

TetraGrip: A Functional Electrical Stimulation (FES) Device for Enhancing Upper Limb Function in People with Tetraplegia – Clinical Aspects, Subject Recruitment and changes in SCI incidence.

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Our other paper on the Tetragrip system outlines the technical development of the system and its testing on an able-bodied volunteer to assess its repeatability and reproducibility. Once the functioning of the system was satisfactory, participants with tetraplegia were recruited to this study after ethical approval was granted by IRAS (Ref no: 238528) and by Bournemouth University. The main objectives were:

- To test the usability of the Tetragrip system on people with Tetraplegia
- To test whether the repeated use of the Tetragrip system improves the person's ability to grip and grasp objects.

We based our recruitment estimates on our previous work implanting the Freehand system in the 1990s, with eligible subjects being identified through therapists, experienced in the assessment of suitability for FES systems, based in The Duke of Cornwall Spinal Treatment Centre in Salisbury, and through an advertisement in the newsletter released by INSPIRE, the charity funding this research.

We started recruitment late in 2021 once able to do so after the Covid epidemic, but unlike our work in the 1990s on the Freehand system, we had great difficulty in finding suitable participants. After considerable effort and extending the recruitment period we were eventually able to identify only 13 potential participants of whom only four were suitable for more detailed study. The other nine were either denervated at the level of their injury, did not have sufficient shoulder control or their hand function was too good. Of the four remaining participants, one improved to such an extent during their involvement that they no longer needed a system such as Tetragrip, one had to drop out due to other, non-related, medical complications and one decided that she did not want to wear the electrode sleeves and hence withdraw from the study. The final participant was able to use the system well but did not have time to complete the programme as they were working full time.

We received good feedback from the study participants about the system's overall design, including its aesthetics as well as its functionality. Since the electrode sleeve must be worn close to the skin to ensure stable contact of the electrode on the skin, they all appreciated the design which enabled this while allowing them to don and doff the sleeve quickly and safely. A number of recommendations emerged:

- i. reduce the number of leads from the stimulator and incorporate the wires within the sleeve.
- ii. make the electrode functional without applying water, or significantly prolonging the time it remains functional after water is applied.

Due to the problems with recruitment, we began exploring the reasons why this should be. It was soon apparent that the nature of spinal cord injuries has changed considerably over the last thirty years since we were recruiting for the Freehand study, with the age at injury, its cause, level of injury and severity all being significantly different. These findings have great implications for the development of such systems such as Tetragrip in the future. Possible reasons for these changes will be explored.