

Every year the number of diabetic patients increases, what results in more limb amputations every year. Due to bad blood circulation in the systems of these patients, their veins and tissues get damaged. Mostly the tissues in the furthest limbs get damaged, resulting in wounds on their toes, feet and ankles, also called ulcers. These wounds can get infected when a patient does not notice them in an early stage. Not feeling these wounds has to do with numbness in the toes, what is a common side effect of diabetic foot syndrome. When antibiotics are not sufficient anymore to heal the wounds, surgery or even amputation is needed for these people. Diabetic foot syndrome is the main reason for amputations among the population. Due to increasing numbers of diabetic patients, the demand for preventing aids raises.

PROCS B.V. and BAAT Medical Products B.V. developed a foot orthosis to help the patients by preventing wounds. This foot orthosis is currently made of silicone and gives support to the feet of the patient. On the sole extra support is given, to prevent ulcers, to improve the blood circulation of the patients and to decrease the pressure points on the feet. Most diabetic patients also suffer from hammertoes. Here the toes are crooked resulting in the use of incorrect pressure points. The orthosis makes sure that this will be rectified.

Now the problem is that these orthoses are handmade to each individual patient and only locally available, with a long waiting time. To be able to help as many patients as possible the production method needs to be improved. By making it a production process, the producing can be speed up and it can easily be repeated worldwide. Besides it should lower the cost price to fit within the range of the reimbursement to make it widely more available.

Within the research there is looked into the values of the current orthosis to form a requirements list. Different production methods with their accompanying materials are researched. This resulted in testing two types of processes which enable patient specific orthosis; 3D printing and casting. With these methods three types of elastic materials were found interesting; silicone, TPU and a composite material. To compare the possible processes and materials, test plans are written according to the requirements list. During this research the following tests were executed: compression, pull, surface finish, friction, cleaning and casting test. For some tests the wished value was known due to the currently used product. Other tests values were found within the research. All tests were executed in the workshop of BAAT Medical Products B.V..

From the results of these tests conclusions can be drawn whether the examined processes and materials are fitting for this application. It is concluded that both 3D printing and casting are suitable processes, both processes are applicable with silicone. It is expected that the TPU could also be a fitting material, but due to COVID-19 this material was not delivered in time. The effect of adding a pattern into the sole of the orthosis was also tested. This decreased the local stiffness and thus compression of the orthosis as expected. From the tested materials silicone was the best fit and the processes both had different improvement points. But what all materials showed was hysteresis, here the loaded path differed from the unloaded path. This is unwanted for this application since it needs to withstand loading and unloading frequently. When a patient is walking the material gets compressed (loaded path) and then tries to re-form to its original shape (unloaded path). Since this process gets repeated within a short time, it is important to check that hysteresis has no negative implications for the long haul. Besides the hysteresis test, different patterns need to be tested since the theoretical values clashed with the found values. Furthermore the friction test has to be redone differently, since there were too many variables within the test results. It is important to achieve a minimum friction coefficient, because shear force is one of the main reason for ulceration. More recommendations are written for improving the processes and

materials to make sure it is the best fit for the new production process of the current foot orthosis.