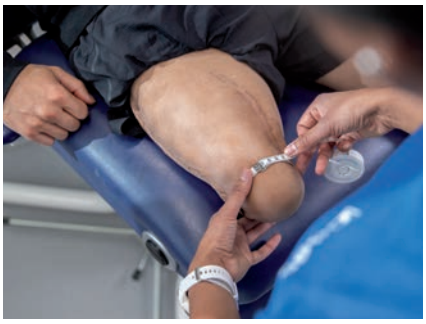
SIGNIFICANTLY IMPROVED TEST TIME

The way this new socket was made enables a user to always have **the best possible solution**. – Luc, male, Direct Socket TF user

CONCLUSION

Study results* showed significant improvement in all outcome measures for the 36 subjects that completed both 6-weeks and 6-months follow-ups. CLASS sub-scales showed significantly improved stability, suspension, comfort, and socket appearance. The PLUS-M and APMPPRO tests indicated an improved mobility when using a Direct Socket TF. In addition, the improvement in K-Level and less use of assistive devices were observed with the AMPPRO instrument, indicating improved user mobility and performance. The quality of life of the amputees also increased, as measured in Quality-Adjusted-Life-Years (QALY) from the EQ-5D-5L test. Finally, Direct Socket improves the user's satisfaction with their prosthetic device and services.

DIRECT SOCKET TF CASTING PROCESS



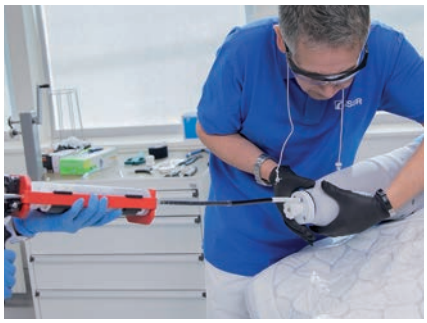
1. Residual limb examination
The residual limb is examined, and the patient is asked about possible discomfort or sensitive areas. Measurements are taken for liner and brim.

2. Casting liner
A locking liner is used for the manufacturing process of the Direct Socket, but multiple suspension systems are still possible when the socket is ready.

3. Silicone insulation sheet
The first silicone insulation sheet is pulled over the liner and a silicone cap seals the end.

4. Flexible silicone brim
A flexible silicone brim is put in place to create a comfortable upper edge of the socket.

5. Basalt fiber braids
Multiple layers of glass/basalt/carbon braid are placed over / rolled over the residual limb one by one.



6. Resin injection
The second silicone insulation sheet is pulled over the braids. After that, the resin is injected and moved up over the entire socket area.

7. Final result
After 10 minutes curing time, the socket is taken off, grinded and the full prosthesis assembled. The socket can be fit.

8. Training
The prosthesis is handed over to the patient, and training can start.

REFERENCES

Marable W.R, Smith C, Sigurjónsson B.Þ, Atlason I.F, Johannesson G.A. Transfemoral socket fabrication method using direct casting: outcomes regarding patient satisfaction with device and services. Canadian Prosthetics & Orthotics Journal. 2020;Volume 3, Issue 2, No.6.

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