**Mechanics** 

# **Projection of Orthopedic Supinators Considering the Loads on Locally Over-Pressure Areas**

## Merab Shalamberidze<sup>\*</sup>, Zaza Sokhadze<sup>\*\*</sup>, Malvina Tatvidze<sup>§</sup>

\*Department of Design and Technology, Akaki Tsereteli State University, Kutaisi, Georgia \*\*Department of Mathematics, Akaki Tsereteli State University, Kutaisi, Georgia \$Department of Chemical Technologies, Akaki Tsereteli State University, Kutaisi, Georgia

(Presented by Academy Member Guram Gabrichidze)

The paper introduces the processes of projecting the individual orthopedic supinators for patients with diabetic foot syndrome considering the loads on locally over-pressure areas. Twenty patients with diabetic foot syndrome were involved in the research. For examination of the patients' feet the pedograph method was used. Geometric forms for the over-pressure areas of the foot plantar part were recorded on the pedograms by curved lines. The curved lines were described by means of singular Dirichlet boundary value problem for differential equations of integral lines. By the use of a certain integral the areas of locally over-pressure areas were calculated and the loads on those areas were determined. EVA polymers of different stiffness were used to make individual orthopedic supinators. Individual orthopedic supinators were made on the computer controlled machine, considering the loads on the over-pressure areas. Trial use of supinators shows positive results. The outcomes of the research are especially important for treatment of the patients with diabetic foot syndrome.  $\bigcirc 2021 Bull. Georg. Natl. Acad. Sci.$ 

Orthopedic supinators, diabetic foot, differential equations

Given the bio-mechanics of human movement, the lower limbs and feet are the basis of musculoskeletal system, whose slightest deviation from the anatomical and physiological norms causes disorder of the whole structure. Functional disorders of the musculoskeletal system are often associated with various deformities of the feet. The situation is much more complicated in patients with diabetes mellitus and diabetic foot syndrome. According to the World Health Organization (WHO) and the International Federation of Diabetes (IDF), 6% of the world's population has diabetes mellitus, in about 70-80% of which the so-called diabetic foot syndrome develops over time.

Improper distribution of loads on the plantar part of the foot and wearing of uncomfortable shoes cause trauma to locally over-pressure areas of the feet in diabetic patients. Due to loss of pain sensation the patients cannot notice the foot traumas. Infection penetrates the wound through the damaged skin and the so-called diabetic foot syndrome develops. After a certain period of time, the limb gangrene develops

followed by amputation. After amputation of one limb, the load on the other leg increases, which is an additional risk factor for development of gangrene on the other limb against the background of existing diabetes and its complications.

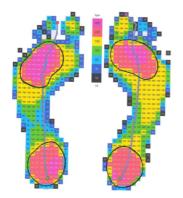


Fig. 1. Foot pedogram.

While walking the foot performs difficult mechanical movements and the skeletal system of the foot as well as the soft tissues are under heavy load. Especially, the plantar part of the foot, particularly the heel and metatarsophalangeal (MTP) joints are under heavy load. In some cases the local load on these areas reaches 400-450 kPa, which is 2.5 times higher than the norm, and appears to be the provoking factor of additional pathological changes in patients with diabetes and diabetic foot syndrome. The skin maceration, bruises, calluses, ulcers and other pathological changes develop on the locally overpressure areas of the plantar part of the foot, which are unnoticed due to diminution/loss of pain, temperature and tactile sensations. The injured areas of the feet are easily infected and a diabetic ulcer develops. Diabetic foot ulcers, gangrene and amputation cause great harm to patients' health, lower quality of life and lead to premature disability. Treatment of diabetic foot using individual orthopedic remedies is a proven method, which is reflected in the works of many scientists [1-8].

The use of individual orthopedic foot protectors for prevention and treatment of patients with diabetes mellitus, especially the patients with diabetic foot syndrome, is absolutely necessary, which has no alternative.

Given this problem, the goal of our work is to study the patients with diabetic foot syndrome and protect them from further complications. To achieve that goal, a pedograph study of the feet of patients with diabetic foot syndrome was conducted, based on which individual orthopedic supinators were designed and manufactured taking into account the loads on the areas of locally over-pressure areas.

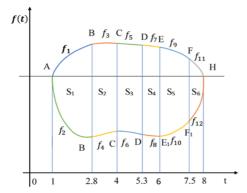
The study involved 20 patients who were diagnosed with: type 2 diabetes mellitus, diabetic angiopathy, diabetic peripheral sensorimotor neuropathy, diabetic foot. All patients had an initial stage of ulcer on the plantar part of the foot, namely on the heel and toe joints.

Pedograph studies of patients with diabetic foot syndrome were performed on Novel pedograph Emed-25 at/D (Germany).

The supinators for diabetic foot syndrome patients were made individually based on pedograph examination data. For production of orthopedic supinators the combination of ethylene vinyl acetate copolymers (EVA polymer) of different stiffness were used.

The paper presents the results of the pedograph research of one of the patients' foot (Fig. 1). The analysis of the pedogram shows that the main load falls on the heel and metatarsophalangeal joints of the

plantar part of the foot. The areas marked red on the pedogram are locally over-pressure areas with the load of 200 kPa and above.



**Fig. 2.** Geometric form of the line of locally over-pressure area at the metatarsophalangeal joint area of the plantar part of the left foot.

The locally over-pressure areas on the pedogram were marked by lines. Geometrical forms of those lines were built by means of singular Dirichlet boundary value problem for differential equations of integral lines [9-12].

To describe the shape of the line shown in Fig. 2, it was preliminarily divided into twelve parts. Each numbered section was described by means of the integral lines of solutions to the differential equations given below. Of the integral lines the twelve parts identical to the geometric forms of locally over-pressure area at the metatarsophalangeal joint area of the plantar part of the left foot were selected, namely:

1. AB curve corresponds to that part of the solution of equation

$$f_1(t) = \left(-\frac{1}{3} - \frac{1}{3}c\right)t + \frac{1}{3}c\frac{1}{t^2} + \frac{2}{3}t + \frac{t^2}{2} + \frac{t^4}{6}$$

for which c = 0 and corresponds to the set of  $[-1,7; -0,8] \times [-2,4; 2]$ 

i.e. 
$$f_1(t) = -\frac{1}{3}t + \frac{2}{3}t + \frac{t^2}{2} + \frac{t^4}{6} = \frac{t^4}{6} + \frac{t^2}{2} + \frac{1}{3}t$$

2. BC curve corresponds to that part of the solution of equation

$$f_3(t) = \left(-\frac{1}{3} - \frac{1}{3}c\right)t + \frac{1}{3}c\frac{1}{t^2} + \frac{2}{3}t + \frac{t^2}{2} + \frac{t^4}{6},$$

for which c=1 and corresponds to the set of [0,6; 2,3]×[4,1; 0,55]

i.e. 
$$f_3(t) = -\frac{1}{3}\frac{1}{t^2} + \frac{2}{3}t + \frac{t^2}{2} + \frac{t^4}{6}$$

3. CD curve corresponds to that part of the solution of equation

$$f_5(t) = \left(-\frac{1}{3} - \frac{1}{3}c\right)t + \frac{1}{3}c\frac{1}{t^2} + \frac{2}{3}t + \frac{t^2}{2} + \frac{t^4}{6},$$

for which c=1 and corresponds to the set of [2,7; 2,1]×[2,7; 4]

i.e. 
$$f_5(t) = -\frac{1}{3}\frac{1}{t^2} + \frac{2}{3}t + \frac{t^2}{2} + \frac{t^4}{6}$$

4. DE curve corresponds to that part of the solution of equation

$$f_{7}(t) = \left(-\frac{1}{3} - \frac{1}{3}c\right)t + \frac{1}{3}c\frac{1}{t^{2}} + \frac{2}{3}t + \frac{t^{2}}{2} + \frac{t^{4}}{6},$$

for which c=1 and corresponds to the set of  $[0,5; 8,05] \times [0,47; 8,55]$ 

i.e. 
$$f_7(t) = -\frac{1}{3}\frac{1}{t^2} + \frac{2}{3}t + \frac{t^2}{2} + \frac{t^4}{6}$$

5. EF curve corresponds to that part of the solution of equation

$$f_9(t) = \frac{t^3}{2} - \frac{1}{3}c\frac{1}{t^2} - \left(1 - \frac{1}{3}c\right)t + \frac{1}{2},$$

for which c=0 and corresponds to the set of  $[-1,5; -0,8] \times [-1,1; 0,9]$ 

i.e. 
$$f_7(t) = \frac{t^3}{2} - t + \frac{1}{2}$$

6. EH curve corresponds to that part of the solution of equation

$$f_9(t) = \frac{t^3}{2} - \frac{1}{3}c\frac{1}{t^2} - \left(1 - \frac{1}{3}c\right)t + \frac{1}{2},$$

for which c=5 and corresponds to the set of  $[-2,5;-0,9] \times [-4,8;-0,95]$ 

i.e. 
$$f_7(t) = \frac{t^3}{2} - \frac{5}{3}\frac{1}{t^2} + \frac{2}{3}t + \frac{1}{2}$$

7. AB1 curve corresponds to that part of the solution of equation

$$f_2(t) = \left(-\frac{1}{3} - \frac{1}{3}c\right)t + \frac{1}{3}c\frac{1}{t^2} + \frac{2}{3}t + \frac{t^2}{2} + \frac{t^4}{6},$$

for which c=1 and corresponds to the set of [-2,3; 6,1]×[-1.05; 1.5]

i.e. 
$$f_2(t) = -\frac{1}{3}\frac{1}{t^2} + \frac{2}{3}t + \frac{t^2}{4} + \frac{t^4}{6}$$

8.  $B_1C_1$  curve corresponds to that part of the solution of equation

$$f_4(t) = \frac{t^3}{2} - \frac{1}{3}c\frac{1}{t^2} - \left(1 - \frac{1}{3}c\right)t + \frac{1}{2}$$

for which c=0 and corresponds to the set of [-0,3; 0,9]×[-0,5; 0,1]

i.e. 
$$f_4(t) = \frac{t^3}{2} - t + \frac{1}{2}$$

9.  $C_1D_1$  curve corresponds to that part of the solution of equation

$$f_6(t) = \frac{t^3}{2} - \frac{1}{3}ct^{-2} - \left(1 - \frac{1}{3}c\right)t + \frac{1}{2},$$

for which c=0 and corresponds to the set of  $[2,1; 3,8] \times [1,8; 1,9]$ 

i.e. 
$$f_6(t) = -\frac{1}{3t^2} + \frac{2}{3}t + \frac{t^2}{2} + \frac{t^4}{6}$$

10.  $D_1E_1$  curve corresponds to that part of the solution of equation

$$f_8(t) = \left(-\frac{1}{3} - \frac{1}{3}c\right)t + \frac{1}{3}c\frac{1}{t^2} + \frac{2}{3}t + \frac{t^2}{2} + \frac{t^4}{6}$$

for which c=1 and corresponds to the set of  $[-0,5;10,4] \times [-0,45;11,8]$ 

i.e. 
$$f_8(t) = -\frac{1}{3}\frac{1}{t^2} + \frac{2}{3}t + \frac{t^2}{2} + \frac{t^4}{6}$$

11. E<sub>1</sub>F<sub>1</sub> curve corresponds to that part of the solution of equation

$$f_{10}(t) = \left(-\frac{1}{3} - \frac{1}{3}c\right)t + \frac{1}{3}c\frac{1}{t^2} + \frac{2}{3}t + \frac{t^2}{2} + \frac{t^4}{6},$$

for which c=5 and corresponds to the set of  $[-0,8; 0,1] \times [-0,5; 2,6]$ 

i.e. 
$$f_{10}(t) = -\frac{4}{3}t + \frac{5}{3}\frac{1}{t^2} + \frac{t^2}{4} + \frac{t^6}{4}$$

12. F<sub>1</sub>M curve corresponds to that part of the solution of equation

$$f_{12}(t) = \frac{t^3}{2} - \frac{1}{3}ct^{-2} - \left(1 - \frac{1}{3}c\right)t + \frac{1}{2},$$

for which c=0 and corresponds to the set of  $[-0,45; 0,9] \times [-1,8; -0,1]$ 

i.e. 
$$f_{12}(t) = \frac{t^3}{2} - t + \frac{1}{2}$$

Using a computer programe the mentioned lines were rotated and joined, on the basis of which the geometric form of locally over-pressure area at the metatarsophalangeal joint area of the plantar part of the left foot was obtained, which is an exact analogy to the circle shown in Fig. 2.

Thus, based on the use of pedograph, mathematical, and computer programming research methods, the complex geometric form of the locally over-pressure areas presented on the pedogram is described.

An important novelty of the research is that the individual orthopedic supinators should be designed and manufactured with account of the loads on the locally over-pressure areas. To solve the given problem, it is necessary to compute the area of each over-pressure area and the force fallen on it, and then determine the load fallen on the area.

The area of the geometric figure shown in Fig. 2 was computed by means of the defined integral, namely:

$$S_{1} = \int_{1}^{2.8} \left[ f_{1}(t) - f_{2}(t) \right] dt = \int_{1}^{2.8} \left[ \frac{t^{4}}{6} + \frac{t^{2}}{2} + \frac{1}{3}t - \frac{2}{3}t - \frac{t^{2}}{4} - \frac{t^{4}}{6} \right] dt = \int_{1}^{2.8} \left[ \frac{t^{2}}{4} - \frac{t}{3} - \frac{1}{3t^{2}} \right] dt = \left( \frac{t^{3}}{12} - \frac{t^{2}}{6} + \frac{1}{3t} \right) \Big|_{1}^{2.8} \approx 4.8 \text{ cm}^{2}$$

$$S_{2} = \int_{2.8}^{4} \left[ f_{3}(t) - f_{4}(t) \right] dt = \int_{2.8}^{4} \left[ \frac{1}{3t^{2}} + \frac{2}{3}t + \frac{t^{2}}{2} + \frac{t^{4}}{6} - \frac{t^{3}}{2} + t - \frac{1}{2} \right] dt = \int_{2.8}^{4} \left[ \frac{t^{4}}{6} - \frac{t^{3}}{2} + \frac{1}{3t^{2}} + \frac{5}{3}t - \frac{1}{2} \right] dt = \left( \frac{t^{5}}{30} - \frac{t^{4}}{8} - \frac{1}{3t} + \frac{5}{6}t^{2} - \frac{1}{2}t \right) \Big|_{2.8}^{4} \approx 4.2 \text{ cm}^{2}$$

$$S_{3} = \int_{4}^{5.3} \left[ f_{5}(t) - f_{6}(t) \right] dt = \int_{4}^{5.3} \left[ \frac{1}{3}\frac{1}{t^{2}} + \frac{2}{3}t + \frac{t^{2}}{2} + \frac{t^{4}}{6} + t - \frac{1}{2} \right] dt =$$

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$$\int_{4}^{53} \left[ \frac{1}{3t^{2}} + \frac{1}{6}t + \frac{t^{2}}{2} + \frac{t^{4}}{6} - \frac{1}{2} \right] dt = \left( -\frac{1}{3t} - \frac{1}{12}t^{2} - \frac{t^{3}}{6} + \frac{t^{5}}{30} - \frac{1}{2}t \right) \Big|_{4}^{53} \approx 4.7 \text{ cm}^{2}$$

$$S_{4} = \int_{5,3}^{6} \left[ f_{7}(t) - f_{8}(t) \right] dt = \int_{5,3}^{6} \left[ \frac{1}{3}\frac{1}{t^{2}} + \frac{2}{3}t + \frac{t^{2}}{2} + \frac{t^{4}}{6} - \frac{t^{2}}{3} - \frac{2}{3}t - \frac{t^{2}}{2} - \frac{t^{4}}{6} \right] dt =$$

$$\int_{5,3}^{6} \left[ \frac{1}{3t^{2}} - \frac{t^{2}}{12} \right] dt = \left( -\frac{1}{3t} - \frac{t^{3}}{36} \right) \Big|_{5,3}^{6} \approx 3.1 \text{ cm}^{2}$$

$$S_{5} = \int_{6}^{7,5} \left[ f_{9}(t) - f_{10}(t) \right] dt = \int_{6}^{7,5} \left[ \frac{t^{3}}{2} - t + \frac{1}{2} + \frac{4}{3}t - \frac{5}{3}\frac{1}{t^{2}} - \frac{t^{2}}{4} - \frac{t^{6}}{6} \right] dt =$$

$$\int_{6}^{7,5} \left[ -\frac{1}{6}t^{6} - \frac{1}{2}t^{3} - \frac{5}{3}\frac{1}{t^{2}} - \frac{1}{4}t^{2} + \frac{1}{3}t + \frac{1}{2} \right] dt = \left( -\frac{t^{7}}{42} + \frac{t^{4}}{8} + \frac{5}{3t} - \frac{t^{3}}{12} + \frac{t^{2}}{6} + \frac{1}{2}t \right) \Big|_{6}^{7,5} \approx 5.1 \text{ cm}^{2}$$

$$S_{6} = \int_{7,5}^{8} \left[ f_{11}(t) - f_{12}(t) \right] dt = \int_{7,5}^{8} \left[ \frac{t^{3}}{2} - \frac{5}{3}\frac{1}{t^{2}} + \frac{2}{3}t + \frac{1}{2} - \frac{t^{3}}{2} + t - \frac{1}{2} \right] dt =$$

$$\int_{7,5}^{8} \left[ -\frac{5}{3t^{2}} + \frac{5}{3}t \right] dt = \left( -\frac{5}{3t} + \frac{5t^{2}}{6} \right) \Big|_{7,5}^{8} \approx 2.8 \text{ cm}^{2}$$

The total area of the locally over-pressure area at the metatarsophalangeal joint area of the plantar part of the left foot is equal to:  $S = \sum_{k=1}^{6} S_k \approx 4.8 + 4.2 + 4.7 + 3.1 + 5.1 + 2.8 \approx 24.7 \text{ cm}^2$ .

The force fallen on the mentioned area is equal to 781.2 Newtons (according to the data of the pedograph), and the average load of the calculated area is equal to 31.6 N / cm2. The over-pressure area of a part of left foot heel and the locally over-pressure areas of the right foot were described in the same way. The areas were computed, and the loads were determined according to the methods discussed above.

The analysis of the over-pressure areas on the plantar part of the foot shows that the load is quite high and is absolutely inadmissible for patients with diabetic foot syndrome. Based on the studies discussed above and for effective treatment, a combination of soft (for locally over-pressure areas) and relatively stiff (for the main frame of the supinator) materials were selected. Soft materials were selected considering the local loads on the plantar part of the foot. In the process of research, the combination of EVA polymers was used, namely: EVA polymer with the stiffness of 20 Shore A for the over-pressure areas, and EVA polymer with the stiffness of 40 Shore A for the main frame. By means of combination of these materials a healing effect can be achieved.

The complex forms shown in Fig. 2 were made from soft material of EVA polymer of 20 Shore A stiffness on a computer-controlled machine (Ped-Cad, Germany). The mentioned forms were also made for the main frame of the supinator from EVA polymer of 40 Shore A stiffness. In the next step, the ready forms of the locally over-pressure areas were preliminarily glued into the supinator material (frame) and the final form of the supinator was made on the computer controlled machine (Ped-Cad) taking into account the locally over-pressure areas (Fig. 3).



Fig. 3. Individual orthopedic supinators.

Supinators of combined materials were made for every 20 patients involved in the studies and were given to them for trial use. The results of the six-month trial use are as follows: the patients accustomed to the supinators on the very first day, none of the patients reported any unpleasant subjective sensation. The results were monitored every month. After 6 months of trial use of supinators the results were distributed as follows: ulcer was no longer observed in 15 patients, ulcer size significantly reduced in 3 patients, condition was unchanged in 2 patients.

#### Conclusion

Based on pedograph examination of patients with diabetic foot syndrome the locally over-pressure areas of the plantar part of the foot are identified. The lines of complex geometric forms of the over-pressure areas on each patient's pedograms are described by means of solutions to singular Dirichlet boundary value problem for differential equations of integral lines. By means of a definite integral the areas of locally over-pressure areas and the loads falling on those areas are computed. Based on the method of mathematical research an algorithm for describing those lines is worked out, computer programs are developed, and individual orthopedic supinators are made on the computer controlled machine taking into account the locally over-pressure areas. The trial use of supinators show positive results indicating the effectiveness of the study. The latter is especially relevant for treating the patients with diabetic foot syndrome.

The work was fulfilled with the financial support of Shota Rustaveli National Science Foundation of Georgia, Grant FR № 217386.

### მექანიკა

# ორთოპედიული სუპინატორების პროექტირება ლოკალურად გადატვირთული უბნების ფართებზე მოსული დატვირთვების გათვალისწინებით

მ. შალამბერიძე\*, ზ. სოხაძე\*\*, მ. თათვიძე $^{s}$ 

\*აკაკი წერეთლის სახელმწიფო უნივერსიტეტი, დიზაინისა და ტექნოლოგიის დეპარტამენტი, ქუთაისი, საქართველო

\*\*აკაკი წერეთლის სახელმწიფო უნივერსიტეტი, მათემატიკის დეპარტამენტი, ქუთაისი, საქართველო §აკაკი წერეთლის სახელმწიფო უნივერსიტეტი, ქიმიური ტექნოლოგიის დეპარტამენტი, ქუთაისი, საქართველო

(წარმოდგენილია აკადემიის წევრის გ. გაბრიჩიძის მიერ)

სტატიაში წარმოდგენილია დიაბეტური ტერფის სინდრომით დაავადებულთათვის ინდივიდუალური ორთოპედიული სუპინატორების პროექტირების პროცესები ლოკალურად გადატვირთული უბნების ფართებზე მოსული დატვირთვების გათვალისწინებით. კვლევის პროცესში ჩართული იყო დიაბეტური ტერფის სინდრომით დაავადებული 20 პაციენტი. პაციენტების ტერფების კვლევას ვაწარმოებდით პედოგრაფიული მეთოდით. პედოგრამებზე ვარეგისტრირებდით ტერფის პლანტარული ნაწილის გადატვირთული უბნების გეომეტრიულ ფორმებს მრუდი წირების საშუალებით. მრუდი წირების აღწერას ვაწარმოებდით დირიხლეს სინგულარული სასაზღვრო ამოცანის დიფერენციალური განტოლებების ინტეგრალური წირების საშუალებით. განსაზღვრული ინტეგრალის საშუალებით გამოანგარიშებულია ლოკალურად გადატვირთული უბნების ფართები და განსაზღვრულია ამ ფართებზე მოსული დატვირთვები. ინდივიდუალური ორთოპედიული სუპინატორების დასამზადებლად გამოყენებული იყო სხვადასხვა სიმაგრის EVA\_პოლიმერები. პროგრამული მართვის ჩარხზე დამზადებულია ინდივიდუალური ორთოპედიული სუპინატორები გადატვირთულ უბნებზე მოსული დატვირთვების გათვალისწინებით. სუპინატორების საცდელი ტარების შედეგად მიღებულია დადებითი შედეგები. მიღებული კვლევის შედეგები განსაკუთრებით აქტუალურია დიაბეტური ტერფის სინდრომით დაავადებული პაციენტების მკურნალობის პროცესში.

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Received March, 2021