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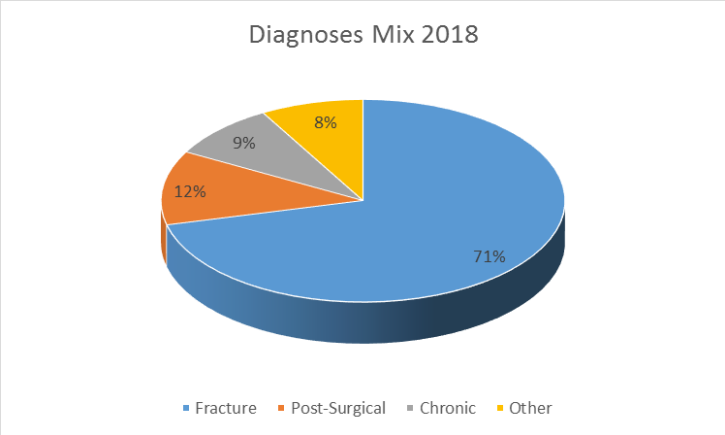

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- Robert E. Fischell Medical Device Institute
- Department Of Aerospace Engineering, Clarke School of Engineering, University of Maryland
- FDA, Center for Devices and Radiation Health, Office of Science and Engineering Laboratories

Publications and Data:

- Minute Porosity of 3D Printed Casts and Splints May Allow Water Entry, Diana Hall (ActivArmor), Lex Schulteis (Univ of Maryland), *et al*. ACSM 2017 Supplement (https://activarmor.com/wp-content/uploads/2020/08/Poster-for-ACSM-2017.pdf)
- Skin Compatibility with 3D Printed Casts and Splints, Diana Hall (ActivArmor), Lex Schulteis (Univ of Maryland), et al. Abstract presented at ACSM 2019.

Research abstracts presented at:

AAOS American Academy of Orthopaedic Surgeons

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Research Publications

Application of 3D–printed and patient-specific cast for the treatment of distal radius fractures

Yan-Jun Chen, Hui Lin, Xiaodong Zhang, Wenhua Huang, Lin Shi & Defeng Wang
3D Printing in Medicine volume 3, Article number: 11 (2017)
https://threedmedprint.biomedcentral.com/articles/10.1186/s41205-017-0019-y

Background: Distal radius fracture is common in the general population. Fracture management includes a plaster cast, splint and synthetic material cast to immobilise the injured arm. Casting complications are common in those conventional casting technologies. 3D printing technology is a rapidly increasing application in rehabilitation. However, there is no clinical study investigating the application of a 3D–printed orthopaedic cast for the treatment of bone fractures. We have developed a patient-specific casting technology fabricated by 3D printing. This pioneering study aims to use 3D–printed casts we developed for the treatment of distal radius fractures, to provide the foundation for conducting additional clinical trials, and to perform clinical assessments.

Method: Ten patients with ages between 5 and 78 years are involved in the clinical trial. Patients are applied 3D–printed casts we developed. Orthopaedic surgeons carried out a six-week follow-up to examine clinical outcomes. Two questionnaires were developed for the assessment of clinical efficacy and patients' satisfaction. These questionnaires are completed by physicians and participating patients.

Results: A 3D–printed cast creates a custom-fitted design to maintain the fractured bone alignment. No loss of reduction is found in all patients. Compartment syndrome and pressure sores are not present. Patient comfort gets positive scores on the questionnaire. All (100%) of the patients opt for the 3D–printed cast instead of the conventional plaster cast.

Conclusions: This pioneering study is the first clinical trial on the application of a 3D–printed cast for the treatment of forearm fractures. The novel casting technology heals the fracture effectively without casting complications. The 3D–printed cast is patient-specific and ventilated as well as lightweight, and it features both increased patient comfort and satisfaction.

Initial Experiences with Upper Extremity 3D-Printed Ventilated Casts

Sun, Michael M.D., Orthopedic Surgeon, Cedars-Sinai Medical Group, Los Angeles, CA
ASSH Annual Meeting Research Abstract Poster, October 2020

Background: 3-dimensional (3D) printed ventilated casts may offer advantages over traditional plaster or fiberglass casts in areas such as weight, breathability, hygiene, ease of skin examination, and ease of reuse. Limited data is available on the clinical outcomes associated with the use of 3D printed casts.

Methods: A retrospective review was performed of patients at our institution who had a 3D printed cast applied for upper extremity post-surgical immobilization or fracture care. Outcomes examined included cast-related complications such as fitment issues and skin irritation, and, in patients whom casts were utilized for fracture care, progression of fracture healing to suggest that adequate stability had been achieved.

Results: Of 33 patients who received a 3D printed cast, no instances of cutaneous complications were observed. Of 14 patients in whom the cast was used for fracture care, 1 patient who was poorly compliant with cast wear had delayed healing.

Conclusions: Patient-specific 3D printed ventilated casts may offer a viable alternative to traditional casting techniques for patients with extremity injuries or for post-surgical immobilization.

Conventional vs 3-Dimensional Printed Cast Wear Comfort

Jack Graham, Mark Wang, Kaela Frizzell
Published August 27, 2018
https://doi.org/10.1177/1558944718795291

Background: The objective of this study was to determine the functionality of 3-dimensional (3D) printed orthoses for upper extremity immobilization compared with conventional immobilization.

Methods: Twelve healthy volunteers were fitted with a 3D custom printed short arm cast and a short arm fiberglass cast in separate sessions. The Jebsen Hand Function Test (JHFT) was used to test function and dexterity in each cast. All volunteers completed a modified version of the Patient-Rated Wrist Evaluation (PRWE). Skin complications were recorded.

Results: There were no significant differences during the JHFT between casts, although one-third of the participants in the 3D cast could perform the tasks in a normal time, which they could not in the fiberglass cast. The average PRWE function score was lower in the 3D cast group than in the fiberglass group (45.5 vs. 80.8). Minor skin irritation was noted in 42% of patients in the fiberglass cast group compared with only 1 patient (8%) in the 3D cast group. One patient in the fiberglass group required a cast change due to inappropriate fit. Conclusions: Both casting techniques demonstrate similar objective function based on the JHFT. Patient satisfaction, comfort, and perceived function are superior in the 3D printed casts.

Total Contact Cast Replacement 3D Printed Walking Boot Offloading Testing

David Shofler, DPM MSHS

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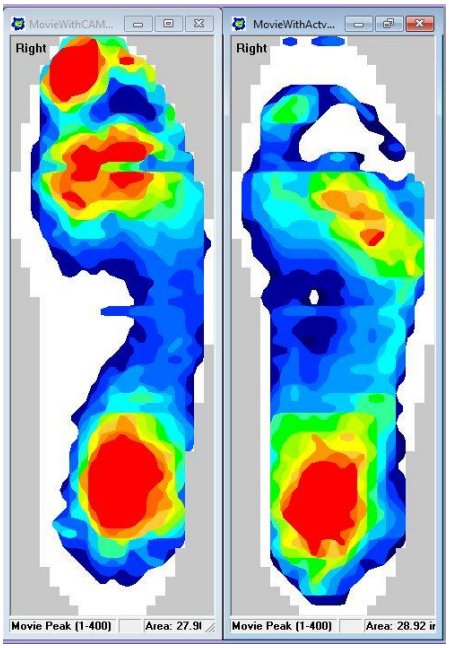
Western University College of Podiatric Medicine, Pomona, California

Using a Tekscan pressure tester, an ActivArmor 3D printed AFO was tested, along with a traditional CAM walker. The attached image shows maximum plantar pressures, with the results from the CAM walker on the left-hand side and the results from the ActivArmor cast on the right. With red areas indicating higher pressures, the image reflects that the forefoot pressures were offloaded with the device.



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ORIGINAL RESEARCH

Custom-Molded Offloading Footwear Effectively Prevents Recurrence and Amputation, and Lowers Mortality Rates in High-Risk Diabetic Foot Patients: A Multicenter, Prospective Observational Study

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Background: Recurrence of high-risk diabetic feet, after wound, healing is a common challenge among diabetic patients. Continuous use of an offloading device significantly prevents recurrence of high-risk diabetic feet, although patient adherence is imperative to ensuring this therapy's clinical efficacy. In this study, we explored clinical outcomes of patients with a high-risk diabetic foot who had been prescribed with custom-molded off-loading footwear under different adherence conditions.

Methods: A total of 48 patients (17 females and 31 males) with high-risk diabetic feet, who had been with prescribed offloading footwear in 13 medical centers across 4 cities, were enrolled in the current study. The patients were assigned into either continuous offloading therapy (COT, n = 31) or interrupted offloading therapy (IOT, n = 17) groups, according to their adherence to the therapy. All patients were followed up monthly, and differences in recurrence, amputation, and deaths between the groups were analyzed at 4 months after therapy.

Results: Forty-eight patients met our inclusion criteria and were therefore included in the final analysis. Among them, 31 were stratified into the COT group and adhered to offloading therapy throughout the study period, whereas 17 were grouped as IOT and exhibited interrupted adherence to offloading therapy. We found statistically significant differences in recurrence rates (0 vs 38.46%, $p < 0.01$), amputation (0 vs 11.76%, $p < 0.01$), and deaths (0% vs 5.88%, $p < 0.01$) between the groups during follow-up.

Conclusion: Patients' adherence is imperative to efficacy of custom-molded offloading footwear during treatment of high-risk diabetic foot. Further studies are needed to elucidate the role of improved design of the offloading device and the need for enhanced patient education for improved adherence.

Keywords: custom-molded offloading footwear, high-risk diabetic foot, patient adherence

Introduction

High-risk diabetic foot is prone to injury, infection and ulceration in diabetic patients.[1] Previous studies have reported that the 1- and 5-year recurrence rates of high-risk diabetic feet 31.6%,[2] and approximately 70%,[3] respectively. Refractory recurrence and slow healing rates have been linked to leg amputation and patient mortality. Moreover, high-risk diabetic feet have been associated with non-traumatic amputation, with more than 70% mortality rates within 5 years after amputation.[4] Therefore, reducing the recurrence rate of high-risk diabetic feet can significantly improve amputation and lower mortality rates in this group of patients.

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High-risk diabetic foot recurrence is mainly attributed to abnormal lower limb movements and changes in plantar biomechanics.[5–8] Chronic overload and friction to the feet, which are caused by wearing conventional shoes, can cause damage to the skin on the sole or dorsal foot, thereby exacerbating a patient's gait and balance ability over time. These changes ultimately lead to recurrence of foot ulcers and amputation. Soft tissues are prone to continuous overload, even after healing, a phenomenon that results in tissue necrosis and recurrence of high-risk diabetic foot.[9] However, amputations and deaths can be prevented if patients receive appropriate care.[10–12] According to the International Working Group on the Diabetic Foot (IWGDF), use of an offloading device can effectively prevent recurrence in high-risk diabetic foot patients.[12] Moreover, this device can reduce plantar pressure on the painful part of the foot, by changing the center of gravity line, thereby improving body balance. Consequently, the device rationally distributes the pressure on the bottom of the foot and absorbs vibration, thus preventing recurrence of high-risk diabetic foot.[13,14] Previous studies have demonstrated that continued use of the offloading device to improve plantar biomechanics and COT can effectively prevent recurrence of diabetic high-risk feet.[15–18] Notably, patient adherence has been shown to play an important role in clinical outcomes during offloading therapy.[19,20] In the present study, we explored the effects of patient adherence on diabetic foot recurrence, amputation, and mortality using offloading therapy in high-risk diabetic foot patients.

Methods and Study Design

A total of 87 patients, who were diagnosed with high-risk diabetic feet between January 1, 2018 and December 31, 2020, were enrolled at 13 medical centers across four cities in China. Inclusion criteria were adopted from the United States Medicare Guidelines. A patient was deemed eligible for the Medicare diabetic therapeutic footwear benefits if the treating physician provided a written statement certifying existence of at least one of the following conditions: 1) had undergone previous partial amputation of either foot; 2) had a history of previous foot ulceration on either foot; 3) had a history of pre-ulcerative calluses on either foot; 4) was diagnosed with peripheral neuropathy with evidence of callus formation on either foot; 5) presented with foot deformity; 6) presented with poor circulation on either foot; or 7) had a prescription for a particular type of foot wear from a physician. Conversely, a participant was excluded if he or she 1) had a history of major amputations; 2) was diagnosed with neurologic or psychiatric disease; 3) was unable to walk without walking aids; 4) had visual impairment that was difficult to either treat or correct; 5) was diagnosed with unstable cardiovascular or unstable ischemic cerebrovascular diseases; (6) had severe renal dysfunction or severe liver dysfunction; 7) was diagnosed with a malignant tumor; 8) had osteoarticular diseases unrelated to diabetes; and 9) declined offloading therapy.

A total of 48 high-risk diabetic foot patients (17 females and 31 males) who were undergoing therapy with offloading device (Depth Inlay Shoes, Dave Med LLC, Chongqing, China) met the inclusion criteria and were ultimately recruited in the study. All patients were followed up monthly, through a face-to-face or telemedicine approach, because of COVID-19. At 4 months after offloading therapy, differences in recurrence, amputation, and mortality rates between the groups were determined and the effect of the offloading device evaluated. The definition of interrupted offloading therapy (IOT, n=17) group was based on discontinued offloading footwear therapy, for more than 4 weeks. Patients were divided into either continuous offloading therapy (COT, n=31) or IOT (n=17) groups, based on their level of adherence to offloading therapy. The patients' demographic information and clinical characteristics, including age, gender, height, BMI, diabetes duration, Wagner classification, diabetic neuropathy, diabetic retinopathy, foot deformity, vibrating perception threshold, history of amputation, plantar callus, peripheral artery disease, ischemia, osteoporosis, and methods of diabetes control were recorded and analyzed at the beginning of study. Patients were advised to wear the offloading device for 1–2 hours every day for the first week after discharge. Next, they were advised to wear the offloading device every day, if there did not experience any discomfort or foot grinding a week after discharge.

Statistical Analysis

Descriptive statistics, including proportions, means, and standard deviations were calculated. Differences between patients undergoing COT and those who presented with discontinuation of offloading therapy were determined using a *t*-test, while baseline data were analyzed using a Chi-square test. All statistical analyses were performed using SPSS 26 software (IBM, Armonk, NY). $P<0.05$ was considered statistically significant for all of the analyses.

Results

A total of 48, out of 88, patients (including 17 women and 31 men) met our inclusion criteria and were included in the final analysis. A summary of the research design is presented using a flow chart in Figure 1. Results revealed no statistically significant differences in baseline data between the two groups (Table 1). Patients were fitted with molded offloading insole (Figure 2). A comparison of patients' main clinical outcomes between the two groups, 4 months after offloading therapy, revealed no DFU recurrence in 21 cases that previously had DFU, and none of the 31 patients the COT group had neither undergone amputation nor died during the study period. In contrast, the 13 patients with a history of DFU in the IOT group had a recurrence rate of 38.46% (5/13), with amputation and mortality rates of 11.76% and 5.88%, respectively. We found statistically significant differences in recurrence, amputation and mortality rates between patients in the COT and IOT groups ($p<0.01$) (Figure 3).

Discussion

High-risk diabetic foot causes great pain and high economic burden to patients and their families. To manage the condition, diabetic foot offloading footwear, comprising functional socks and custom insoles, has been used in some developed countries and is included in the medical insurance coverage.[21] However, offloading device is not covered by medical insurance in most developing countries. Efficacy of using the offloading device for diabetic patients with high-risk foot for preventive treatment remains controversial. For example, Gao et al,[22] Bus et al[23] and Maciejewski et al[24] reported that the offloading device was effective in preventing recurrence of diabetic foot ulcers. In contrast, Macfarlane et al[20] found no significant effects in use of the offloading device in high-risk diabetic feet patients. Notably, the authors attributed the lack of significant effects to low adherence.

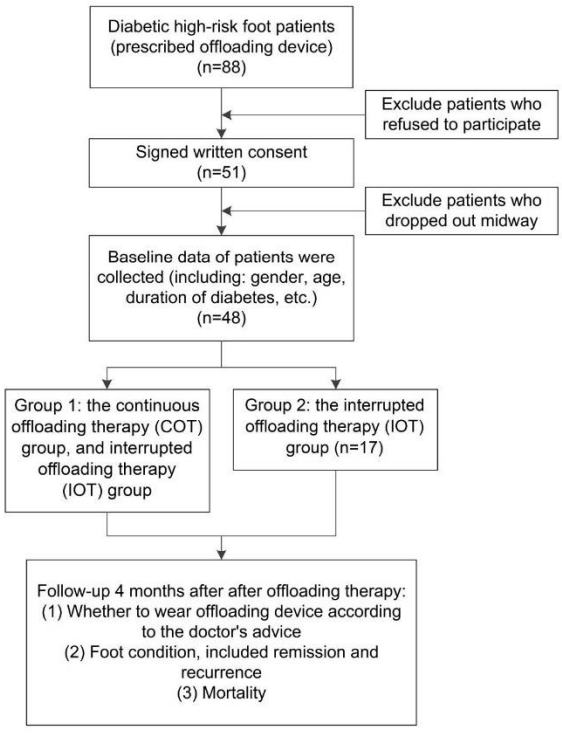

Figure 1 A flow chart describing the study design.

Results from our previous study, in which we explored use of offloading device in neuropathic diabetic foot, revealed that the device changed plantar biomechanics using wearable sensor technology.[8,25] Notably, this offloading therapy significantly improved clinical outcomes in these patients although one case who underwent IOT presented with recurrence during interruption of the therapy.[8] In the current study, we further explored the effects of interrupting offloading therapy on recurrence and mortality rates in high-risk diabetic foot patients. To the best of our knowledge, this is the first multicenter study analyzing the use of offloading footwear therapy intervention in diabetic patients with high-risk foot. The findings from the present study, coupled with literature review, indicated that use of offloading device significantly reduced the risk of foot ulcer recurrence, amputation and mortality.[26] In the current study, a total of 48 patients who were prescribed with the offloading device between 2018 and 2020 were selected for follow-up and exploration of the effect of patient based on clinical outcomes. Results showed that with high-risk diabetic foot patients with poor compliance to offloading therapy exhibited high recurrence, amputation, and mortality rates.

The poor adherence was attributed to several reasons: Firstly, patients were not willing to undergo the therapy. Secondly, the weight, appearance and comfort of the offloading device limited its use.[27,28] Thirdly, some medical staff did not pay enough attention to the auxiliary and preventive treatment effects of the offloading device, while social awareness was low. Results from follow-up showed that some patients psychologically resisted offloading therapy.[29,30] In addition, although clinicians recommended that the offloading device be worn for a long period, patients were worried about the associated

Table 1 Baseline Characteristics of All Patients Participating in This Study

Variables	All Patients (n=48)	COT Group (n=31)	IOT Group (n=17)	P-value
Age, years	64.92±12.38	62.77±11.50	68.82±13.03	0.106
Height, cm	162.74±8.27	162.85±8.41	162.62±8.34	0.933
BMI, kg/m^2	24.46±2.99	24.35±2.45	24.60±3.61	0.804
Diabetes duration, years	11.33±7.56	11.91±7.57	10.59±7.71	0.595
Gender, %				
Female	17(35.42)	9(29.03)	8(47.06)	0.212
Male	31(64.58)	22(70.97)	9(52.94)	
Wagner classification, %				
0–3	36(75.00)	24(77.42)	12(70.59)	0.862
4–5	12(25.00)	7(22.58)	5(29.41)	
Diabetic retinopathy, %				
Yes	23(47.92)	17(54.84)	6(35.29)	0.195
No	25(52.08)	14(45.16)	11(64.71)	
Foot deformity, %				
Yes	16(33.33)	10(32.26)	6(35.29)	0.831
No	32(66.67)	21(67.74)	11(64.71)	
VPT>25volt, %				
Yes	18(37.50)	12(38.71)	6(35.29)	0.815
No	30(62.50)	19(61.29)	11(64.71)	
History of DFU, %				
Yes	34(70.83)	21(67.74)	13(76.47)	0.741
No	14(29.17)	10(32.26)	4(23.53)	
History of amputation, %				
Yes	16(33.33)	8(25.81)	8(47.06)	0.135
No	32(66.67)	23(74.19)	9(52.94)	
Plantar callus, %				
Yes	20(41.67)	14(45.16)	6(35.29)	0.507
No	28(58.33)	17(54.84)	11(64.71)	
Diabetic neuropathy, %				
Yes	42(87.50)	27(87.10)	15(88.24)	1
No	6(12.50)	4(12.90)	2(11.76)	
PAD, %				
Yes	23(47.92)	13(41.94)	10(58.82)	0.263
No	25(52.08)	18(58.06)	7(41.18)	
Ischemia, %				
Yes	31(64.58)	18(58.06)	13(76.47)	0.202
No	17(35.42)	13(41.94)	4(23.53)	
Osteoporosis, %				0.263
Yes	25(52.08)	18(58.06)	7(41.18)	
No	23(47.92)	13(41.94)	10(58.82)	
Methods of blood glucose control, %				
Insulin	2(4.16)	1(3.22)	1(5.88)	
Anti-hyperglycemic drugs	20(41.67)	13(41.94)	7(41.18)	0.907
Anti-hyperglycemic drugs and Insulin	26(54.17)	17(54.84)	9(52.94)	

Abbreviations: COT, continuous offloading therapy; IOT, interrupted offloading therapy; BMI, body Mass Index; VPT, vibrating perception threshold; DFU, diabetic foot ulcer; PAD, peripheral artery disease.

expenses. In addition, the patients had a negative perception of the device, mainly because wearing it implied that they had not fully recovered thus increasing the psychological burden. Although the offloading device is efficacious in preventing amputation and mortality in patients at high risk of diabetic foot, only a handful of clinicians and researchers have described its role.

Improving patient adherence to use of the offloading device can significantly improve clinical outcomes of this therapy in diabetic foot. This adherence may be improved by

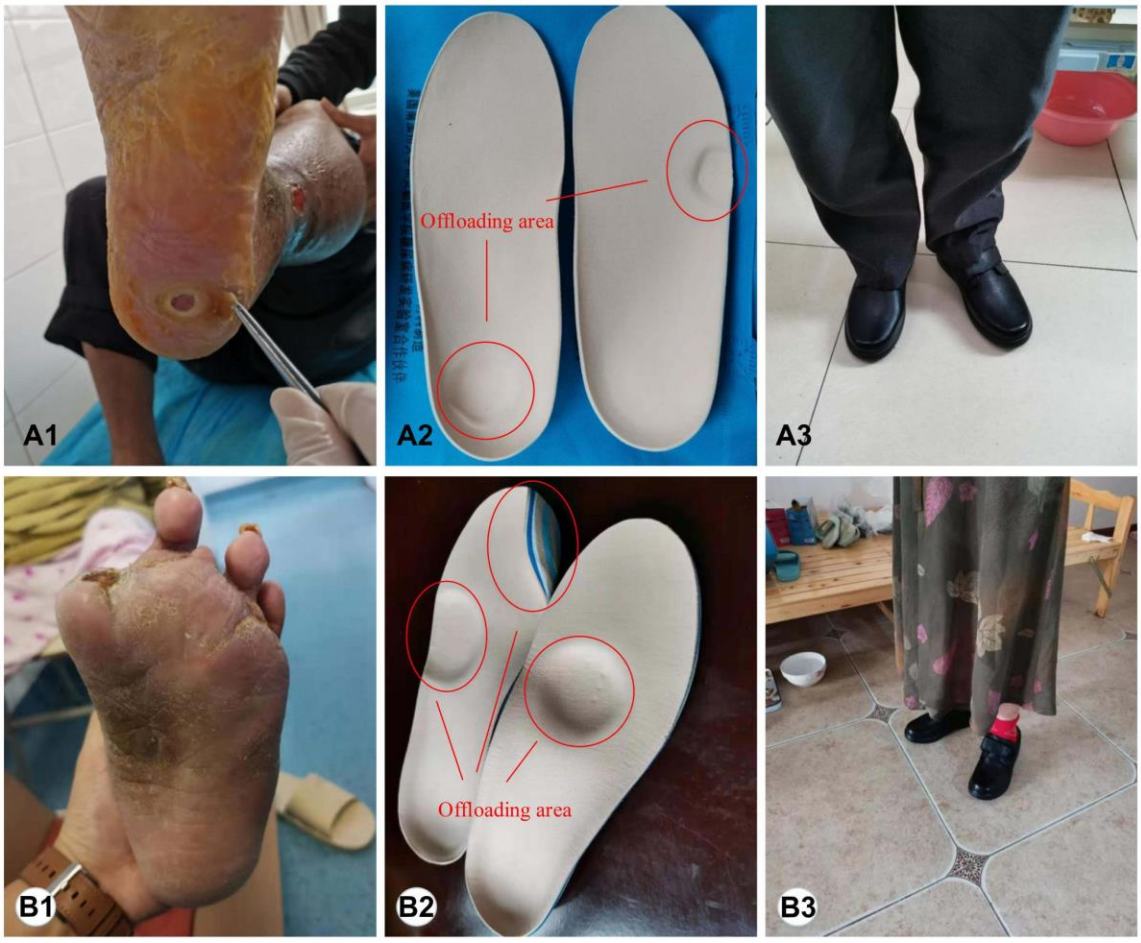

Figure 2 Profiles of patients' foot conditions and offloading therapy. Patient A: Recurrent neuropathic plantar foot ulcer on the left heel and the fifth right plantar metatarsophalangeal joint (**A1**). Personalized offloading insoles (**A2**). Wearing of the offloading footwear (**A3**). Patient B: Recurrent neuropathic plantar foot ulcer on the right foot and amputation of the first and third toes of the left foot (**B1**). Personalized offloading and orthopedic insoles (**B2**). Wearing the offloading footwear (**B3**).

providing patients with more color choices, as well as styles and materials. Health facilities and clinicians should also increase awareness of different approaches for treatment and disease prevention, while patients and medical staff should undergo health education to equip them with information regarding the positive effects of offloading therapy.[31] We hypothesize that increased health education for patients and medical staff will improve the level of foot self-care knowledge and patient behavior towards the therapy. Furthermore, medical personnel should undergo regular training on prevention and adjuvant treatment of diabetic foot using offloading device to improve their effectiveness in providing care for patients with high-risk foot.

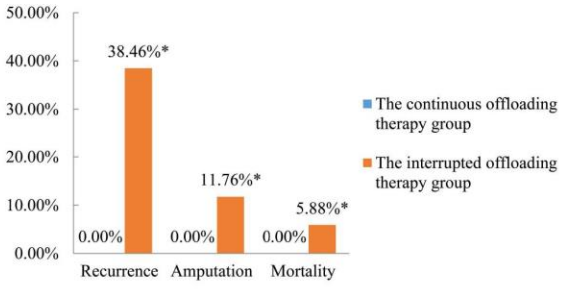

Figure 3 Clinical outcomes of patients included in the study. *There were statistically significant difference in recurrence, amputation and mortality rates between patients in the continuous offloading therapy and those e in the interruption offloading therapy groups (P<0.01).

Results of the present study further confirm efficacy of the offloading device as an adjuvant therapy for patients with diabetic high-risk foot. This is because wearing an offloading device significantly lowers the number of patients with high-risk diabetes feet, and subsequently reduces the socioeconomic burden, risk of infections,

amputation, and death of patients associated with this condition.

This study had a few limitations. Firstly, our sample size was relatively small. Future studies should enroll more patients to establish barriers regarding continuous use of offloading footwear and help improve diabetes-related foot ulcers. Secondly, the follow-up was short due to the COVID-19 pandemic.

Conclusion

Findings for the present study showed that the offloading device is an efficacious auxiliary therapeutic strategy for prevention of recurrence and amputation, and lowering mortality rates in diabetic foot patients. Notably, patient adherence is imperative to efficacy of this therapy.

Data Sharing Statement

The data are available on reasonable request from the corresponding author (wuquandeng@cqu.edu.cn).

Ethics Approval and Informed Consent

The study complied with the Declaration of Helsinki. The study, named Footwear and Offloading Optimum Therapy (FOOT) study, was approved by the institutional review board (IRB) of Chongqing University Central Hospital (ChiCTR1900022468). All protocols were conducted in accordance with the declaration of Helsinki. All participants provided written informed consent to participate in the study.

Acknowledgments

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Disclosure

The authors report no conflicts of interest in this work.

References

1. Boulton AJ. The diabetic foot: from art to science. The 18th Camillo Golgi lecture. *Diabetologia*. 2004;47(8):1343–1353. doi:10.1007/s00125-004-1463-y
2. Jiang Y, Wang X, Xia L, et al. A cohort study of diabetic patients and diabetic foot ulceration patients in China. *Wound Repair Regen*. 2015;23(2):222–230. doi:10.1111/wrr.12263
3. Turns M. The diabetic foot: an overview for community nurses. *Br J Community Nurs*. 2012;17(9):422,424–427,430–433. doi:10.12968/bjcn.2012.17.9.422
4. Armstrong DG, Boulton AJM, Bus SA. Diabetic foot ulcers and their recurrence. *N Engl J Med*. 2017;376(24):2367–2375. doi:10.1056/NEJMra1615439
5. Arts ML, Waaijman R, De Haart M, et al. Offloading effect of therapeutic footwear in patients with diabetic neuropathy at high risk for plantar foot ulceration. *Diabet Med*. 2012;29(12):1534–1541. doi:10.1111/j.1464-5491.2012.03770.x
6. Bus SA. Priorities in offloading the diabetic foot. *Diabetes Metab Res Rev*. 2012;28(Suppl 1):54–59. doi:10.1002/dmrr.2240
7. Deng W, Deng F, Chen B, et al. Association between peripheral neuropathy and biomechanics performance in patients with type 2 diabetes mellitus. *Diabetes*. 2019:68. doi:10.2337/db19-626-P.
8. Du C, Wang H, Chen H, et al. The feasibility and effectiveness of wearable sensor technology in the management of elderly diabetics with foot ulcer remission: a proof-of-concept pilot study with six cases. *Gerontology*. 2021;67(4):493–502. doi:10.1159/000513729
9. Van Netten JJ, Raspovic A, Lavery LA, et al. Prevention of foot ulcers in the at-risk patient with diabetes: a systematic review. *Diabetes Metab Res Rev*. 2020;36(Suppl 1):e3270. doi:10.1002/dmrr.3270
10. Lazzarini PA, Pacella RE, Armstrong DG, et al. Diabetes-related lower-extremity complications are a leading cause of the global burden of disability. *Diabet Med*. 2018;35(9):1297–1299. doi:10.1111/dme.13680
11. Pickwell KM, Siersma VD, Kars M, et al. Diabetic foot disease: impact of ulcer location on ulcer healing. *Diabetes Metab Res Rev*. 2013;29(5):377–383. doi:10.1002/dmrr.2400
12. Bus SA, Van Netten JJ, Lavery LA, et al. IWGDF guidance on the prevention of foot ulcers in at-risk patients with diabetes. *Diabetes Metab Res Rev*. 2016;32(Suppl 1):16–24. doi:10.1002/dmrr.2696
13. Waaijman R, De Haart M, Arts ML, et al. Risk factors for plantar foot ulcer recurrence in neuropathic diabetic patients. *Diabetes Care*. 2014;37(6):1697–1705. doi:10.2337/dc13-2470
14. Ahmed S, Barwick A, Butterworth P, et al. Footwear and insole design features that reduce neuropathic plantar forefoot ulcer risk in people with diabetes: a systematic literature review. *J Foot Ankle Res*. 2020;13(1):30. doi:10.1186/s13047-020-00400-4
15. Ha Van G, Siney H, Hartmann-Heurtier A, et al. Nonremovable, windowed, fiberglass cast boot in the treatment of diabetic plantar ulcers: efficacy, safety, and compliance. *Diabetes Care*. 2003;26(10):2848–2852. doi:10.2337/diacare.26.10.2848
16. Waaijman R, Keukenkamp R, De Haart M, et al. Adherence to wearing prescription custom-made footwear in patients with diabetes at high risk for plantar foot ulceration. *Diabetes Care*. 2013;36(6):1613–1618. doi:10.2337/dc12-1330
17. Chantelau E, Haage P. An audit of cushioned diabetic footwear: relation to patient compliance. *Diabet Med*. 1994;11(1):114–116. doi:10.1111/j.1464-5491.1994.tb00240.x

18. Hingorani A, Lamuraglia GM, Henke P, et al. The management of diabetic foot: a clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. *J Vasc Surg*. 2016;63(2Suppl):3S–21S. doi:10.1016/j.jvs.2015.10.003
19. Jarl G, Alnemo J, Tranberg R, et al. Gender differences in attitudes and attributes of people using therapeutic shoes for diabetic foot complications. *J Foot Ankle Res*. 2019;12(1):21. doi:10.1186/s13047-019-0327-0
20. Macfarlane DJ, Jensen JL. Factors in diabetic footwear compliance. *J Am Podiatr Med Assoc*. 2003;93(6):485–491. doi:10.7547/87507315-93-6-485
21. Wooldridge J, Bergeron J, Thornton C. Preventing diabetic foot disease: lessons from the Medicare therapeutic shoe demonstration. *Am J Public Health*. 1996;86(7):935–938. doi:10.2105/AJPH.86.7.935
22. Gao Y, Wang C, Chen D, et al. Effects of novel diabetic therapeutic footwear on preventing ulcer recurrence in patients with a history of diabetic foot ulceration: study protocol for an open-label, randomized, controlled trial. *Trials*. 2021;22(1):151. doi:10.1186/s13063-021-05098-8
23. Bus SA, Waaijman R, Arts M, et al. Effect of custom-made footwear on foot ulcer recurrence in diabetes: a multicenter randomized controlled trial. *Diabetes Care*. 2013;36(12):4109–4116. doi:10.2337/dc13-0996
24. Maciejewski ML, Reiber GE, Smith DG, et al. Effectiveness of diabetic therapeutic footwear in preventing reulceration. *Diabetes Care*. 2004;27(7):1774–1782. doi:10.2337/diacare.27.7.1774
25. Jiang X, Li N, Yuan Y, et al. Limb salvage and prevention of ulcer recurrence in a chronic refractory diabetic foot osteomyelitis. *Diabetes Metab Syndr Obes*. 2020;13:2289–2296. doi:10.2147/DMSO.S254586
26. Bus SA, Haspels R, Busch-Westbroek TE. Evaluation and optimization of therapeutic footwear for neuropathic diabetic foot patients using in-shoe plantar pressure analysis. *Diabetes Care*. 2011;34(7):1595–1600. doi:10.2337/dc10-2206
27. Johnson M, Newton P, Goyder E. Patient and professional perspectives on prescribed therapeutic footwear for people with diabetes: a vignette study. *Patient Educ Couns*. 2006;64(1–3):167–172. doi:10.1016/j.pec.2005.12.013
28. Paton JS, Roberts A, Bruce GK, et al. Patients' experience of therapeutic footwear whilst living at risk of neuropathic diabetic foot ulceration: an interpretative phenomenological analysis (IPA). *J Foot Ankle Res*. 2014;7(1):16. doi:10.1186/1757-1146-7-16
29. Vileikyte L, Rubin RR, Leventhal H. Psychological aspects of diabetic neuropathic foot complications: an overview. *Diabetes Metab Res Rev*. 2004;20(Suppl 1):S13–8. doi:10.1002/dmrr.437
30. Beattie AM, Campbell R, Vedhara K. What ever I do it's a lost cause. The emotional and behavioural experiences of individuals who are ulcer free living with the threat of developing further diabetic foot ulcers: a qualitative interview study. *Health Expect*. 2014;17(3):429–439. doi:10.1111/j.1369-7625.2012.00768.x
31. Jiang X, Yuan Y, Ma Y, et al. Pain management in people with diabetes-related chronic limb-threatening ischemia. *J Diabetes Res*. 2021;2021:6699292. doi:10.1155/2021/6699292

ActivArmor Case Studies

ActivArmor Case Study 1

Date of Case: August 2019

Author: Dr. Kevin Kaplan, Orthopedic Surgeon and NFL team physician

Case Presentation:

Professional NFL football player who had surgery for a scapholunate ligament repair. He needed protection on his wrist for training camp and wanted to be able to use his arms as a defensive lineman.

Exam/Diagnosis/Assessment:

Skin incision was healed. He had limited wrist flexion secondary to the surgery and was working on his range of motion during the preseason.

Treatment:

The player was being treated as per the normal postoperative rehabilitation protocol. I prescribed an ActivArmor cast to be made with the player in wrist extension which was his functional position as a lineman.

Outcomes:

The player was able to successfully make the team because of his ability to function while healing and not disturbing the repair. He remains an integral part of the Jaguars and has not had any wrist issues since being treated.

ActivArmor Case Study 2

Date of Case: October 2021

Author: Dr. Kevin Kaplan, Orthopedic Surgeon and NFL team physician

Case Presentation:

High school football safety sustained a minimally displaced 5th metacarpal fracture. The athlete wanted to play despite the injury.

Exam/Diagnosis/Assessment:

The skin was intact. He was neurovascularly intact. He had minimal deformity of the mid shaft of his 5th metacarpal. The player had tenderness to palpation over the fifth metatarsal.

Xrays showed a minimally displaced 5th metacarpal shaft fracture.

Treatment:

The player was prescribed an ActivArmor cast and was allowed to return to football as tolerated with serial X-rays to ensure no displacement.

Outcomes:

The player successfully played with his ActivArmor cast and even with the cast was able to lead the team in interceptions and help the defense go to the state championship. His fracture remained stable and healed uneventfully

ActivArmor Case Study 3

Date of Case: Summer 2020

Author: Lindsey Snow, MOT,OTR,CHT,ATC,LAT

Case Presentation:

Pt. is a female in late 40's. Three years ago a brain tumor was found and she had extensive brain surgery that left her with months of rehabilitation to learn to walk and perform all daily living tasks again. She returned to cross fit where she injured her wrist following a heavy lift.

Exam/Diagnosis/Assessment:

Pt. had visit with orthopedic hand surgeon and following MRI showed a scapholunate ligament tear that required surgical repair.

Treatment:

Post surgery pt was depressed because her comeback from brain tumor was cross fit. She couldn't find a cast that she could sweat in and clean that was ruined from one workout. Pt. was introduced to ActivArmor and returned to cross fit following doctor restrictions wearing AA brace. Pt. was resilient and within a year qualified for the FIRST EVER crossfit games for adaptive athletes of 2021. Pt. was able to meet this goal while continuing her workouts safely using AA device.

Outcomes:

Pt. reported no skin break down during workouts, injury healing time she's convinced was quicker secondary decreased depression and getting back into a gym sooner.

ActivArmor Case Study 4

Date of Case (approx.): July 2021

Author: Lindsey Snow, MOT,OTR,CHT,ATC,LAT

Case Presentation:

Freshman, male football player fell and fractured wrist playing football.

Exam/Diagnosis/Assessment:

Pt. required pinning of wrist and a protection orthosis. When pins were removed pt. was eager to return to workouts however MD was hesitant secondary pt. age and understands how rough teenage boys can be.

Treatment:

Pt. and MD were educated on ActivArmor device and it was a go. Pt. returned back to workouts and was able a completely different patient after receiving the device and interacting with his team. I saw more smiles.

Outcomes:

Pt. worked out for hours a day and no skin break down. Pt. did have some tan lines in the shape of AA that let me know he was wearing his brace :) Pt. returned back without a beat and says "thank goodness I had this because my conditioning continued to improve and I didn't stink in front of the ladies"

ActivArmor Case Study 5

Date of Case: September 2020

Author: Lindsey Snow, MOT,OTR,CHT,ATC,LAT

Case Presentation:

Pt. fell and had a radial head fracture that was non op. Pt. was scheduled for a late honeymoon (Male, mid 30's) secondary COVID and when he had to tell his wife the river trip needed to be canceled secondary being in a cast.

Exam/Diagnosis/Assessment:

Radial head fracture, non op but required elbow and wrist immobilization

Treatment:

Pt. was fitted for a long arm AA orthosis and was able to go on the river trip and enjoy his honeymoon.

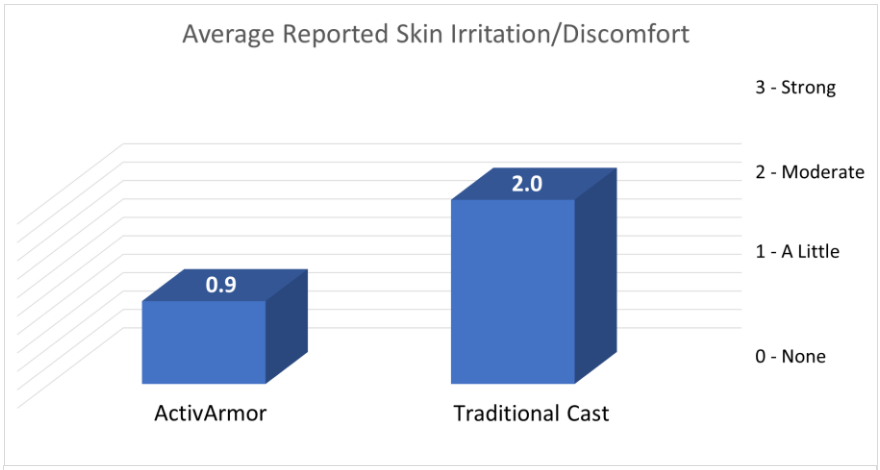
Outcomes:

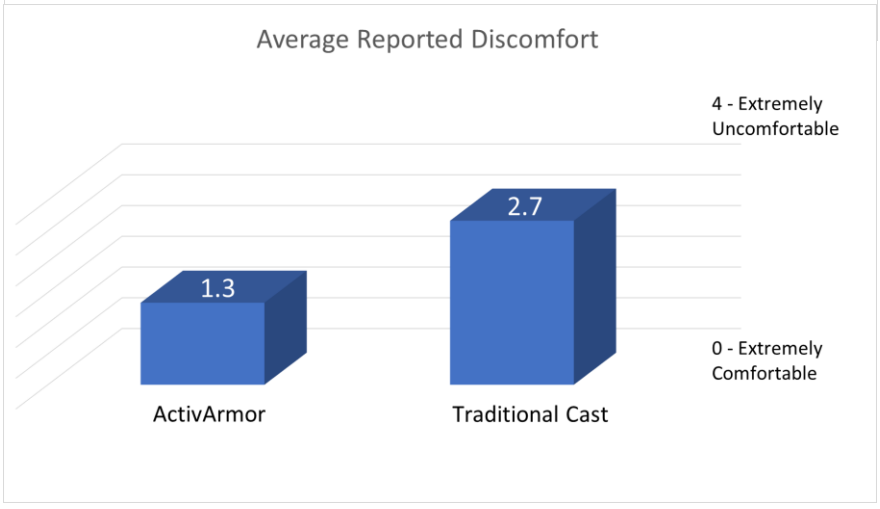
Pt. radial head fully healed after follow up in 6 weeks and pt. reported success with river trip. He said his skin condition was amazing even after being in the river for 2 full days and ended with happy wife, happy life!

ActivArmor Bacterial Load Study (December 2019): 6 volunteers wore a traditional cast on one arm/leg and an ActivArmor cast on the other for 10 days. Upon removal, the patient's skin was swabbed with sterile saline and incubated on Agar plates. The bacterial colonies were recorded (see photos at right).

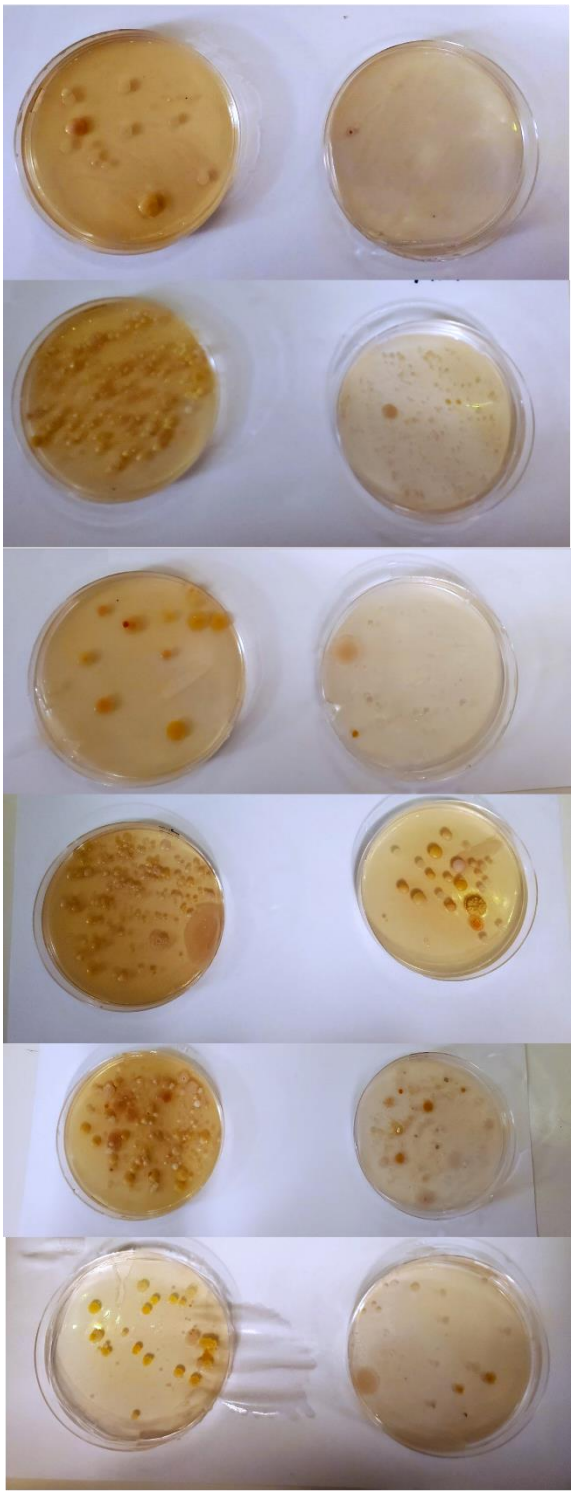
> ***"It actually decreases the bacterial level, because you can actually wash underneath."***
>
> — Michael Fitzmaurice, MD, Fitzmaurice Hand Institute, Scottsdale, AZ

ActivArmor Patient Comparative Survey Results (December 2019): 15 volunteers were put in both traditional and ActivArmor casts and asked to compare their experiences quantitatively on a numerical scale. The statistical results are exhibited in the charts below.





Traditional Cast **ActivArmor**

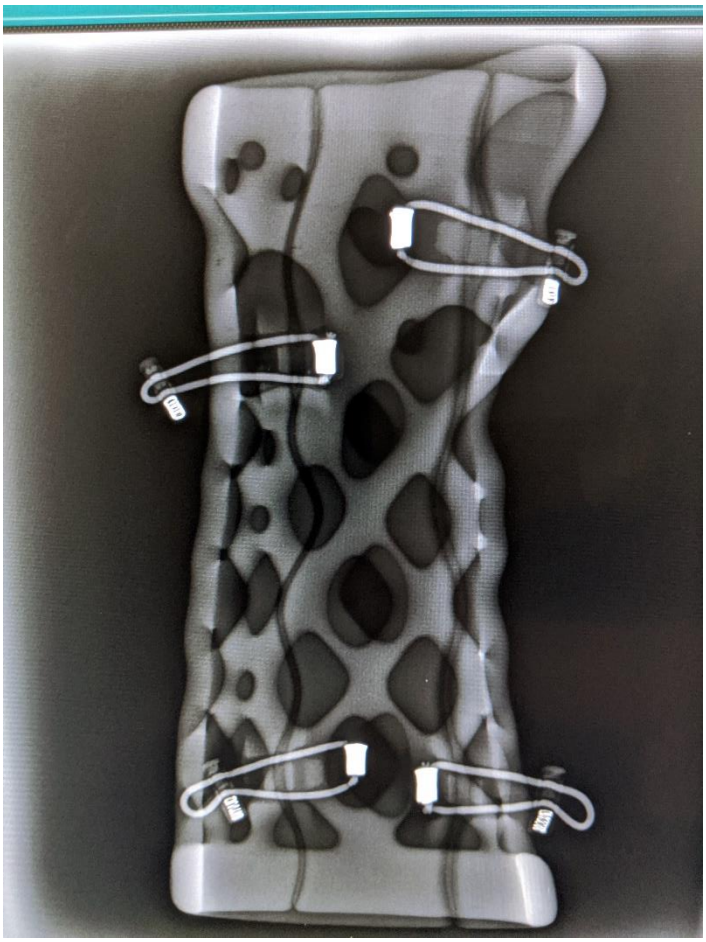


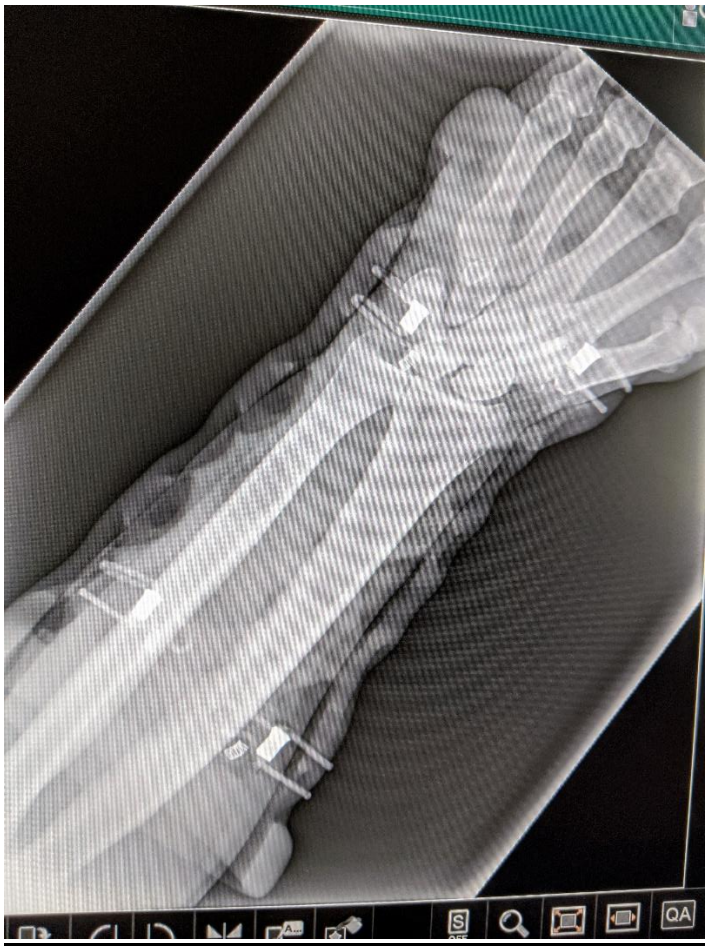
"You don't get the skin breakdown that you do with traditional casts. Less risk of skin infection; you can view the incision as well as pin sites, where you can't monitor those in a traditional cast. So these are great for post-op patients. We've seen the same healing rates, I'd say… better [with ActivArmor] because it's a ***great fit and it's a great immobilizer****."*

- Jason Browder, PA, Alpine Orthopedics, Gunnison, CO

Radiolucency Studies

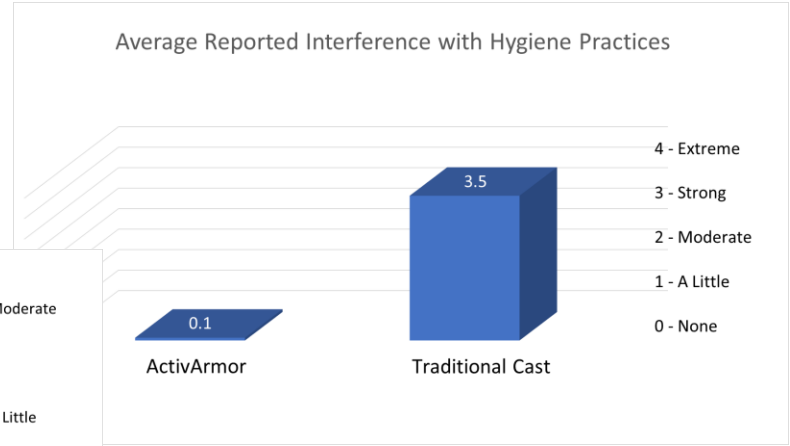
ActivArmor devices are made from ABS (Acrylonitrile Butadiene Styrene) plastic and are radiolucent.

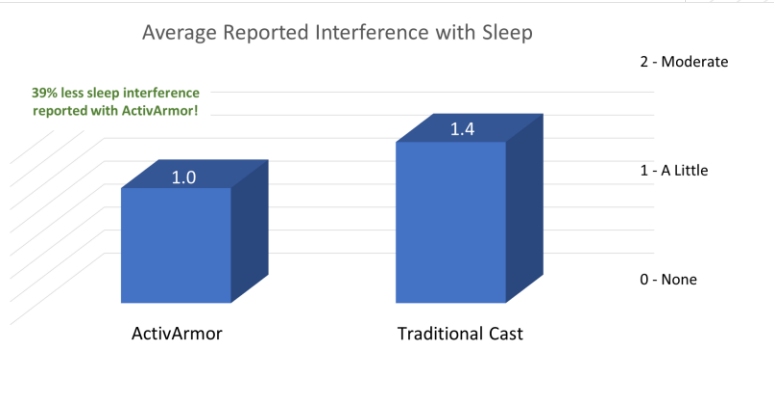




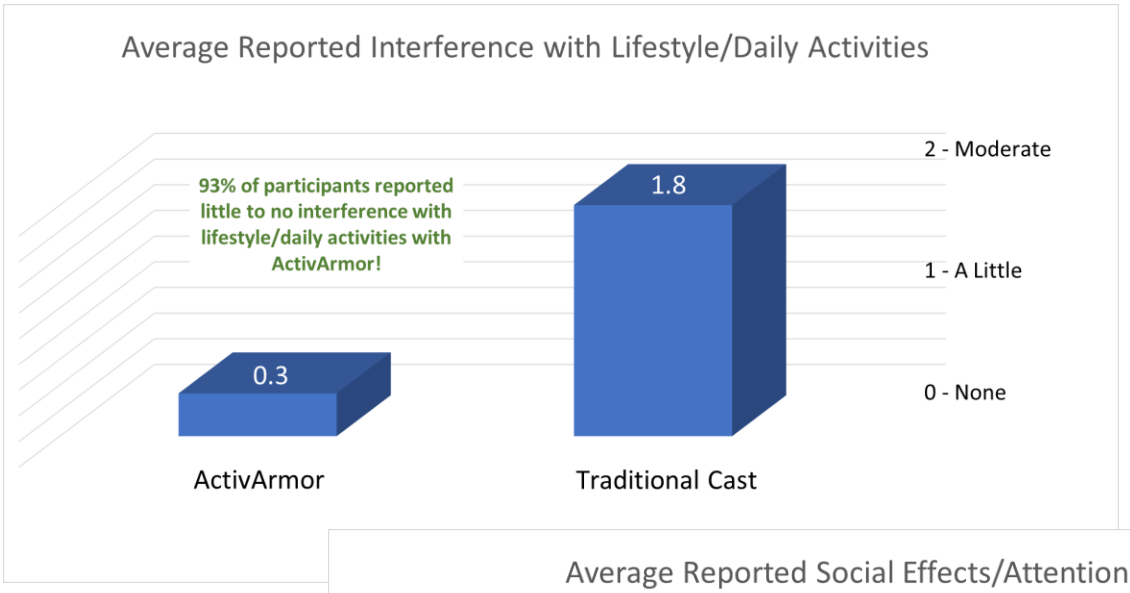
Sleep and Hygiene Studies (December 2019):

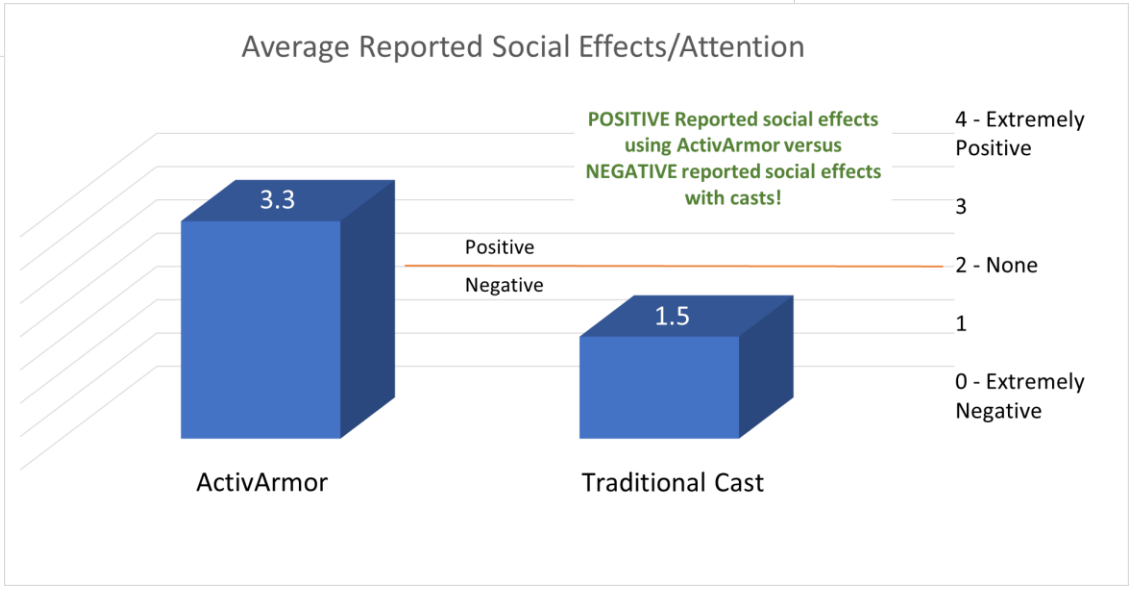
15 volunteers were put in both traditional and ActivArmor casts and asked to compare their experiences quantitatively on a numerical scale. The statistical results are exhibited in the charts.



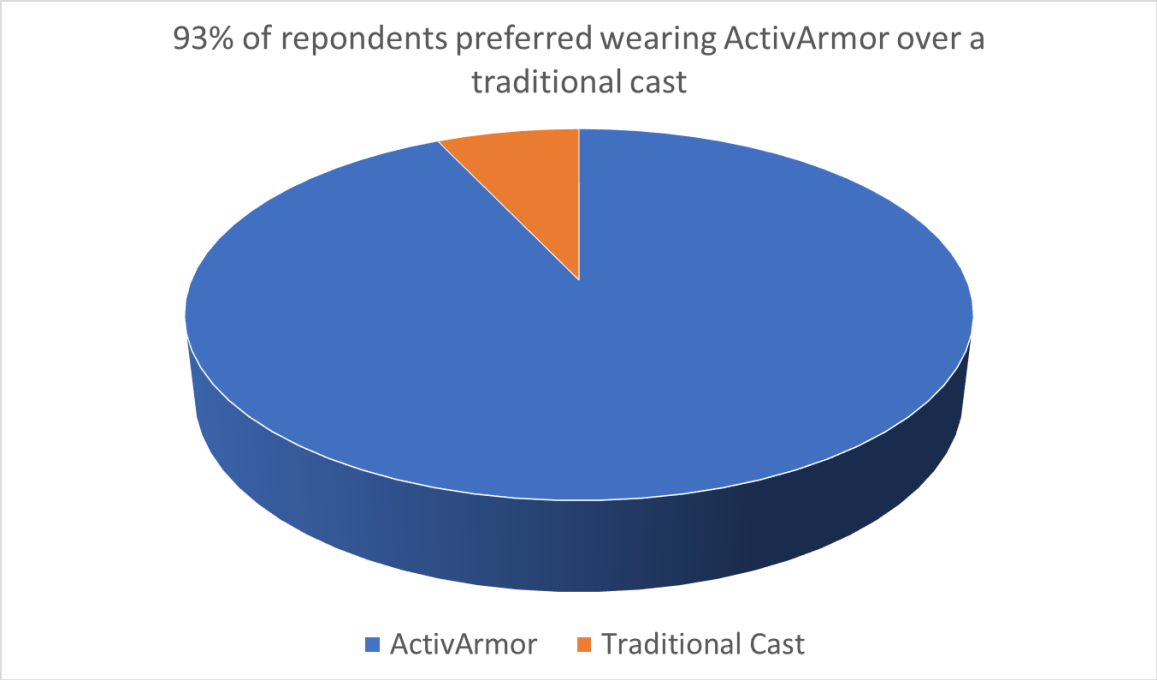


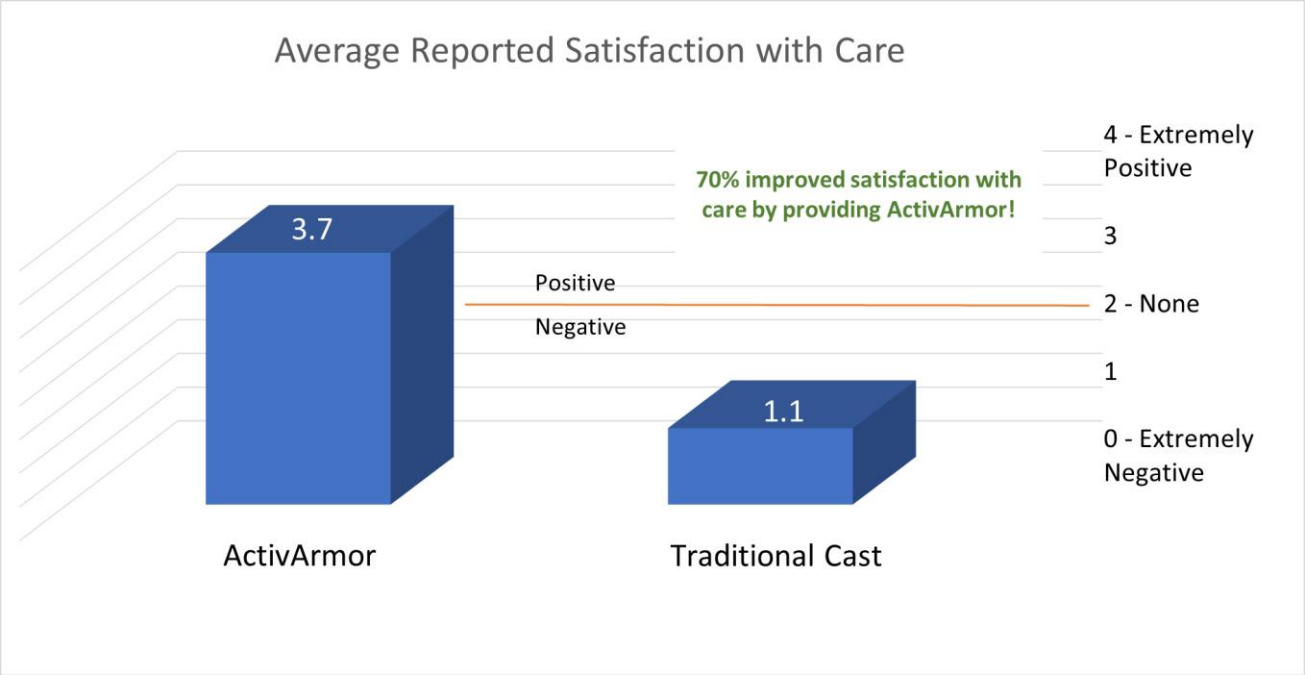
Patient lifestyle and social effects (December 2019): 15 volunteers were put in both traditional and ActivArmor casts and asked to compare their experiences quantitatively on a numerical scale. The statistical results are exhibited in the charts.





Patient Satisfaction (December 2019):





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