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# User experiences, preferences and choices relating to functional electrical stimulation and ankle foot orthoses for foot-drop after stroke

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**User experiences, preferences and choices relating to Functional Electrical  
Stimulation and Ankle Foot Orthoses for foot-drop after stroke**

Word count: 3452

## **Abstract**

**Objectives:** This study explores experiences, preferences and choices relating to use of Ankle Foot Orthosis (AFO) and FES for foot-drop by people who have suffered a stroke and by their carers, with the aim of informing clinical decision making.

**Design:** Semi-structured interviews explored individual experiences through a phenomenological approach. The Interpretative Phenomenological Analysis framework was used to enable organisation and interpretation of qualitative interview data.

**Setting:** Participants who had used both transcutaneous FES and one of several types of AFOs were recruited from a single FES Clinic.

**Participants:** Nine people who had suffered a stroke and four carers were recruited purposively, including people between two and nine years post-stroke, with different degrees of difficulty in walking.

**Results:** Participants described experiences, preferences and choices relating to AFO and FES use. All but one person (patient and carer) preferred FES use and related this to experiences of being able to move the ankle more freely, walk more normally, safely and independently, and experiencing greater comfort. Several people also used AFOs when the FES equipment failed, when travelling, and for use near water. One person rationed their use of FES on a daily basis due to allergic reactions.

**Conclusions:** The consensus in this sample demonstrated positive and negative experiences of both FES and AFO use. Participants weighed up pros and cons and despite predominant preferences for FES, many also used AFOs due to some

drawbacks of FES. Further research and development are required to reduce drawbacks and further explore user experiences.

**Key words:** stroke; foot-drop; user; carer; AFO; FES

## **Introduction**

This article uses qualitative data to explore experiences, preferences and choices relating to AFO and FES use among people with foot-drop after stroke and their carers. Numerous people survive stroke and require orthotic support to reduce the impact of lower limb disability. In the year 2000 an estimated 1.1 million people in Europe had strokes [1] and many experience impaired motor function in the lower limb - approximately 72% of a sample of 1259 survivors of a first stroke in the UK [2]. Impaired mobility often results from altered neural transmission and reduced active control of the foot during walking, leading to 'foot-drop' [3]. Walking becomes less safe and efficient, requiring greater effort [4][5], and the impact on function and participation should be minimised.

Foot-drop is frequently managed using a splint called an Ankle Foot Orthosis (AFO). This is advocated for those who demonstrate benefit in clinical guidelines for stroke from the Royal College of Physicians (RCP)[6]. A systematic review addressed the impact of AFOs on the gait of hemiplegic adults [7]. Thirteen studies compared walking barefoot or in shoes with AFO use, eight of which included stroke survivors (9 crossover designs and 4 single case studies). The majority of studies (six) used posterior plastic AFOs, two used metal AFOs and hinged AFOs, and one study each used an air-stirrup brace, plastic anterior, one-bar rigid, and tone-inhibiting dynamic AFOs. Significant improvements were found in seven out of nine studies that evaluated walking speed, and five of seven studies that measured stride length. Gait pattern and energy expenditure required when walking also improved. Most studies

demonstrating improvements used posterior plastic AFOS, although improvements were also demonstrated with the one-bar rigid and hinged AFOs, and the air-stirrup brace. High variability in results may also have resulted from varied trial characteristics, a lack of randomised controlled trials (RCTs), and small samples. More recent evidence was reviewed by the RCP's revised clinical guidelines [6][8], which judged four studies to be of good quality. All were randomised controlled crossover trials [9][10][11][12], including 10 to 28 participants in acute and chronic phases post-stroke. Different AFOs were used: a carbon composite anterior AFO [9], plastic rigid AFO [10], metallic and plastic custom-made AFOs [11], and a custom-made semi-rigid AFO [12]. Statistically significant improvements were demonstrated in step length, walking speed, timed up-and-go, time walking up stairs, energy cost, postural sway and standing symmetry. Seventy per cent found increased self-confidence. No changes were demonstrated in cadence, step time, double support time, oxygen consumption and heart rate. However, studies of participant satisfaction raised concerns about the cosmetic appearance, ease of application, reduced ankle movement, and weight of the AFO; these included studies using posterior and anterior rigid AFOs [7]. The lack of rigorous qualitative evidence regarding individuals' experiences of AFOs indicates a need for further work.

Another approach to management of foot-drop is called Functional Electrical Stimulation (FES), the electrical stimulation of nerves that generate contraction of the muscles required to lift the foot, first developed in 1961 by Liberson [13]. Two systematic reviews have investigated orthotic effects [14][15]. The first included seven non-randomised trials and one RCT, with varied rigour, and found positive

effects on walking speed (both implanted and transcutaneous electrodes) and physiological cost index (transcutaneous electrodes) [14]. More recently, four RCTs and four non-randomised trials were included in a meta-analysis that looked at both orthotic and therapeutic effects of single-channel or multi-channel transcutaneous FES (5 studies) or single-channel TENS (3 studies). It identified significantly higher gait speeds in three of the trials using FES [15]. The recently updated RCP guidelines [6] state that FES should only be considered non-routinely for people with foot-drop that is not well controlled using AFOs, and who demonstrate evidence of benefit.

The relative efficacy of FES and AFO requires further rigorous comparative investigation. One study has compared customised AFOs (varied in design), transcutaneous FES, and no orthotic in a small sample of fourteen people with chronic stroke [16]. FES and AFO use both demonstrated significantly improved function, with a trend towards superiority of AFO. However, participants used their own individualised AFOs, and received only a single day of FES training. The study also found a preference for FES use in twelve of fourteen participants, which requires further exploration.

A survey into perceptions of a transcutaneous FES model [17] included fifty-five per cent of all past and present FES users from the clinic, 73% (n=78) and 85% (n=45) of whom were stroke survivors, respectively. Primary reasons for FES use were described by most as reduced effort in walking, and increased confidence. However, survey design is usually optimal when based on initial open exploration of

individuals' experiences, and there is a distinct lack of published qualitative research in this area.

When deciding on management strategies, it is important to consider user views as well as cost and efficacy; the former has been emphasised at a government level [18]. There is increasing evidence in different fields of health care that user preferences and satisfaction are important to decision-making and outcomes of management. Studies have shown that respect for treatment preferences has increased satisfaction with health care in people with mental health conditions and heart failure [19][20], and improved management outcomes in mental health and addiction care [19][21]. However, the strength of the preference in relation to mental health management was important, associated with choices to initiate treatment and twelve-week adherence rate [22].

The evidence suggests that considering individuals' preferences is important in relation to different conditions, affecting choices to initiate treatment, adherence, satisfaction, and outcomes. However, the relationships are not necessarily clear, and no studies were located that addressed the management of foot drop after stroke. Therefore an exploratory study was designed to provide greater insight into experiences that influence preferences and choices. This was well suited to a qualitative approach that focuses on interpreting the words of individuals to gain insights into their experiences. Therefore, this qualitative study explored experiences of FES and AFO use among people in the chronic stage of stroke and among their



carers. The purpose was to inform clinical decision-making that aims to achieve optimal engagement with management strategies, and ultimately, outcomes.

## **Method**

### **Study design**

The aim was to explore lived experiences, described and interpreted through a phenomenological perspective, to encompass a collaborative and interpretative approach [22]. Face-to-face, semi-structured interviews enabled focus on the individual aspects of FES use [23]. The \*\*\*\* Research Ethics Committee and NHS \*\*\*\* approved the study (Reference: 06/S1101/37).

### **Sampling and recruitment**

A purposive sample of people who had suffered a stroke (PwS) and carers was sought through the FES Clinic at the \*\*\* (\*\*\*). Inclusion of PwS required previous use both of AFO and FES to manage foot-drop. Existing clinical data were used to identify people with different degrees of impairment and chronicity (6-metre walk speed on clinic entry; years since stroke: Table 1). The only exclusion criterion was severe communication limitations, for practical reasons. To ensure their representation, carers of people with severe communication difficulties were invited. Carers were defined as individuals who provided informal care.

## **Protocol**

A flexible topic guide was designed to address the study aims, with reference to relevant literature [23] (example questions in Table 1). Participants were asked about experiences of strategies for managing foot-drop, including transcutaneous FES (peroneal nerve stimulation) and different types of AFO (detailed in Table 1).

Informed consent was obtained and interviews and analysis were conducted by an experienced qualitative researcher with physiotherapy training but no involvement in the FES Clinic, who aimed to remain neutral. One interview occurred in a quiet hospital room, with all others in participants' homes according to preference; they lasted 44 minutes on average (range: 20-73 minutes).

### **Data analysis**

Data analysis employed 'Interpretative Phenomenological Analysis' (IPA), which aims to interpret meanings associated with experiences, communicated by individuals through language [24]. The detailed process of transcription, participant verification [23], analysis, and rigour checking are provided in Figure 1,

[insert Figure 1 about here]

### **Results:**

Nine PwS and four carers agreed to participate. All carers were married to the PwS. Participant characteristics are listed in Table 1. Characteristics are generalised to a

degree to ensure anonymity; due to the small size of the pool of potential participants, combining data increases the risk of identifiability.

After data analysis, it was evident that participants were processing information from various experiences of AFO and FES use. Some experiences were linked with preferences for either AFO or FES use, and tended to focus on comfort, impacts on gait, and perceived normality of gait. However, other information was used to inform actual choices for daily use, and tended to be more pragmatic, relating to allergic reactions to FES electrodes, and the functionality of equipment. Figure 2 illustrates the three levels of experience, preference and choice that were interpreted from the results.

[Insert Figure 2 about here]

Interestingly, most participants made use of both FES and AFO at different times. Only Donald used his prefabricated post leaf spring AFO most of the time, while Paul alternated use of the same type of AFO and FES on a daily basis. All other participants used FES as their primary strategy, and kept their AFOs for specific purposes. All but Donald indicated that they preferred to use FES, but that specific negative experiences made it necessary to use AFOs as well. It appeared that the strategies were seen to have relatively complementary functions, but that neither was perfect alone.

Results are presented according to preferences, and quotations are used to trace back to related experiences, as well as to illustrate where preferences and choices were not in line.

### **Descriptions of preferring AFO**

Only Donald described a preference for using his prefabricated post leaf spring AFO the majority of the time – whenever he walked: ‘splints we use every day. The first thing I do in the morning is put my shoes and splint on now’. He saw this as routine, whereas FES was used as exercise equipment when his mobility was lower than usual: ‘when I’m confined to my bed for, say a fortnight or more, I put the electrodes on... and that then gets me back walking a lot quicker.’ It became clear through discussion that Donald found the wire connections of FES difficult to manage. Therefore, his choices related to negative experiences of FES, and positive views about AFOs as being easier to manage on a day-to-day basis.

### **Descriptions of preferring FES**

All other participants preferred using FES, and related this to a variety of experiences of both strategies. Several PwS and one carer valued the ability to exercise, strengthen, and mobilise the ankles and lower legs when using FES. David compared FES to his custom made solid AFO: ‘normally I would use the FES to go the gym... doing the equipment stuff it was strengthening my ankle whereas the weakness in this [AFO], it doesn’t, because the ankle is fixed in it.’ Shona also described greater flexibility of function when using the FES, compared with the post leaf spring AFO:

‘[the AFO is] restrictive from the point of even bending and getting down and getting up.’

Several aspects of gait were also felt to be facilitated more by FES use, including speed and increased foot lift during swing phase, with reduction in risk of tripping.

Paul explained: ‘being able to lift the foot and not trip, that’s the main benefit through it, is the lifting of the foot. ... I can’t put the foot out with the splint the same way as I can with that [FES]’. Liam stated: ‘I’m a lot slower with that [AFO]’. They used post leaf spring and custom made AFOs, respectively.

People compared experiences of FES and AFO use that related to function, independence, and perceptions of normality. Christopher commented on his prefabricated toe-off AFO: ‘if you’ve got a splint on, you are always, you always know that it’s there. There are times now when I forget I’ve got this thing [FES] on... psychologically, that you’re more normal. And people will say to you... how’s the foot? It’s fine, because I don’t think of it now... So that it looks better, it feels better, and I feel I can walk better’. Others felt that FES required less conscious thought during walking, which may link with comments regarding a reduced sense of awareness of having a disability, for the self and for others. Steven had used a prefabricated post leaf spring AFO and felt that FES gave ‘the action of walking as a normal person... it makes you look like a normal person that’s standing up, taking two steps forward and not thinking about it... [with AFO] I was always wondering, like, what’s my next step? Where am I? What’s going to happen to me now?’ As a carer, Aaron also felt that the FES enabled his wife’s gait to look more natural than

when using her custom made solid AFO. Marie explained that she felt more able to leave her husband unsupervised with FES than when using his prefabricated post leaf spring AFO: ‘Even after he had it [AFO], if he got up to go anywhere I got up with him and walked with him... occasionally I would let him go on his own... But nothing like with the stimulator [FES], he is totally on his own.’

Several additional reasons for preferring FES related to convenience and comfort. Discomfort was associated with AFO-use for some; Christopher found FES more convenient and comfortable in social situations than his prefabricated toe-off AFO: ‘the advantages are sitting in the house, going out... being able to switch off or on... [with AFO] you try and sit on a bus with your foot straight out.’

However, despite preferences for FES, these were modified by experiences of drawbacks for some, leading to choices to use both FES and AFOs. Participants commented on specific experiences of FES use that they had found to be barriers to its use. Some participants used FES as their primary orthotic, while keeping AFO as an emergency device as they perceived the latter to be less affected by equipment failure.

David did not want to travel with FES: ‘to go to the airport, I wear the splint because I’m safer with that... FES... doesn’t give you that amount of confidence, because it can break down.’ Christopher agreed: ‘This [FES]... doesn’t tell you when your battery’s gone dead. ... I carry my splint in the back, the boot of the car.’ Marie was concerned about using FES during air travel: ‘I’ve just never had the confidence to go through the airport with the stimulator on in case they think there’s a bomb.’

Several participants also commented that FES is limited near water, for example, Daniel stated: ‘you do use the splint when you come out of the shower because they always said don’t put it onto wet legs.’

Negative experiences of FES use necessitated lengthier or more frequent periods of AFO use. Paul described severe allergic reactions to the electrode pads: ‘I had terrible rashes... so I’m in the situation now where I’m working between the pads and a splint... I still think the benefit is knowing if I’m going [for] a long walk I can put it [FES] on and get out.’ David could not put FES on independently due to upper limb motor deficits: ‘the basic problem... about the FES is I can’t put it on myself, I need my wife to do that.’

To summarise, while the majority of participants in the study expressed preferences for the use of FES over AFO, they frequently chose to use both for other reasons, informed by experiences of their use. When considering the different types of AFO used, themes did not seem to differ substantially; and all used the same type of transcutaneous FES. There also seemed to be some convergence in the themes from PwS and carers, with agreement on issues such as the value of flexibility at the ankle and greater normality of walking when using FES, but concerns about it in other contexts, such as when travelling and near water.

## **Discussion**

The results of this qualitative analysis demonstrated a preference among most participants for using FES as the primary tool for managing foot-drop after stroke, although different experiences of both tools led to frequent choices to supplement FES with use of different types of AFO in specific situations.

Comparison of the study findings with those of previous qualitative research is limited by availability. Experiences of FES have been explored by Taylor and colleagues in a previous survey [19], and numerous similarities were found with the current findings. Taylor et al found that 70.1% of FES users did not use any other device, and that over 78% of participants felt more confident when using it; reduced effort when walking was the most commonly stated reason for preferring FES [19]. Further reasons that were common to both studies are: reduced risk of tripping and falling, increased speed of walking and distance, and more ability to exercise. Drawbacks to FES were also found in both studies [19], including descriptions of the need for help in putting on FES, and allergic reactions to electrodes. Several drawbacks found by Taylor et al. [19] did not arise in the current study findings, including reduced mobility, increased spasticity, and pain.

Evidently there are similarities in the findings of a few studies of FES users' views, although there is little material for comparison in relation to AFO use. This must also be viewed in the light of quantitative evidence relating to their efficacy. The RCP document more rigorous evidence for the use of different types of AFO than for FES [6]. While there is some evidence for the efficacy of both orthotic devices, and further high quality studies are required, user views should also be considered. As evidence



supports the potential for individuals' preferences to influence both participation in, and outcomes of, management, it is important to know more about individuals' experiences and views, and enable these to influence clinical decision making in appropriate ways. However, this study supports previous findings that highlight the complexity of relationships between preferences and choices [22]. Further studies should explore experiences, preferences and choices relating to different types of AFO and FES.

It is important to note that not everyone has the capacity to benefit from either strategy and clinical reasoning is paramount. The current study suggests that while many participants in this study had positive experiences of FES that affected their preferences, they were also frequently unable to rely on it alone, due to drawbacks that require further development and investigation.

The implications of this study should be viewed in relation to potential influences of the study context. Participants described many different positive and negative experiences of both AFO and FES use, and as a qualitative article, this study does not provide a direct comparison of cost-effectiveness. These results represent experiences that were described in relation to preferences and choices, not precluding value placed on different aspects of both tools. In order to explore experiences of both FES and AFO, participants were recruited from a pilot FES clinic. Because FES is not provided as standard clinical practice in the UK, comparative data were only available in this context. Some participants had attended the FES service due to dissatisfaction with current management, although not all. A valuable study would link qualitative

interviews with a randomised controlled trial of FES and AFO use for people with no previous experience of either. Until that is available, these early data provide useful insights. The rigour of the process was optimised by including participant verification, systems for checking the rigour and completeness of analysis, and by providing contextual information to enable the reader to judge the relevance of results to their situation [23].

## **Conclusions**

This study explored interview data from nine people who had suffered a stroke and four carers who described choosing between AFOs and FES for managing foot-drop after stroke. All but one person preferred using FES, due to improved ability to move the ankle, walk more normally, safely and independently, and experiencing greater comfort. However, some people described using AFOs in specific circumstances, such as when experiencing or anticipating FES equipment failure, when travelling, and when near water. One person was unable to use FES all the time due to allergic reactions. These findings provide valuable information for people who are involved in the management of stroke survivors with foot drop; they may contribute to decision-making, alongside other factors influencing appropriateness and efficacy.

The evidence has highlighted the value of pursuing more high quality RCTs and comparisons between AFO and FES use that incorporate exploration of user views. Further development of each strategy, and investigation of cost-effectiveness are required.

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## **Conflict of Interest Statement**

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper. The funders of the study had no role in study design, data collection, analysis or interpretation, or in the writing and submission of this paper.

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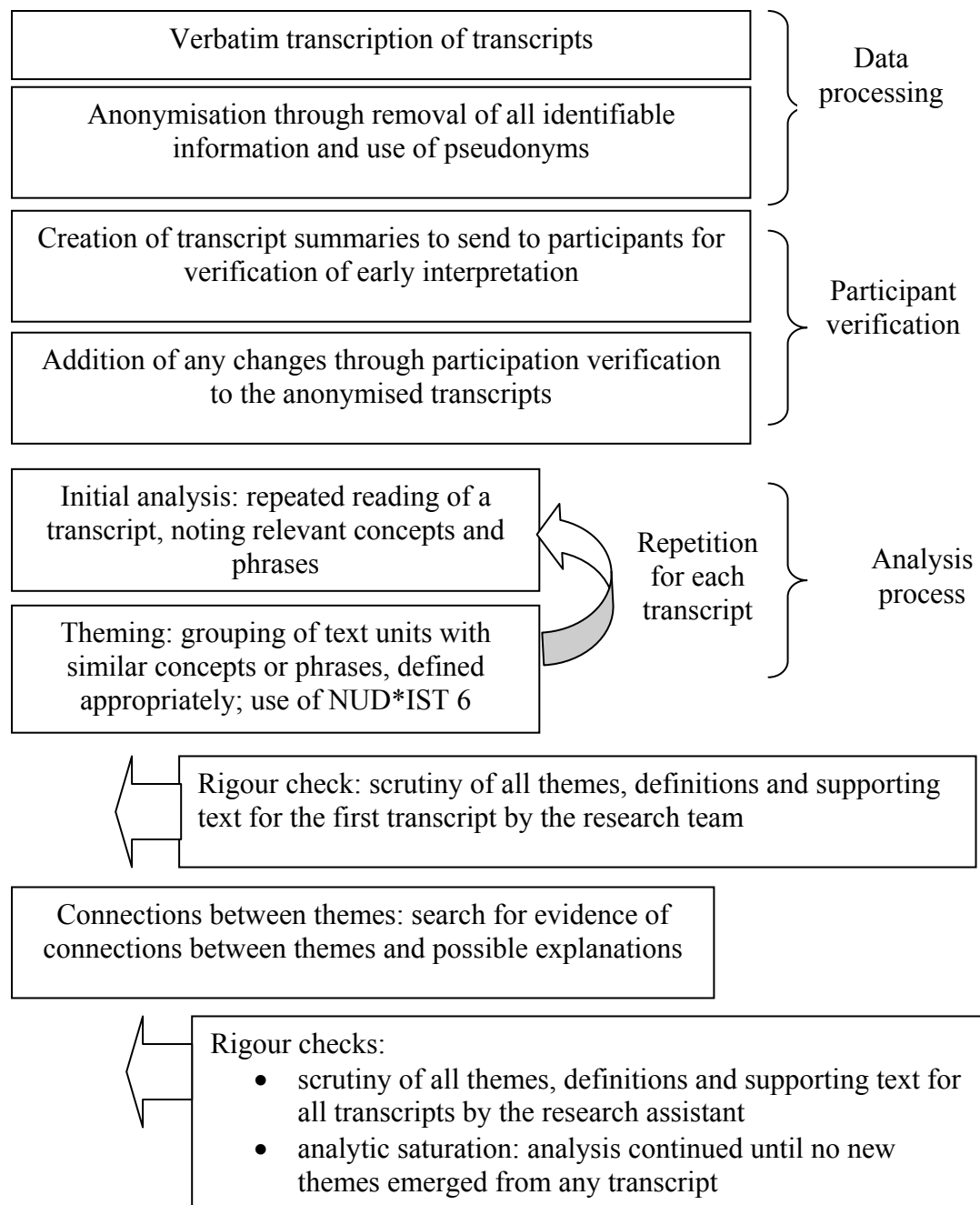


Figure 1. Summary of the data processing, verification and analysis process



Table 1: Participant and interview characteristics

| Interviewee characteristics                                                                                                                                                                                                  |              |           | Characteristics of the FES user (person who suffered a stroke) |                            |                                          |                          |                                                 |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|-----------|----------------------------------------------------------------|----------------------------|------------------------------------------|--------------------------|-------------------------------------------------|
| Pseudonyms                                                                                                                                                                                                                   | Male/ Female | Age Range | Left/right hemi-plegia                                         | Years since stroke (range) | 6-m walk speed on clinic entry (seconds) | Years of FES use (range) | Range of years of AFO use <sup>1</sup> (& type) |
| <b>Interviews with people who suffered a stroke; example questions:</b> What strategies did you try at the start of your rehabilitation? What did you think of that strategy? How did it affect the way you spent your time? |              |           |                                                                |                            |                                          |                          |                                                 |
| Kevin                                                                                                                                                                                                                        | Male         | 60-64     | Right                                                          | 0-2                        | 15                                       | 1                        | 0-2<br>(PLS AFO)                                |
| Paul                                                                                                                                                                                                                         | Male         | 65-69     | Right                                                          | >2-4                       | 17                                       | 2                        | 0-2 <sup>2</sup><br>(PLS AFO)                   |
| Matthew                                                                                                                                                                                                                      | Male         | 65-69     | Right                                                          | >8-9                       | 15                                       | 1                        | >8-10<br>(PLS AFO)                              |
| David                                                                                                                                                                                                                        | Male         | 65-69     | Left                                                           | >4-5                       | 14                                       | 3                        | >2-4 <sup>2</sup><br>(CMS AFO)                  |
| Steven                                                                                                                                                                                                                       | Male         | 60-64     | Right                                                          | >2-4                       | 31                                       | 3                        | early in rehabilitation<br>(PLS AFO)            |
| Liam                                                                                                                                                                                                                         | Male         | 60-64     | Left                                                           | >4-6                       | 23                                       | 2                        | >4-6 <sup>2</sup><br>(CMS AFO)                  |
| Christopher                                                                                                                                                                                                                  | Male         | 75-79     | Left                                                           | >6-8                       | 17                                       | 4                        | >2-4 <sup>2</sup><br>(PTO AFO)                  |
| Jack                                                                                                                                                                                                                         | Male         | 70-74     | Left                                                           | >4-6                       | 17                                       | 2                        | >4-6<br>(CMS AFO)                               |
| Donald                                                                                                                                                                                                                       | Male         | 70-74     | Left                                                           | >2-4                       | 31                                       | 2                        | >4-6 and ongoing<br>(PLS AFO)                   |
| <b>Carer interviews &amp; data relating to the person they care for (with severe communication difficulties); example questions:</b> What strategies did [name                                                               |              |           |                                                                |                            |                                          |                          |                                                 |

| of person with stroke] try at the start of your rehabilitation? What did you think of that strategy? How did it affect the way you spent your time? |        |       |       |      |    |   |                                      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|--------|-------|-------|------|----|---|--------------------------------------|
| Aaron                                                                                                                                               | Male   | 55-59 | Right | >4-6 | 16 | 3 | >2-4<br>(CMS AFO)                    |
| Daniel                                                                                                                                              | Male   | 60-64 | Right | >4-6 | 33 | 2 | >2-4 <sup>2</sup><br>(CMS AFO)       |
| Marie                                                                                                                                               | Female | 65-69 | Right | >6-8 | 20 | 2 | >4-6 <sup>2</sup><br>(PLS AFO)       |
| Shona                                                                                                                                               | Female | 40-44 | Right | 0-2  | 16 | 2 | early in rehabilitation<br>(PLS AFO) |

1. Note: all participants felt the need for ongoing management of foot drop. Unless otherwise stated, the duration of AFO use has been estimated by subtracting years of FES use from years since stroke. Ranges are presented to protect anonymity. 2. Accounts indicated that both AFO and FES are both used for different purposes.

PLS AFO = Prefabricated post leaf AFO; CMS AFO = Custom made solid AFO; PTO AFO = Prefabricated toe-off AFO

Figure 2. Interpretative theory relating to user experiences, preferences and choices in the use of AFO and FES for foot-drop after stroke

