

# 3D Printed Casting and Splinting System

## Methods

This value analysis brief presents information on the potential clinical and economic benefits of using the ActivArmor 3D Printed Casting and Splinting System for on-site fabrication of custom-fitted and designed plastic orthoses for immobilization. The referenced data were obtained through published research on both ActivArmor orthoses and other comparable custom-fabricated products (as referenced), due to limited published data on ActivArmor devices. Unpublished studies were also included in this analysis due to limited published economic data for the ActivArmor 3D Printed Casting and Splinting System.

## Background

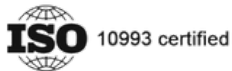
Traditional fiberglass casting methods are used for immobilization of acute orthopedic injuries like fractures. Total Contact Cast (TCC) is the gold-standard for treatment of diabetic pedal neuropathic joint disease, also known as Charcot Foot. (1)

There are many known issues with fiberglass and plaster casting methods including:

- *Not adjustable for swelling, which can put patients at risk for compartment syndrome*
- *Can't observe the underlying skin, which can hide infections*
- *Can't treat the underlying skin, including lacerations or incisions*
- *Must be sawed off and re-applied for exams, which takes clinical staff time, creates medical waste, can result in cast saw burns and/or poor patient experiences*
- *Traps moisture and bacteria, which can cause skin maceration, itch and smell*
- *Restricts basic hygiene practices like bathing and hand sanitizing, which can result in lifestyle restrictions and transmission of viruses*
- *Additional office visits due to cast issues/discomfort disrupt clinical flow and reduce capacity/patient throughput*

According to the NIH, over 10% of pediatric patients have unplanned office visits due to cast problems (2)

## Potential Clinical Benefits



- **MORE HYGIENIC** - Allow patients to wash and sanitize while immobilized, to improve patient quality of life, satisfaction, and **reduction in viral transmissions**
- **ACCESS TO SKIN** - Allow for skin/incision observation and treatment during healing, to **reduce complication/infection rates**
- **BREATHABLE** - Doesn't trap moisture/bacteria against the skin; to **reduce patient discomfort complaints and skin breakdown**
- **ADJUSTABLE** - able to be tightened or loosened for changes in swelling to **reduce the incidence of malunions or compartment syndrome**

In clinical trials, 3D printed casts have been found to effectively hold reduction and maintain fractured bone alignment. (3) In multiple clinical studies (3) (4) (5), no instances of cutaneous complications, compartment syndrome or pressure sores were present, and adequate stability for healing was achieved. In case studies, ActivArmor casts demonstrated 'excellent' clinical effectiveness and patient satisfaction metrics. (6)

Radiolucency tests showed optimal visualization through X-ray, in both locked-on and removable configurations.



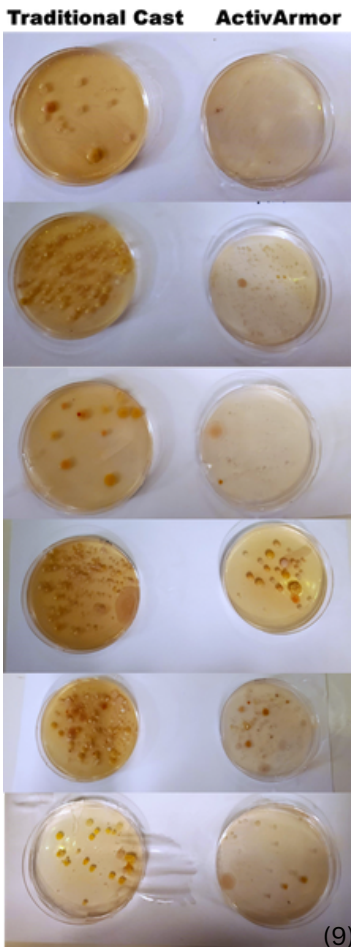
“You don’t get the skin breakdown that you do with traditional casts. Less risk of skin infection; you can view the incision as well as pin sites, where you can’t monitor those in a traditional cast. So these are great for post-op patients. We’ve seen the same healing rates, I’d say... better [with ActivArmor]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

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

Bacterial Load Case Study

***"It actually decreases the bacterial level, because you can wash underneath."***

— Michael Fitzmaurice, MD,  
Fitzmaurice Hand Institute,  
Scottsdale, AZ

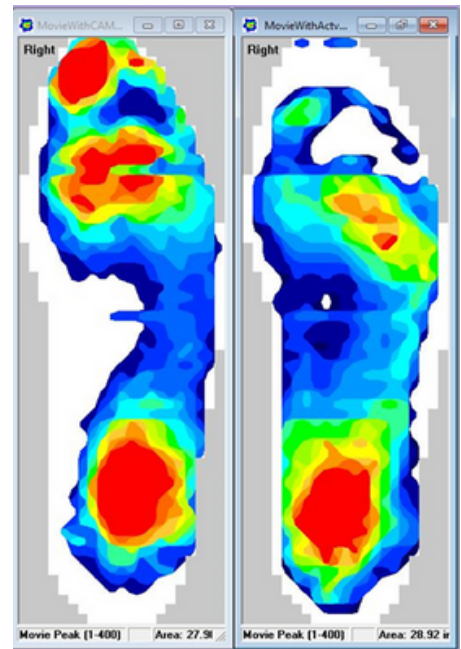


3D Printed Walking Boot Offloading Study

In multicenter observational studies, custom-molded offloading boots effectively prevented recurrence of wounds, the necessity for amputation and mortality rates in high-risk diabetic foot patients. (7) Patients with diabetes are prone to foot injury, infections and ulcerations, and the recommended treatment is Total Contact Casting (TCC). TCC's often have to be replaced weekly for observation and treatment of the patients' wounds, which increases patient-care costs and reduced clinical capacity for providers. Diabetic foot patients are prone to injury and infection due to circulation issues and neuropathy, leading to further increases in costs due to higher amputation and mortality rates. TCC's are difficult to apply in a clinical setting, to accommodate for diabetic insoles and offloading of wounds/ulcers, so custom walking boots are frequently necessary. These custom CAM walkers often take weeks or months to be fabricated by DME suppliers at high cost to patients with high deductibles or without adequate insurance coverage.

In offloading pressure tests, ActivArmor walking boot tests showed decreased plantar pressure points in comparison to CAM walkers. (8)

ActivArmor custom walking boots took only a few days to fabricate, and were able to be printed on-site at a fraction of the cost of the custom CAM boots.



***Custom offloading boots have been shown to reduce wound recurrence, amputation and mortality rates in high-risk diabetic foot patients***

Potential Economic Benefits



Fiberglass casting is billed as a procedure code with casting supplies. The application process time includes preparation of the casting materials, molding materials to the patient, wrapping layers of cotton and fiberglass, and then clean-up. (10) At each check-up or for any casting issues or adjustments, a cast saw must be used to remove the cast and the process repeated to re-apply as needed.

ActivArmor custom orthoses are billed as DME, using commonly-used custom splinting codes, including L-3906 (wrist cockup), L3808 (thumb spica/mp block), L3913 (hand-based), L-3763 (long-arm), L-2108 (AFO), and L-4631 (offloading boot).

***A digital casting system can improve billable margins and reduce overall patient-care costs***



No HIPAA information is shared



**Works with ANY  
3D printing  
technology**

Utilize existing equipment  
down-time



**Turn your medical  
modeling or sim lab  
cost-center into a  
Profit Center!**

The ActivArmor digital design and fabrication process includes a 1-minute scan using a free iPhone app, a simple design process on ActivArmor's cloud-based software, and an on-site print on any 3D printer, in any material desired. (Print times may vary based on the printer and design.)

ActivArmor offers a turnkey package including an affordable high-speed printer, or custom offsite fabrication services, depending on clinician preferences, for a tailored experience for your facility.

### Citations

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5. Jack Graham, Mark Wang, Kaela Frizzell. Conventional vs 3-Dimensional Printed Cast Wear Comfort. Published August 27, 2018, <https://doi.org/10.1177/1558944718795291>
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8. David Shofler, DPM MSHS, Western University College of Podiatric Medicine, Pomona, California Total Contact Cast Replacement 3D Printed Walking Boot Offloading Testing
9. 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.
10. Miller, John & Armstrong, David. (2014). Offloading the diabetic and ischemic foot: Solutions for the vascular specialist. *Seminars in vascular surgery*. 27. 68-74. 10.1053/j.semvascsurg.2014.10.002.

## Improve patient satisfaction rates and new patient referrals

3D printed casts have been proven to improve the patient experience and satisfaction rates in clinical tests. (5)

The ability to practice basic hygiene, like bathing or washing your hands before you eat, is an essential part of your patients' lives, and is becoming the standard-of-care, with the advancement of improved infection-control policies. The ActivArmor 3D Printed Casting and Splinting System keeps facilities at the forefront of innovation, safety and efficacy by empowering orthopedic providers with the ability to design unlimited patient-specific orthoses for fracture-care and support for chronic conditions.

**Build your reputation as  
INNOVATORS, and gain the  
competitive advantage in your  
community with next-gen casts**



[www.ActivArmor.com](http://www.ActivArmor.com)  
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