



# WHITE PAPER



## ACTIVARMOR

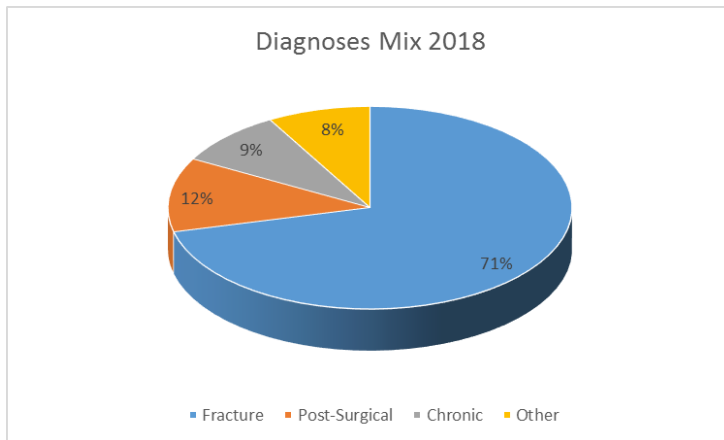
SUPPORT • ACTIVE • LIFESTYLE

“Elegant design and function that our patients love. It’s brilliant.”

- Dr. Craig Huston and Dr. Brandon Beauchamp

### Commercially Available and Validated:

- **Over 1,000 patients** have used ActivArmor for healing over the **last 5 years**.
- **Hundreds of physicians across the US** have prescribed ActivArmor orthoses for wide range of diagnoses, including:
  - Distal radius fracture
  - Broken wrist
  - Boxer fracture
  - Thumb and finger fractures
  - Carpal tunnel
  - Post-surgical support, *e.g.* CMC, tendon repair
  - Other chronic conditions and sports support



### Tested and Certified:

- Biocompatibility tested (**ISO 10993-5 certified**)
- Listed with the **FDA** as a Class 1 splint
- **Covered by most insurance**
- Microporosity testing completed for cleanability

### Collaborations and Partnerships:



- 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:



## • 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.

### ● **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:**

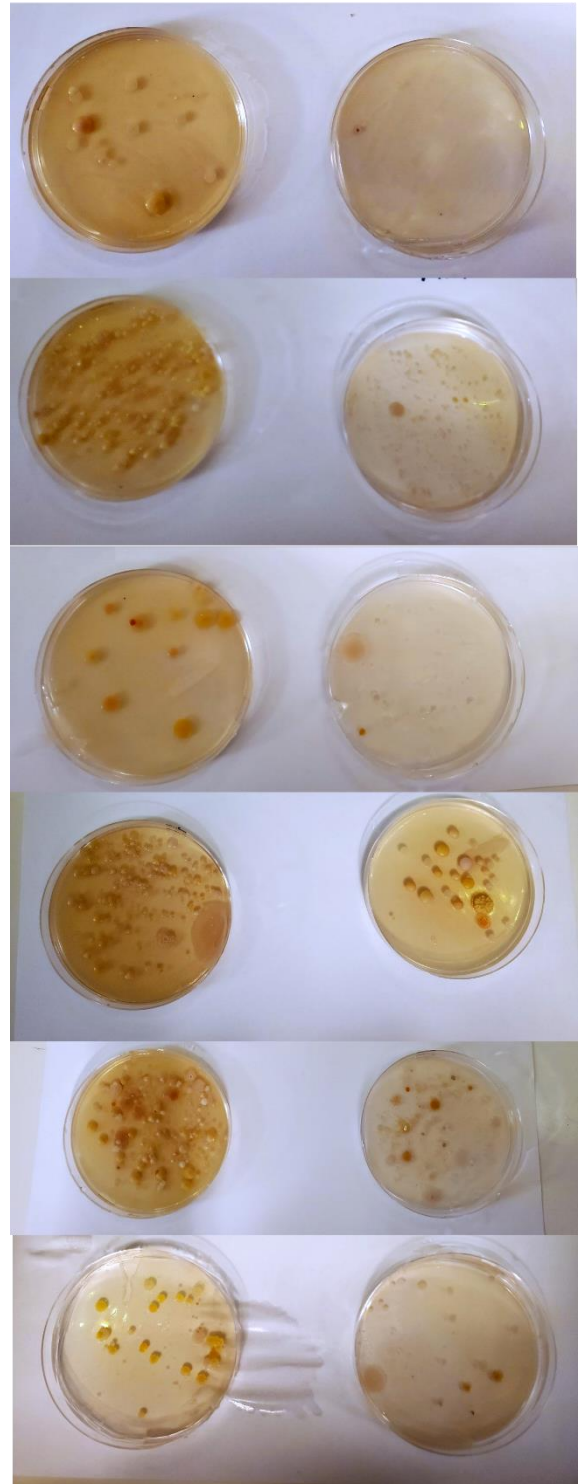
Pt. was fitted for a long arm AA orthosis and was able to go on the river trip and enjoy his honeymoon.

**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).

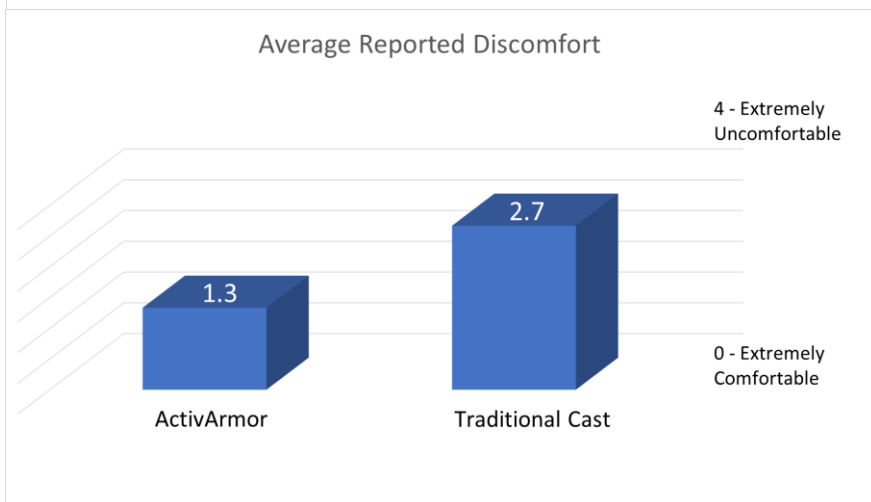
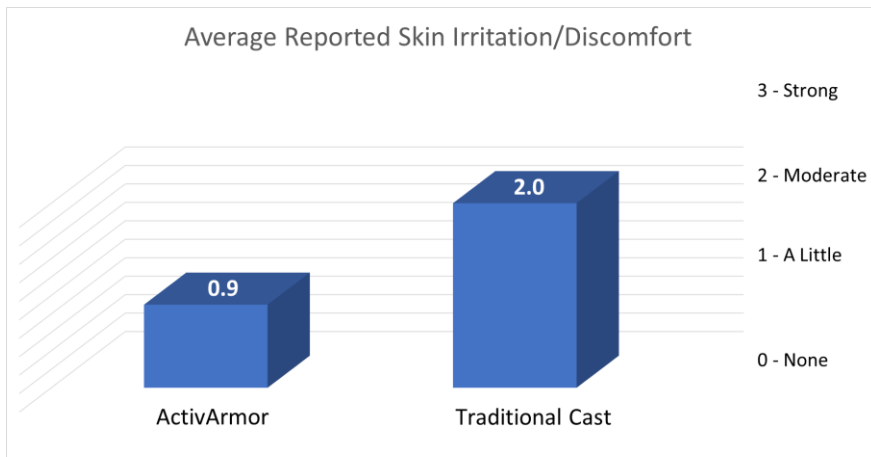
**Traditional Cast      ActivArmor**



***“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.

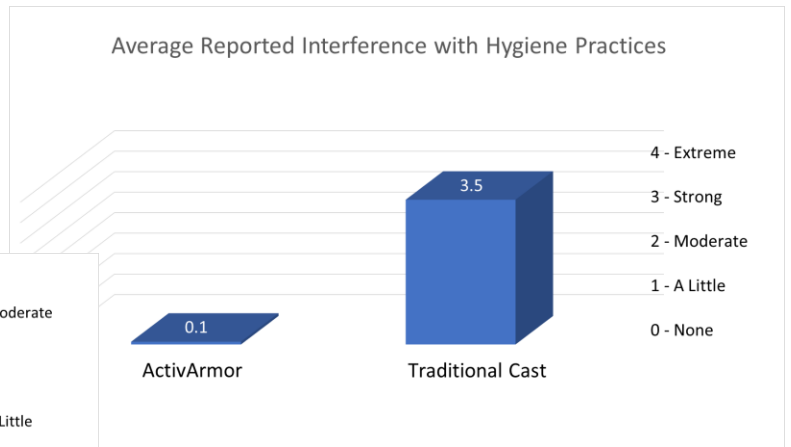
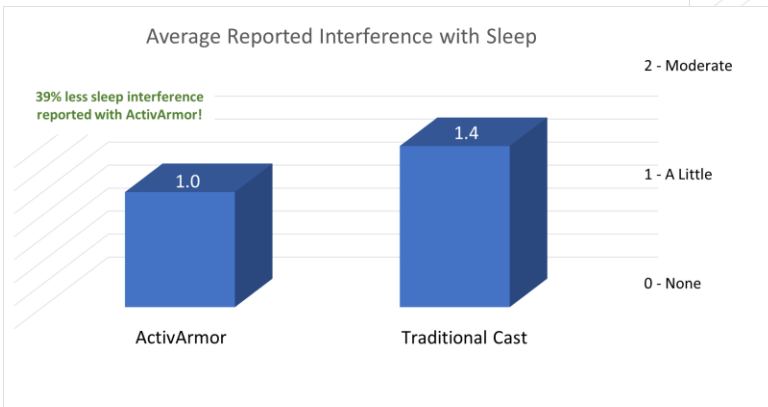


*“You don’t get the skin breakdown that you do with traditional casts. Less risk of skin infection; you can view the incision as well as pin sites, where you can’t monitor those in a traditional cast. So these are great for post-op patients. We’ve seen the same healing rates, I’d say... better [with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

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

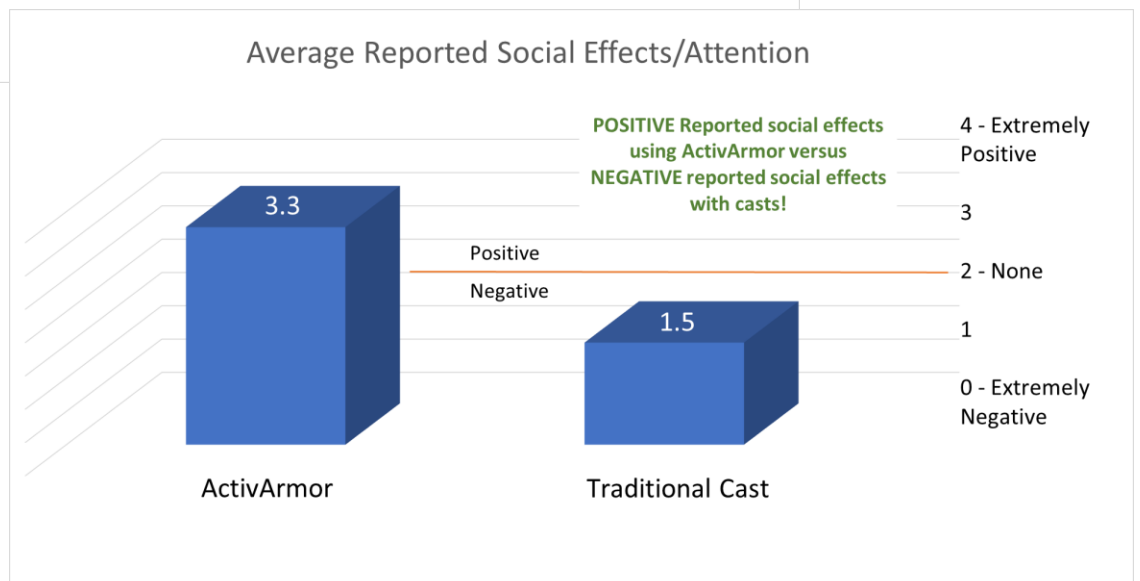
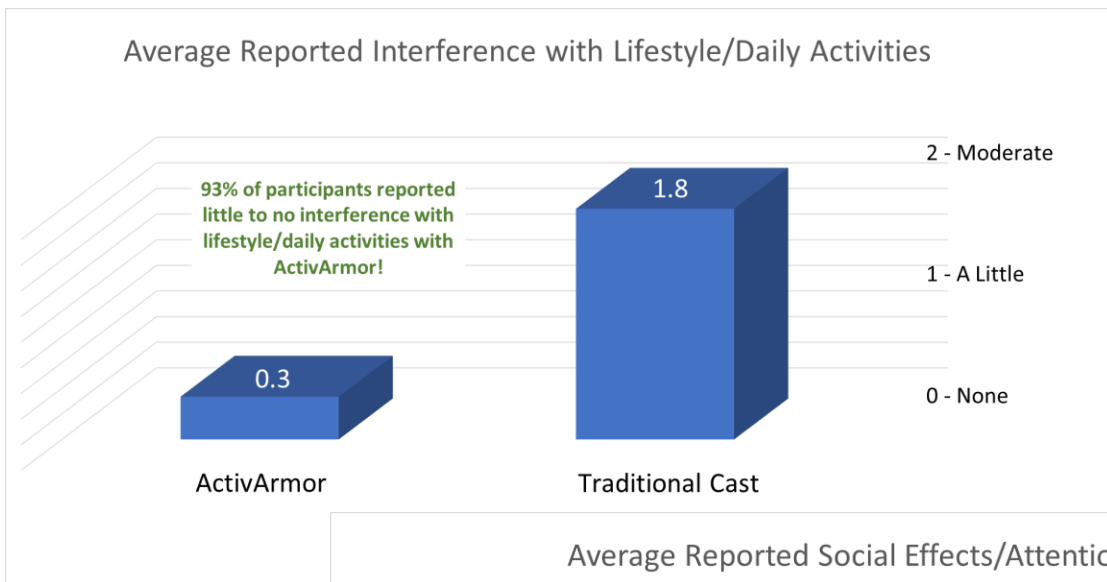
## Sleep and Hygiene Studies (December 2019):

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.



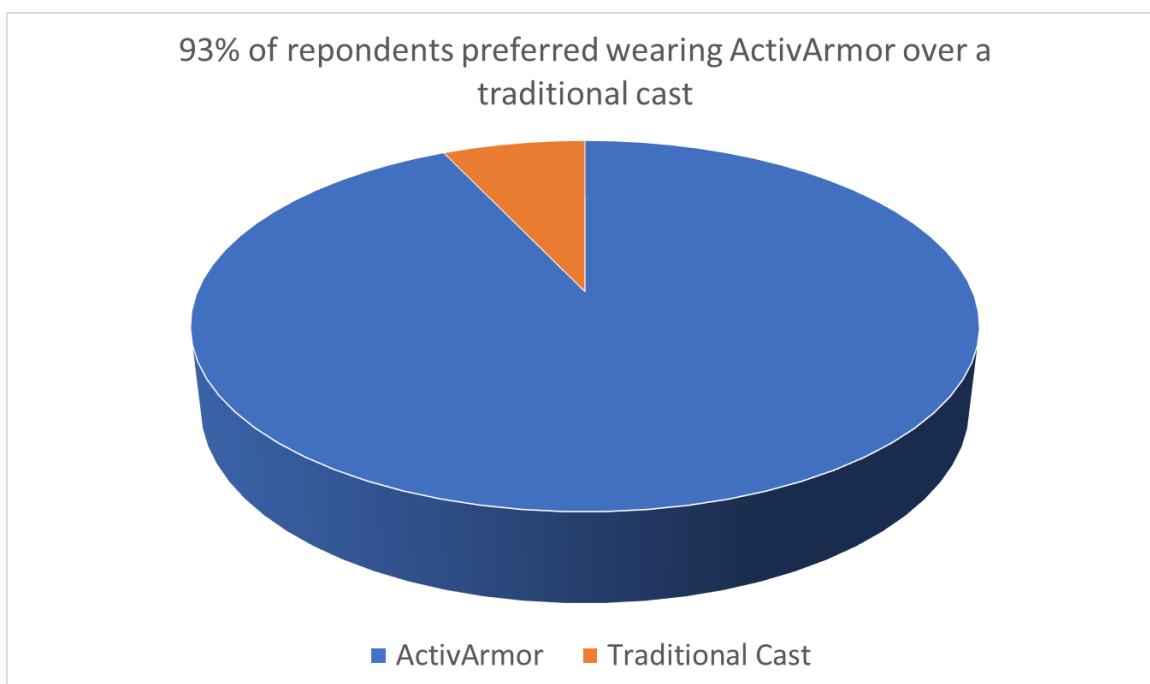
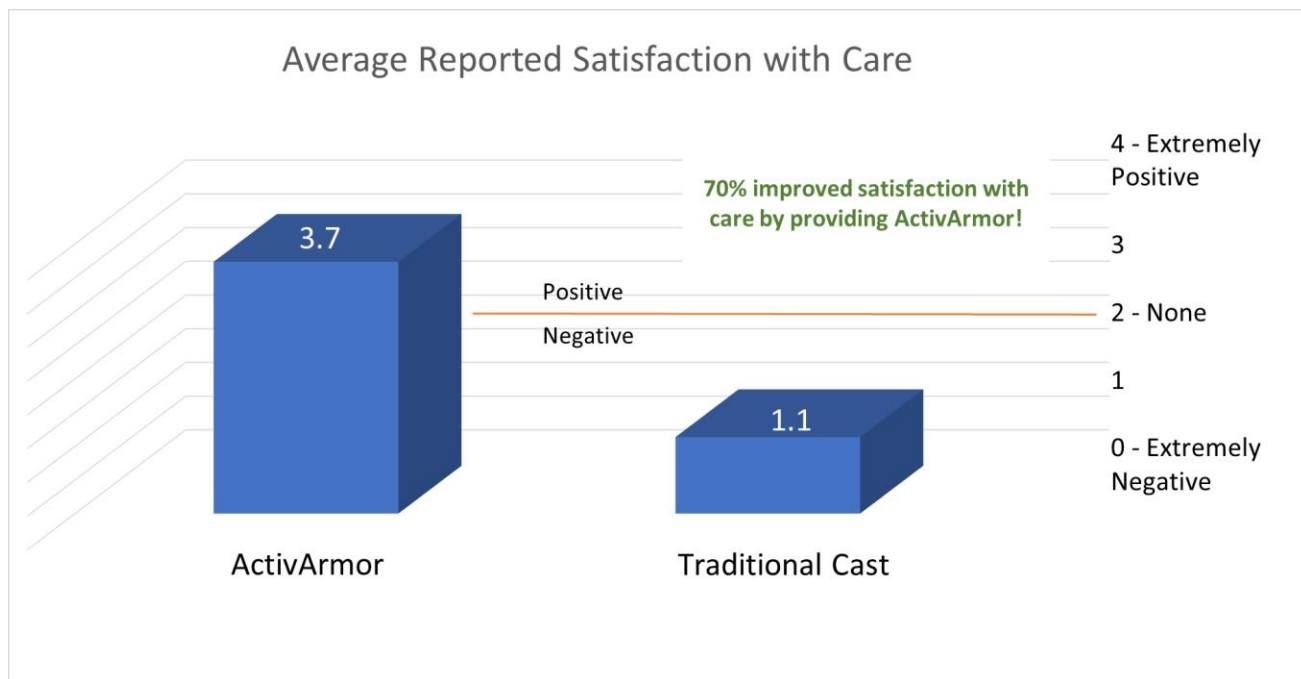
## Patient lifestyle and social effects (December 2019): 15 volunteers were put in both traditional and

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):



### **Research and Publication Opportunities Available!**

Author clinical trials and research abstracts on the latest in high-tech orthopedic devices with ActivArmor.

Be published in top trade journals and present at global conferences as an innovator and leader in Next-Gen precision medicine.

Contact us for details: [www.ActivArmor.com](http://www.ActivArmor.com)

[info@ActivArmor.com](mailto:info@ActivArmor.com)