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Исследование клинической эффективности и безопасности нового метода разгрузки у больных с синдромом диабетической стопы – пневмоортеза на голеностопный сустав и стопу TM Orlett

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Цель. *Оценка клинической эффективности, безопасности и потребительских свойств пневмоортеза на голеностопный сустав и стопу HAS-337 TM Orlett и несъемных иммобилизирующих повязок, выполненных по технологии Total Contact Cast (TCC).*

Материалы и методы. *В исследование были включены 40 больных с сахарным диабетом 1 и 2 типа, имеющих нейропатическую форму синдрома диабетической стопы и хронические неинфицированные раны подошвенной поверхности переднего отдела стопы с длительностью существования не менее 3 недель, площадью не менее 1 см² и глубиной не более II стадии по классификации Wagner.*

Первая группа из 20 пациентов получала разгрузку с помощью несъемного пневмоортеза на голеностопный сустав и стопу HAS-337 TM Orlett, во второй контрольной группе из 20 больных разгрузка осуществлялась с помощью несъемного варианта иммобилизирующей повязки TCC. Больные двух групп были сопоставимы по полу, возрасту, длительности и степени компенсации сахарного диабета, а также исходным размерам раневых дефектов (критерий достоверности p>0,05).

Пациенты с инфицированными ранами, остеомиелитом, остеоартропатией Шарко и заболеваниями периферических сосудов были исключены из участия в исследовании.

Исследование продолжалось в течение 6 месяцев. Измерения подошвенного давления проводились всем больным внутри ортеза или иммобилизирующей повязки TCC и были сопоставлены с результатами аналогичных измерений в тестовой обуви. За основные критерии эффективности разгрузки было принято снижение давления в области язвы и всей стопы, а также скорость заживления раны.

Результаты. *К концу шестого месяца было достигнуто полное заживление всех язвенных дефектов. Среднее время заживления составило 46,1±19,0 дней у пациентов первой группы и 48,3±20,5 дней в контрольной группе (p>0,05). В двух случаях ношение пневмоортеза HAS-337 было остановлено по желанию пациента.*

Пневмоортез снижал максимальное пиковое давление на стопу на 26%, а в зонах локализации раневых дефектов – на 57%. Показатель интеграла давление/время снизился в среднем на 41% (p>0,05). Отмечалось возрастание максимального пикового давления на 48% и интеграла давление/время на 47% в среднем отделе стопы.

Заключение. *Пневмоортез HAS-337 является эффективным и безопасным методом разгрузки, приводящим к излечению 100% не инфицированных нейропатических язв подошвенной поверхности переднего отдела стопы. Не рекомендуется использование пневмоортеза HAS-337 для лечения пациентов с локализацией раневых дефектов в среднем отделе стопы и пяточной области.*

Ключевые слова: *сахарный диабет; диабетическая стопа; педография; разгрузочная повязка; ортез на стопу*

Clinical efficacy and safety of a new method for pressure off-load for patients with diabetic foot syndrome: ankle-foot pneumoorthosis with TM Orlett

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Aim. *The purpose of this study was to assess the clinical efficacy, safety and consumer properties of ankle-foot pneumoorthosis with a HAS-337 TM Orlett compared with non-removable total contact cast (TCC) immobilization.*

Materials and methods. *Our study included 40 patients with diabetes mellitus type 1 (DM1) and type 2 (DM2) with neuropathic diabetic foot syndrome and chronic uninfected wounds of the plantar surface of the forefoot, with wound duration of at least 3 weeks, wound areas not less than 1 cm2 and wound depths not more than stage II based on Wagner's classification. We excluded patients with infected wounds, osteomyelitis, Charcot osteoarthropathy or peripheral vascular disease. Our test group included 20 patients who received pressure off-load using ankle-foot pneumoorthosis with a HAS-337 TM Orlett. For a control group (n = 20), pressure off-load was achieved using TCC immobilization. Both groups were comparable with regard to age, gender, duration and degree of diabetes*

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compensation and by original wound defect sizes (p >0.05). The study duration was 6 months. Plantar pressure was measured inside the orthosis or TCC and was compared with test shoe measurements. Our major criteria for pressure relief were reduced pressures in the wound area and the whole foot and the rate of wound healing.

Results. *At the end of the 6-month period, complete healing of all ulcers was achieved. The average healing time was 46.1±19.0 days for the test group and was 48.3±20.5 days for the control group (p >0.05). Two patients who wore pneumoorthosis with HAS-337 were discontinued upon patient request.*

With pneumoorthosis, the maximum peak pressure on the foot and wound defect areas was reduced by 26% and 57%, respectively. The pressure/time integral decreased on average by 41% (p >0.05). Furthermore, in the midfoot area with pneumoorthosis, the maximum pressure increased by 48% and the pressure/time integral increased by 47%.

Conclusions. *Using pneumoorthosis with HAS-337 was an effective and safe method for pressure off-load, resulting in 100% healing of uninfected neuropathic ulcers of the plantar surface of the forefoot. However, pneumoorthosis with HAS-337 is not recommended for those patients with wound defects in the midfoot and heel areas.*

Keywords: *diabetes mellitus; diabetic foot; pedography; pressure relief; ankle-foot orthosis*

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The complete removal of pressure on the wound bed is one of the key requirements for the healing of venous ulcers in patients with diabetic foot syndrome. Pressure off-loading should be continuous as taking even a few steps a day can seriously interfere with neuropathic ulcer healing [1]. A total contact cast (TCC) is the gold standard used for pressure off-load for uninfected ulcers in the plantar foot area without critical ischemia, according to the International Working Group on Diabetic Foot [2]. Non-removable devices that eliminate any dependence on patient compliance and significantly improve the results should be preferred.

A randomized study conducted by Ha Van et al. demonstrated that patient adherence to a pressure off-load regimen increased from 10% among those patients using a removable TCC to 98% among those using a non-removable TCC (p = 0.001) [3]. One of the main mechanisms for reducing pressure off-load for patients with removable casts is that they take significantly fewer steps while wearing a cast than without it (345.3 ± 219.1 versus 873.7 ± 828.0 per day; p < 0.01) [4]. Significant improvements in regimen compliance resulted in an ulcer healing rate of 80% during 12 weeks among patients with non-removable casts versus less than 60% for patients with removable casts. The disadvantages of TCC are the relatively high costs of the bandages used (about 5500 Rubles as of December 2014) and the need for highly trained personnel for TCC application. This has necessitated the search for more affordable alternatives. According to a recent study, only ready-to-wear polymer devices, such as Aircast, Walker, and others, provided equivalents of TCC [6].

Aim

the aim of this study was to evaluate the clinical efficacy, safety and consumer properties of an ankle-foot pneumoorthosis, TM Orlett (Manufacturer: Rehard Technologies GmbH, Germany, model HAS-337).

Materials and methods

In total, 40 patients with diabetes mellitus type 1 (DM1) and type 2 (DM2) were included in our prospective open comparative study. All patients had neuropathic diabetic foot syndrome and chronic uninfected wounds of the plantar surface of the forefoot. Our inclusion criteria were having a wound for no less than 3 weeks, a minimum wound area of not less than 1 cm2 and wound depth not more than stage II on Wagner's scale. All patients provided signed informed consent to participate in this study.

The participants were divided into two groups based on

Fig. 1. TM Orlett ankle-foot pneumoorthosis

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Table 1

Clinical and demographic characteristics of the study participants

Group/Parameter	Test group (orthosis HAS-337 TM Orlett)	Control group (non-removable TCC)
Number of patients (n)	20	20
Age, years	54.1 ± 9.9	49.3 ± 12.0
Gender (F/M)	10/10	9/11
DM1/DM2	3/17	5/15
DM duration (years)	13.2 ± 6.3	15.0 ± 8.9
HbA1c, %	8.4 ± 1.4	9.2 ± 1.3
Weight, kg	87.8 ± 20.11	91.3 ± 15.8
Wound area, cm2	3.02 [1.5; 5.83]	3.87 [2.32; 5.86]
R equivalent, mm	8,75 [6.25; 12.5]	9.7 [6.75; 15.1]
Wound depth, Wagner scale: Stage I Stage II	 4 16	 3 17

Note: There were no statistically significant differences between these groups.

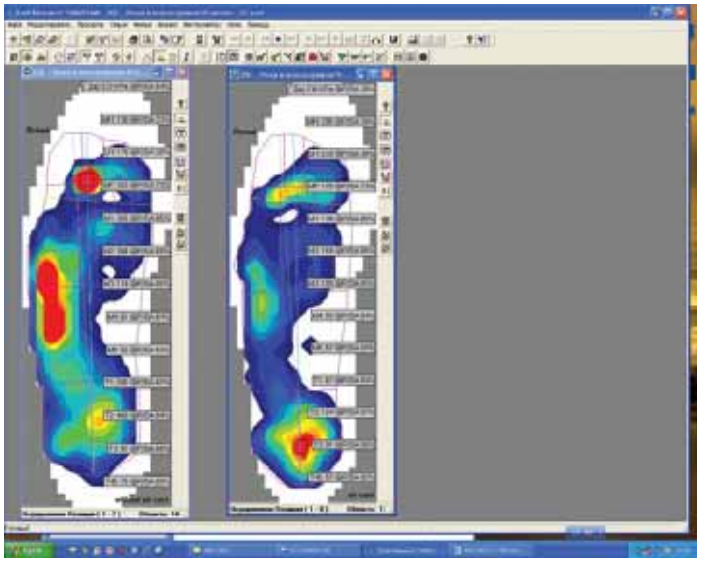

Fig. 2. Graphical representations of pedobarography data in a 2D format

the method used for pressure off-load. Our test group of patients (n = 20) used a TM Orlett ankle-foot pneumoorthosis (Fig. 1) in addition to receiving standard treatment.

Orthosis was fitted and sealed on the first patient visit. Patients were required to wear this device continuously during the study period. The total observation period was 12 weeks (84 ± 2 days). Twelve weekly office visits were scheduled for evaluations. During these visits, wound conditions were evaluated and the wound treatment was provided. Further, the orthosis was put back in place and sealed.

For the control group (n = 20), a non-removable TCC (semi-rigid polymer 'Scotchcast' and 'Softcast' bandages, 3M, USA) was applied according to standard methods used for pressure off-loading [7]. TCC was changed weekly concomitant with wound dressing changes.

In addition to pressure off-loading, all patients received wound treatment according to diabetic foot syndrome care standards (Order of the Ministry of Health, Russian Federation, 12 November 2012).

Both patient groups were comparable with regard to age, gender, duration and degree of diabetes compensation and for original wound defect sizes ($p > 0.05$). The clinical and demographic characteristics of our study participants and their wound defects are shown in Table 1.

Pressure off-loading efficiency was assessed using electronic pedobarography (Tekscan Pressure Measurement System 6.30. Software version: Tekscan Research 6.3. Sensor Type: F-Scan). Computer pedography was conducted for each patient inside an orthosis or inside TCC in real time during a walk (walking in a straight line with not less than 5 steps for each leg or 10 steps in total). Data were analysed for the maximum pressure dynamics and the pressure/time integral and were compared with corresponding measurements made in a test shoe for the same patient. Graphic representations of pedobarography data in 2D format are shown in Figure 2.

During weekly patient visits to the 'diabetic foot' office, the wound status and size were evaluated for treatment efficacy comparisons. To estimate the rate of epithelisation of a wound defect, the defect area was determined by multiplying the maximum length by the maximum width. The equivalent radius of a wound (Re) was determined using the formula proposed by Cavanagh [8]: $Re = (D_{max} + D_{min}) / 4$, where D_{max} = wound maximum diameter and D_{min} = wound minimum diameter, as measured perpendicular to D_{max} in the widest part of the wound.

In addition to the wound status assessment, for the test group of patients, the attending physician completed questionnaires regarding the convenience and comfort of the test orthosis during each visit. These patients were then asked to evaluate the fit of the orthosis, walking comfort, pain during walking in the orthosis and any abrasions and skin redness after removing the orthosis. Subjective symptoms were expressed as points (0–2) and used to evaluate the orthosis performance, including presence and severity of paraesthesia, calf muscle heaviness, fatigue and swelling of legs syndrome.

During the final office visit, patients were asked to give their opinion regarding the weight of the orthosis, ease of putting it on, ease of removal and wearing comfort. The doctor and patient concurrently evaluated therapy efficiency and orthosis performance.

Statistical analysis

Orthosis efficiency was assessed using changes in clinical indicators and by symptom evaluations. At the end of the therapy, the following criteria were evaluated: ease of fitting the device, wearing comfort, safety of side effects monitoring and treatment efficiency (yes/no and on a scale

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from 0, no effect, to 2, very good). EXCEL 2007 and Statistica (StatSoft Inc. USA, version 6.0) were used for statistical analysis. Shapiro-Wilk and Liliefors tests were used to assess data distribution normality, and symptom distribution variances were assessed using F-tests by analysis of variance. Because most measured variables were not normally distributed, median values and 25th and 75th percentiles were used for data presentation: 'Median [25%; 75%]'. Moreover, non-parametric tests were used for study group comparisons using contingency tables and by criteria for χ^2 (chi-square) tests. For quantitative variables, Mann–Whitney U tests were used for group comparisons. P values of <0.05 were considered statistically significant. Our research results, statistically analysed and presented in the form of tables and diagrams do provide insights on the dynamics of the medians of variables, interquartile intervals and their association with other variables in accordance with modern requirements.

Results and discussion

Our study period was 6 months, and the maximum period of observation for each patient was 3 months. Seventeen of the 20 patients in the test group were discharged sooner than 12 weeks because their wounds had healed. Their mean healing time was 46.1 ± 19.0 days (range: 21 to 84 days), which was comparable to that of the control group (48.3 ± 20.5 days). One patient was excluded after the third follow-up office visit due to scheduled visit violations. One other patient was excluded after the fourth follow-up visit due to non-compliance with our orthosis wearing rules. Thus, 18 patients in the test group completed our study. For one patient, complete wound healing had not been achieved by the end of the study period. Considering that 2 instances of mechanical damage occurred to this patient's orthosis, the lack of a positive effect of pressure off-loading was most probably due to this patient's excessive physical activity and weight (110 kg).

The rate of wound defect epithelisation was determined based on the changes in wound areas and was not significantly different between the two groups: 0.73 [0.29; 0.92] cm2/week for the test group and 0.91 [0.71; 1.17] cm2/week for the control group (Fig. 3).

For all patients, an equivalent wound radius was determined and its rate of change was assessed. There were no significant differences in the initial equivalent wound radii or changes in their dynamics between the test and control groups. For the group that used an orthosis for pressure off-load, the rate of equivalent radius change was 0.27 ± 0.13 mm/day, and this rate was 0.3 ± 0.15 mm/day for the control group (p > 0.05).

Orthosis efficacy was also evaluated based on any changes in subjective indicators (paraesthesia, heaviness in the calf muscles, fatigue and leg oedema). At the beginning of the study for the test group, 7 patients reported paraesthesia, 4 reported heaviness in the legs and 5 reported foot fatigue. These symptoms were mild and there were no significant changes during the study period. Further, moderate to severe oedema of the lower extremities was observed in 8 patients; however, oedema severity decreased within 2–3 weeks after patients began to wear the orthosis. In the control group, 12 patients had oedema that lessened within 1–2 weeks after beginning their treatment. There were no significant changes in subjective symptoms.

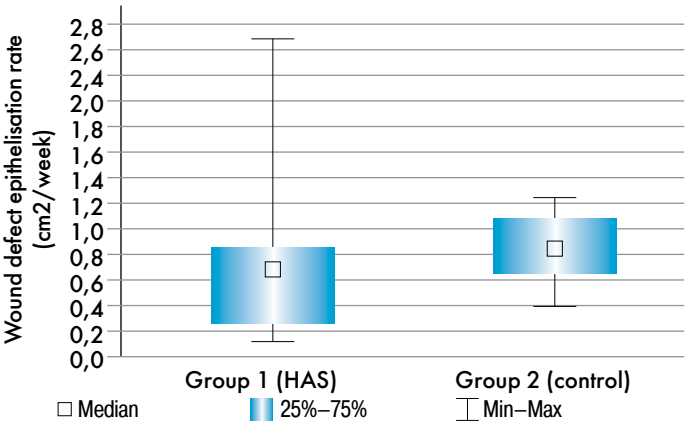

Fig. 3 Wound defect epithelisation rates

Adverse effects, such as shin abrasions, were observed in 4 patients. These complications were moderate in 3 patients and pronounced in 1 patient. All abrasions were recorded during follow-up office visits 1 and 2 and had healed within 2 weeks. To prevent recurrent skin lesions, the orthosis fit was loosened and reduced physical activity was recommended. In the control group, 4 patients developed complications in the form of skin abrasions. In all of these patients as well as in the test group, their abrasions did not require discontinuing treatment and healed sooner than the primary wounds.

Pronounced soreness while walking was reported in 3 patients. These were recorded immediately after beginning the study during follow-up office visit 1. After their orthosis fit was loosened and pneumatic pressure was reduced, their soreness stopped.

One patient on follow-up visit 2 had severe maceration of the skin in the shin area, and 3 patients had moderate skin macerations around their wounds, which required unsealing of the orthosis. Removing the orthosis during the night was recommended to eliminate this problem. All of these lesions healed within 2 weeks.

It is noteworthy that most assessments were conducted during the summer. The occurrence of adverse effects, such as macerations and abrasions of the skin, were likely the result of high ambient temperatures and other adverse climatic factors. In general, wearing the orthosis was tolerated well by patients. Some patients complained about the

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Table 2

Pressure off-loading in the forefoot		
Area of a foot	Maximum contact pressure	Integral pressure/ time
1st finger	68%	42%
2nd finger	67%	56%
3rd finger	75%	65%
4th and 5th fingers	82%	78%
1st metatarsus	50%	33%
2nd metatarsus	48%	28%
3rd metatarsus	52%	32%
4th metatarsus	33%	18%
5th metatarsus	33%	16%
AVERAGE	57%	41%

significant weight of this device. In the opinions of a physician and patients, the efficacy of this orthosis was 1.7 of 2.0 maximum possible points.

Pressure off-loading efficacy in the wound defect areas was confirmed using pedobarography. The tested orthosis exhibited a high degree of pressure off-loading from the plantar surface of the forefoot and metatarsal areas (fingers, interphalangeal and metatarsophalangeal joints) compared with conventional footwear.

The efficacy results for reducing the pressure in the forefoot area inside the orthosis in the zone of interest compared with conventional footwear are shown in Table 2.

Based on our pedobarography data, this ankle-foot pneumoorthosis reduced the maximum pressure by 26% (from -64% to +78%) and in the forefoot target zones (i.e. localized wound defects) by 57% (from -100% to +159%). The pressure/time integral decreased on average by 41% (from -100% to +369%). These results were similar to those obtained in a previous study of TCC, for which the maximum pressure decreased by 20% (from -70% to +84%) and was 55% in the wound area (from -100% to +359%) as compared with conventional shoes [9].

In the tarsus (midfoot) area, the maximum pressure increased by 48%, and the pressure/time integral increased by 47% inside the orthosis. These were most likely because of the effects of the orthosis pneumatic system, which redistributed the load from relevant areas of the plantar surface to the longitudinal arch of the foot. Moreover, an increase in pressure in the hindfoot area was also recorded, with a 10% increase in the maximum pressure and 18% increase in the pressure/time integral, which also may have been due to load redistribution. Our results do not provide for recommending the use of the TM Orlett orthosis for treating patients with wounds in the hindfoot area.

Conclusion

Ankle-foot pneumoorthosis with a TM Orlett (model HAS-337) is an effective and safe means for foot pressure off-loading and can be recommended for treating patients with uninfected neuropathic wounds of the plantar surface of the forefoot. This treatment is comfortable and convenient for most patients. Our TM Orlett pneumoorthosis results were confirmed by pedobarography data and were comparable with the results obtained with an immobilizing TCC, which is the gold standard for pressure off-loading in diabetic foot syndrome treatment. Ankle-foot pneumoorthosis with the HAS-337 TM Orlett can be recommended for standard treatment of patients with diabetes and uninfected neuropathic ulcers on the plantar surface of the forefoot.

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