Chapter

A Mixed Methods Study of the Experiences and Effectiveness of a Soft Brace for Adults with Degenerative Scoliosis

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Abstract

This chapter details a mixed-methods investigation of the experiences and effectiveness of a soft brace for adults with degenerative scoliosis. Study 1 explored patients' experiences of living with scoliosis, together with the pain and quality of life they experienced as a result of scoliosis. The secondary aims of the qualitative aspect of the study were to explore patient perceptions of wearing the soft brace together with the overall functionality and practicalities of the brace design. We found the main experiences of living with scoliosis in people over 50 were one of constant pain and limited activity. The interviews also identified the benefits of wearing the brace along with design issues associated with the comfort and practicalities of wearing the brace. Study 2 investigated the quantitative effects the brace had on adults with degenerative scoliosis. The quantitative questionnaire results were compared with those from the control group who did not receive the brace. Overall, we found that patients in interviews reported improvements in their quality of life, although these improvements were not reflected in the quantitative results. Implications of our findings for the treatment of adults with scoliosis by bracing, and directions for future work are discussed.

Keywords: scoliosis, degenerative, soft brace, experiences, quality of life, disability

1. Introduction

Surgery is the only form of treatment currently offered by the United Kingdom National Health Service (NHS) as standard care for adults who develop scoliosis. However, this treatment method has associated risks, such as trauma to the body, substantial blood loss and a high complication rate [1]. Operative treatment for adult lumbar scoliosis has a complication rate ranging between 56 and 75% with an 18–58% re-operative rate [2]. Compared to adolescents, adults and older adults who develop scoliosis have a greater risk of suffering from surgical complications due to age, as degenerative scoliosis predominantly develops in older adults.

An alternative method of treatment to surgery is bracing. There are several types of braces used to treat adults with scoliosis; the most frequently used brace is the thoracolumbar-sacral orthoses (TLSO). This type of brace is a two-piece plastic brace that is required to be worn full time [3]. One type of TLSO brace is the Boston

brace. This brace is made from prefabricated polypropylene material and is used to treat deformities that range from spinal regions T5 to L4 [4, 5]. Most braces are made up from at least one rigid component that affects the overall comfort and hence the efficacy of the brace. Additionally, most braces require a wearing time in excess of 12 hours, which has the potential to have an impact on wearers' lives.

This mixed methods study evaluated both the subjective patients' views of the effectiveness of the soft brace as well as the objective results of brace effectiveness [6]. The brace encourages corrective movements in the spine through manipulation using soft flexible bands, which are altered on a regular basis depending on the progress of the individual. The brace is made up from three individual sections: pelvic shorts, a body jacket and elastic corrective bands. The pelvic shorts act as an anchor and attachment point for the elastic corrective bands with the jacket acting as the second attaching point. The bands are designed to encourage spinal correction by reactivating (pulling the muscles back into the correct position and training the muscles to stay in that position) the spinal muscles. Furthermore, the brace aims to improve the patients' coronal and sagittal plane balance through the use of the corrective elastic bands as past research has indicated that an improvement in the coronal and sagittal plane can lead to an improvement in pain and/or functionality [7, 8].

To our knowledge, this is the first study to explore the experiences of wearing a spinal brace in a group of older adults with degenerative scoliosis using a qualitative design as previously this type of brace has only been used on adolescents [9–12]. The practicalities of the brace design for adults were unknown. Therefore, the use of a qualitative data collection method allowed for this new information to be gathered. For these reasons, it was decided that semi-structured interviews would provide a deeper understanding of the issues faced by patients with scoliosis than quantitative data by providing a much richer in-depth account and would allow the participants to give detailed descriptions of their experiences of living with scoliosis and wearing the brace [13].

Only two previous studies have examined the views of patients regarding the impact of scoliosis on their lives. Schwab et al. [14] in 2003 reported a self-assessment of 49 patients, 22 of whom had adolescent onset scoliosis and 27 patients who had degenerative scoliosis. Participants had a mean age of 63. The main aim of their study was to investigate the impact scoliosis had on health. They found that when comparing the SF-36 questionnaire data between patients with adult scoliosis against adults who experienced lower back pain, those with scoliosis had significantly higher perceptions of their health than those who had lower back pain. One of the main limitations of this study was that 22 of the patients had adult idiopathic scoliosis and their analysis did not differentiate between the two groups.

The second paper investigated individuals' self-assessment of their health-related quality of life when living with scoliosis [15]. The scores on the SF-36 and the Walter Reed Visual Assessment Scale questionnaires (WRVAS) were collected on 71 individuals who had an age range of 17–66, with a mean age of 33. They concluded that on both the SF-36 and WRVAS, older adults reported more pain than younger ones. However, one of the main issues with the study was that no Cobb angle measurements were taken; this is a limitation as previous research [16] has shown that there are correlations between an individual's Cobb angle and self-assessment. The second limitation is related to the ratio of gender in the sample: of the 71 participants, only 13 were male.

All other papers we found focused upon adult idiopathic scoliosis or solely operative management methods to treat scoliosis and therefore were not relevant to this study. Although the two papers described above did not present qualitative accounts, they are based on the self-assessment of living with scoliosis. The primary

aim of this study was to explore patients' experiences of living with scoliosis using a qualitative approach. The secondary aims of the study were to evaluate patient perceptions of wearing a soft spinal brace and to explore the functionality and practicalities of wearing this type of brace.

2. Study 1: qualitative investigation of patients' experiences of living with scoliosis and using a soft brace.

2.1 Method

2.1.1 Participants

For participants to be eligible for this part of the overall study, they were required to wear the brace for 6 months. This time period was selected as clinicians felt it would be where the most noticeable changes in the patients' health and pain scores would be observed. Furthermore, 6 months gave enough time for any initial teething problems with wearing the brace to be identified and resolved, as well as allowing the patients to reflect on their experiences of wearing the brace over a reasonable period of time. In total, eight participants, 1 male and 7 female, aged 55 and over were eligible for the semi-structured interviews.

2.1.2 Ethical approval

Ethical approval was granted by the NHS and the university research ethics committee of the first author. All participants were provided with a participant information sheet which provided a detailed explanation of the purpose of the study. A consent form asked participants to confirm that they had read the information sheet and fully understood what was being asked and whether they were happy to take part, if they met the inclusion criteria and did not match any of the exclusion criteria. Potential participants were also informed that the interview would be audio-recorded and that they had the right to withdraw their data up to 2 weeks after participating, after which time the data would be anonymised.

2.2 Interview schedule and procedure

2.2.1 Interviews

In this study, participants were asked about their experiences of living with scoliosis before they received the brace and once they had received the brace. From the overall larger themes that were generated from the participants' answers, subthemes were then extracted [17]. Braun and Clarke [17] recommend that thematic analysis should be seen as the foundation method for all qualitative analysis. They describe thematic analysis as a method for identifying, analysing and reporting patterns and themes within data. No specific interview schedule was used when carrying out the interviews; however, a list of overall questions was used to ensure consistency throughout all the interviews.

Semi-structured interviews are a common technique used in qualitative research as the method allows flexibility for both the researcher and the participant in regard to the fluidity and structure of the questions [18]. For this study, the semi-structured interview transcripts were analysed using thematic analysis [17]. Thematic analysis was adopted as it allows flexibility with regard to how the participants'

answers are organised, analysed and grouped [17]. Furthermore, the aim of thematic analysis is to obtain and extract themes from the written transcripts generated from the interviews.

An interview schedule was prepared at the beginning of the study. However, as the interviews were semi-structured, the schedule was only a guide, and based on the responses from the participants, further questions were also asked. The main areas covered by the interview schedule are related to the participants' lives before they received the brace and whether the brace had changed the individuals' quality of life. The questions were focused on gaining an insight into any changes to the participants' scoliosis that they thought were due to wearing the brace. The third set of questions focused on gaining an insight and understanding into the patients' feelings towards the brace. These questions asked the participants if they would change any aspect of the brace's design, and what if any problems they encountered (if any) whilst wearing the brace.

Participants who dropped out of the study were also interviewed, but with a slightly different interview schedule. Instead of the final set of questions focusing on satisfaction, the questions focused on the reasons why the participants dropped out and what could be improved in the future to stop this from occurring. Participants 1–6 continued with the trial, whilst participants 7 and 8 dropped out of the trial shortly after the interviews took place.

2.3 Results

2.3.1 Themes and sub-themes

From the interview transcripts, four major themes emerged as follows: the persistence of pain, the impact of the brace on pain and daily living, problems with the device and trial satisfaction.

2.4 Persistence of pain

The overall emerging theme reported by participants was the persistence of pain as a result of their scoliosis. This replicates earlier work that has found that for patients who have a form of degenerative scoliosis, lower back pain is the most common presenting symptom [19, 20]. Further work has found that older adults with degeneration believe they are in more pain than both younger adults and adults with standard lower back pain [7, 15]. This research study has highlighted the severity of pain that older people with degenerative scoliosis experience. When the researcher asked the participants questions about their pain and how much pain they were in, they reported a number of difficulties in carrying out everyday activities as a result of the severity of their pain as seen below:

> *Some days I cannot move the pain is that bad, it takes me over 40 minutes to do my hair. I wet it, I sit down, I put gel on, I sit down, I brush it and I sit down. (Patient 3)*

Further analysis indicated that the pain the participants were living with had substantial limiting effects on both their activity levels and the activities that they could participate in; these activities were virtually limited to home-based stationary activities such as watching TV. Furthermore, household tasks were also limited to very basic chores such as folding, washing or drying dishes:

> *No nothing, I can do nothing (P8)*

> *I cannot clean the floor and I cannot even stand to do my ironing (P6)*

Participants also identified problems with sleeping before they received the brace, stating that the constant pain they experienced due to their scoliosis significantly disrupted their sleeping patterns.

> *I could not move, and I could not be touched, even the bed covers could not be on me (P4)*

> *I did not sleep very well at all, because if I moved anywhere, I was, I was erm, I was woken up by the pain, I could not get really comfortable, the pain also had a huge impact on my social life, I ended up with no social life at all, people use to come and see me for a while, but you know, over a year that drops off (P5)*

Other individuals also echoed that before receiving the brace, their activity levels were minimal as a result of their scoliosis.

> *I could not walk very far at all. It's affected my life a lot as I used to be dancing all the time, and now I cannot even stand up for a while let alone dance (P6)*

> *It's cut off my social life a lot as I cannot play badminton like I used to (P4)*

In essence, pain was a central theme of the patients' experiences of living with scoliosis: all participants explained that they were in constant pain as a result of their scoliosis. From the responses the participants made in relation to living with scoliosis, it was apparent that pain had a substantial effect on all aspects of their lives and on a daily basis. Upon further analysis, a sub-theme emerged which focused on how the pain limited participation in activities, with some reporting only being able to carry out essential household tasks (P6), to the basic challenges of sleeping (P5). Furthermore, the participants' answers to the questions also gave the researcher a base for comparison before they started the trial and once they received the brace.

2.5 The impact of the brace on pain and daily living

The next theme that emerged from the researcher's questions indicated that the patients experienced a small reduction in pain whilst wearing the brace, which in turn led to a positive impact on their activity levels. When the participants were asked if the brace had allowed them to be able to participate in any additional activities or participate longer in activities they could already do, the participants gave answers such as:

> *Well I can walk further with my walkie frame (P1)*

> *If anything, it's helped me going up and down the stairs as it keeps me more upright, I used to go up and down stairs on my hands and knees but the brace keeps me more upright instead of crawling (P4)*

Further quotes revealed the brace reduced the level of pain that participants reported whilst walking or carrying out everyday tasks.

> *My pain has improved yes, especially when I'm sleeping or doing household chores (P5).*

Yea, it helps, it really helps, it helps to get me out, it gets me moving. (P6)

I have got totally active again since receiving it. (P4)

However, it emerged a reduction in pain was not the belief or views of all the participants, as other participants did not believe they received any benefits from the brace, to the extent that one participant even believed wearing the brace was leading to an increase in their pain.

Yea my back has started to get worse. (P7)

It's affected my sleeping; my sleeping has got worse it feels as if it pulls me into painful positions. (P8)

In summary, the participants generally indicated that the brace was having a positive impact in terms of improving their quality of life and their overall activity levels. With regard to participants 7 and 8, both dropped out of the trial shortly after this interview.

2.6 Problems with the brace

Patients reported several design problems with the brace that limited the amount of time the participants were able or willing to wear the brace. This was particularly problematic as previous research has shown that bracing is only effective when worn for the recommended time (Rowe et al. and Maruyama et al.) [21, 22]. Participants indicated that they were not adhering to the 8 hours a day, 7 days a week, minimum recommended wearing time that was required to achieve maximum efficiency. They gave a number of reasons for this. When asked how long they were wearing the brace, the participants answered:

Well approximately 4 days a week, but it really depends on what I'm doing. (P6)

I wear it when I'm in the house, but I cannot wear it whilst I'm out as I cannot get it off. (P2)

Further probing revealed the main reason the participants were not keeping to the recommended wearing time was the brace's practicality and functionality with regard to using the toilet, due to the design of the shorts.

I find it's really difficult to take it off so I do not when I'm going out. (P2)

Because I find the use of the toilet very difficult if we are going to the theatre or places like that. (P5)

It's a bit awkward to get it off, if you were to need the toilet. (P6) The only problem is going to the toilet. (P3)

Furthermore, additional problem participants identified, as a reason for not fulfilling the recommended wearing time, was the cosmetic appearance of the brace under their clothes.

> *You know, I cannot wear my clothes properly because of that bump in my shoulder from the shoulder strap, in fact it's not the strap, it's the back of the jacket thing that comes across the back of my neck, well it always shows, no matter what I wear. (P4)*

In summary, participants reported several design issues with the brace, which limited the amount of time they could wear the brace for. As a result of these problems, the optimum recommended wearing time was not achieved, which would have reduced any benefit of the brace. The main reason reported for this noncompliance wearing the brace was toileting as a result of the design of the brace shorts, a problem that was exacerbated by the fact that several participants could not remove or fit the brace independently.

2.7 Trial satisfaction

From the final set of questions, the theme that emerged was that participants were happy with the format of the brace trial. This was in regard to the frequency and duration of the clinical visits and the questionnaires the participants had received.

> *No, I think they the questionnaires ask the right thing really, they are simple to answer, I have not found them simple to answer as I've been in a lot of pain last month with my IBS but normally, I'm ok with them. (P4) The questionnaires are simple really; they ask sensible questions and the number of visits is fine also. (P2)*

The answers from the remaining participants who reached the 6-month treatment point also indicated they were happy to continue with the trial. Participants gave generally brief responses to these questions; they did not expand or give any extra information to the questions asked. Participants indicated they were happy with the format of the trial and felt the questionnaires were appropriate; they also indicated they were happy to continue with the trial.

2.8 Interviews with the participants who had withdrawn from the trial

The interviews with the participants who had dropped out of the trial were carried out over the telephone and recorded with their permission; consent forms were sent out in the post prior to the interview. The interview schedule followed the same progression as the treatment group, with the initial questions focused on the participants' life before they received the brace. The participants indicated the primary complaint of living with scoliosis was their persistent pain.

> *Erm, very bad, well to my mind it was very bad, but I'm sure there must be people who are worse. (P7)*

> *Yes, yes I cannot, I can no longer go shopping for example, Christmas shopping for example is an absolute nightmare really, erm, you know the weekly shop, my husband has to do it now, the only time that I'm alright is if I'm pushing the trolley, it's almost like I can run then. (P8)*

The next set of question focused on why the participants dropped out of the trial. Participants provided answers identifying the primary reasons being the fitting of the brace.

> *I could not wear it because I take diuretic tablets and I could not get the brace off and I kept needing to go to the loo all of the time. If something like that could be devised and designed with erm, with easier fittings because I need to have somebody to help me get in and out and quite often, they could not understand it either. (P7)*

Furthermore, one participant indicated the reason they dropped out of the trial was due to the bracing causing them even more pain.

> *I did not wear the brace for any length of time because it hurt my body, that might sound silly but it actually hurt; it hurt my stomach for example, it just seemed altogether too tight and pulling me, although when it was on for a short length of time it was quite good. (P8)*

In summary, it was apparent the design of the brace and its practicalities were the main factors for these participants dropping out. Furthermore, the brace also led one participant to believe their pain increased; however, as stated earlier in this study, this participant was only included due to the small study numbers and at the specific request of the consultants.

2.9 Discussion

The primary aim of this study was to use a qualitative approach to explore the patients' experiences of living with scoliosis. Furthermore, the secondary aims of the study were to obtain rich and in-depth qualitative information with regard to how the brace affected the scoliosis, together with the functionality and practicalities of the brace design. The results and themes generated from the semi-structured interviews indicated that the primary experience of living with scoliosis is one of persistent pain and limited activity, with all participants who were interviewed identifying these two factors as the main issues. Furthermore, the results from the interviews also identified and highlighted design problems and limitations with the brace shorts that were previously unknown. As the brace has previously only been used on adolescents [9, 23, 24], the problems experienced by adults with regard to the design of the shorts were previously unknown. It is unclear why older women had a problem with the design when this issue has not to our knowledge been reported elsewhere.

An additional result from this study was the identification that the literature on adults' experience of living with scoliosis is very sparse. The data obtained from this study contributes significantly to the gap in knowledge with regard to the experiences of living with scoliosis and its effectiveness. From the responses participants gave, the brace did offer a reduction in the participants' reported pain and allowed them to take part in a wider range of activities. However, for a more definitive conclusion and indication as to how successful the brace has the potential to be, this study would need to be carried out on a larger sample size. Furthermore, the participants would need to be willing and able to wear the brace for the recommended time and would need to fully match the study criteria.

Furthermore, as the interviews provided a greater reflection of the experiences of living with scoliosis, it is suggested that each participant should receive a minimum of three interviews in any future trial. The first interview would be scheduled at the beginning of the trial, one in the middle and one at the end of the study. The implementation of three interviews would also allow for a more in-depth comparison to be obtained, as the interviews would be more frequent and the participants would be able to give more detailed descriptions of their experiences of living with the brace.

The information obtained from the qualitative interviews allowed for a greater understanding of patients' experiences of living with scoliosis that the questionnaires failed to capture, such as problems with the brace and the extent to which the brace was helping with their pain and activity levels. Furthermore, Participant 4's answer to the set of questions regarding trial satisfaction also showed how some patients found it difficult to that they experienced was due to IBS or scoliosis. This qualitative study also revealed that patients' experiences of pain had a limited effect on the amount of activity they could do due to their degenerative scoliosis.

3. Study 2: exploratory (pilot) randomised control study (RCT)

3.1 Research design

The study was initially going to be carried out as a randomised control trial (RCT) for 24 months. The RCT study design is considered to be the highest level of scientific testing as it minimises patient control bias [25]. However, halfway through the recruitment process, it became apparent that the numbers required to achieve an RCT would not be met due to a number of factors that were out of the control of the research team. These factors included a drop in patient referrals due to a reform in the referral process from primary care into secondary care, a lack of engagement by treatment centres in terms of not fully understanding which healthcare professionals could refer patients into the trial and a small number of eligible participants who matched the study inclusion criteria. Therefore, after the discussions with the consultants, brace clinicians and research team, it was decided that the best solution to these problems would be to continue the trial as a prospective study with a control group for 6 months. There are several reasons for the reduction in the trial time scale. Firstly, it took over 13 months to gain NHS ethics; secondly, the participant referrals dramatically decreased after the first 12 months due to NHS reforms, and therefore any new entries into the trial would not have finished their treatment program before the scholarship of the primary author concluded. Therefore, recruitment was halted after 18 months. As a result of this, the data presented in this work are from 6 months of data collection.

3.2 Recruitment of participants

The participants for the study were recruited and identified by consultants, physiotherapists and spinal nurses when they attended their regular orthopaedic clinics. When attending these appointments, the patients were screened by their consultants to ensure they were suitable and matched the study criteria. Participants for the study were initially going to be recruited from three different treatment centres; however, only one referred any participants into the trial. Once a participant was referred into the trial, they were randomised into either the treatment or control group; this was done through a computer randomisation program. Participants in the treatment group received the soft brace in addition to the standardised assessment tools described below.

3.3 Participant inclusion/exclusion

To ensure that appropriate patients were recruited for the trial, after a number of discussions amongst the research team, brace manufacturers, surgeons and physiotherapists, a set of inclusion and exclusion criteria was drawn up. This was to ensure

that the participants would be able to fully partake in the trial without having any additional problems or issues placed upon them as a result of participating.

3.4 Inclusion criteria

Patients were included from the study if they had any of the following**:**

- Patients were required to be 50 years old or over, of either gender, to ensure the scoliosis was that of a degenerative origin and not a missed case of adolescent idiopathic scoliosis.
- Patients whose scoliosis had a Cobb angle of ≥20° with associated vertebral rotation, previously confirmed on a full spine standing posterior anterior X-ray. The reason for this was because it was thought if the brace could reduce the pain in patients with a large Cobb angle, it should be able to ease the pain in patients with Cobb angles of over 20°.
- The curve needed to have an apical vertebra (situated at the apex) level at T12 or below (this included double and triple curves) to ensure the scoliosis was degenerative.
- Participants were required to have an ODI score of ≥32 to allow minimal changes in ODI scores to be detected.

3.5 Exclusion criteria

Patients were excluded from the study if they had any of the following:

- Leg pain that was linked to lumbar spine pain, as a number of additional health problems could have led to the development of leg pain
- If the participants were unable to fit the brace on their own or did not have someone to help with this process
- If the participants were not ambulant, as the brace was designed to treat patients who were not confined to bed
- If the participant had already received instrumental thoracic or lumbar surgery as the brace was designed to delay the need for surgery

3.6 Study instrumentation used in this study

The following study questionnaires were used to measure and monitor the effectiveness of the brace. Three questionnaires were used. The first questionnaire that was used to assess pain was the Oswestry Disability Index Questionnaire v2.1a (ODI) [26]. The second questionnaire that was used to assess the patients' quality of life was the EQ5D-5L [27]. The final questionnaire was used to assess the patients' mental and physical health, the Short Form-36 Version 2 (SF-36v2) [12]. The participants in the control group received the questionnaires together with the standard NHS treatment; this comprised a yearly follow-up appointment with their regular consultant to assess whether the curve had progressed to the point where a surgical approach was required.

3.7 Oswestry Disability Index (ODI v2.1a)

The ODI v2.1a questionnaire is one of the most commonly used questionnaires to assess lower back pain. The ODI is one of the most valid and reliable outcome measures with regard to the patient's perception of the 'pain they feel today' [28]. The ODI comprises of 10 sections; each section has six statements (see example below; **Table 1**). Responses are made on a five-point scale. As shown in the example below, the first statement is marked 0, and the last statement is marked 5. All additional statements are scored according to rank, with the highest score being taken if more than one box is marked in each section. Once the questionnaire is complete, the score is then calculated using the following formula: ODI % = Total score/5 × number of questions answered × 100. Therefore, if the ODI score is 40 based on the participant answering 4 for all 10 sections, the percentage of disability is determined: 40/5 × 100 = 80% disability. Since the initial publication, the ODI has been widely validated [29] and deemed to be a reliable measure for detecting small reductions in pain and disability before and after treatment [30].

The ODI correlates positively with the SF-36 and EQ5D questionnaires. In essence, a reduction in pain attained from the ODI correlates with an improvement in mental and physical health on the SF-36 questionnaire and an improvement in quality of life from the EQ5D for patients who had lower back pain [31, 32]. Wittink et al. [32] compared the outcomes of 424 patients with chronic pain who had been referred to a multidisciplinary pain centre where each patient was required to complete the SF-36, Multidimensional Pain Inventory (MPI) and the ODI before or on the date of their first appointment. They found that the MPI, SF-36 and ODI had good psychological measurements. The study also concluded that the ODI had the least amount of respondent burden and was easier to score, although the questionnaire does not provide as much detail as the MPI or the SF-36.

3.8 EQ5D-5L

The EQ5D-5L is a widely used generic measurement of health-related quality of life that requires patients to self-report problems with regard to five elements: mobility, self-care, usual activities, pain/discomfort and anxiety/depression [33]. The questionnaire is split into two parts with the first part containing five questions that explore different elements of health, with each of the five questions containing three levels of severity, no problem, some problem or extreme problem, allowing patients to be classified into 1 of 243 states [34, 35]. An example question (see **Table 2**) from the EQ5D questionnaire is seen below:

Section 2: personal care	**Score**
I can look after myself normally without causing extra pain	0
I can look after myself normally but it causes extra pain	1
It is painful to look after myself and I am slow and careful	2
I need some help but manage most of my personal care	3
I need help every day in most aspects of self-care	4
I do not get dressed, wash with difficulty and stay in bed	5

Table 1.
Example ODI questions.

Please mark accordingly
I have no problems in walking about
I have slight problems in walking about
I have moderate problems in walking about
I have severe problems in walking about
I am unable to walk about

Table 2.
Example EQ5D questions.

From these 243 health states, a time trade-off (TTO) is calculated; this TTO is used to represent a person's quality of life. A value of 1 represents full health and a value of 0 represents being dead [36]. For this research study, the TTO scores were calculated using the software provided by EuroQual who designed the questionnaire. The second part of the EQ5D-5L requires the patient to indicate how 'good' or 'bad' their perception of their own general health is by marking a visual analogue scale (VAS). A VAS is a measurement tool that aims to measure an attribute of health that is believed to be on a continuous range across a continuous value. The scale ranges across a horizontal line that starts at 0 representing no pain and moves gradually to 100 representing extreme pain. The line is 100 mm in length and words are placed at the start of the continuum (0) representing no pain, and at the end of the line a100mm line representing extreme severe pain (see **Figure 1** below.)

The validity and reliability of the EQ5D questionnaire have previously been confirmed by Brazier et al. [37] who compared the results of the EQ5D to the SF 6D (a development from the SF-36). Brazier's research study [37] found that on a data set of 2436 patients with a wide range of medical conditions ranging from lower back pain, chronic obtrusive pulmonary disease and irritable bowel syndrome, the questionnaire showed signs of being sensitive to change and having a strong coefficient of internal consistency.

3.9 SF-36v2

The last questionnaire used in this study was the SF-36v2. This questionnaire is a multidimensional, non-diagnostic-specific measure of pain that consists of eight health scales: physical functioning (10 items), role limitations—physical (4 items), bodily pain (2 items), general health (5 items), vitality (4 items), social functioning (2 items), role limitations due to emotional problems (3 items) and mental health (5 items) [38]. The scale is directly transformed into a 0–100 scale based on the assumption that each question carries equal weight. The lower the score, the greater the disability; in essence, a score of 0 is equivalent to a maximum disability, and a score of 100 is equivalent to no disability. The SF-36v2 has been reported to be both a reliable and valid measurement of health and has been shown to be sensitive to changes in health conditions [39].

Figure 1.
Example of a visual analogue scale.

3.10 Procedure

Medical staff including consultants, physiotherapists and spinal nurses were the primary recruiters for participants for the study. Participants were recruited when they attended their regular orthopaedic clinics. Once consent was attained, the participants were then randomised into either the treatment or control group by a computer randomisation program. As part of the standard NHS procedure, on arrival the participants received a routine clinical examination. This included the measurement of the Cobb angle and pelvic/shoulder tilt, in addition to a posterior/anterior X-ray using the soft brace X-ray protocol. The soft brace X-ray protocol was used for all clinical visits as it provided a standardised foot position, which in turn kept the patient's posture natural and standardised from visit to visit. The protocol also allowed for direct comparison of frontal and lateral X-rays and increased the inter-session reliability. If the participant fulfilled the study criteria, they were offered the opportunity to participate in the trial; if they declined, they then continued along the standard NHS treatment pathway.

If the patient chose to participate in the study, they were given the participant information sheet (PIS) together with the series of questionnaires described above to complete (ODIv2.1a, EQ5D-5 L and SF-36v2). Further information about the trial and details of future clinical appointments were also included in the PIS. The information sheet gave details about future clinical appointments, how the trial would run and what was expected of the individual with regard to their participation (such as being able and willing to attend the clinical appointments, adhere to the 8 hours wearing time and complete the questionnaires on time). The lead researcher then explained to the patients that they would be randomly allocated by a computer program into either the treatment group where they would receive the brace and questionnaires or the control group where they would follow the standard NHS treatment and also receive the study questionnaires. If participants were placed in the treatment group, they were given an appointment where the brace was fitted by a trained soft brace clinician.

The baseline questionnaire data were then administrated and collected by the lead researcher. A follow-up appointment was also made 1 month into treatment where an additional in-brace X-ray was taken as specified by the study protocol. This additional X-ray was not part of the standard NHS treatment; however, it was deemed necessary to assess whether the brace was having any immediate effect on the shape and position of the spine. This extra dose of radiation that the patients received as a result of the additional X-ray was deemed to be acceptable by the research ethics committee. Patients were also informed that they would be required to attend future appointments at 1, 3 and 6 months. This was in addition to their standard clinical appointments to see their regular consultant at 12 months to assess the long-term effects of the brace. Upon attending these routine clinic visits, the brace was adjusted by the soft brace clinicians if it was deemed to be too loose or ill-fitting as a result of any changes in their shape and/or posture.

The brace is recommended by the manufacturer to be worn for 8–12 hours per day for the first 3 months and then adjusted to the individual's requirements after this. These adjustments included changing the wearing time and/or adapting the position of the bands if they had become loose or ill-fitting. Apart from the first appointment, which lasted approximately 90 minutes, each follow-up clinical visit lasted no longer than 40 minutes. The first appointment was slightly longer as this was where the participants were fitted and measured for their brace, whilst also providing them with the opportunity to ask the chief investigator (CI) or clinicians any further questions regarding their participation in the trial.

The participants in the control group received the ODIv2.1a, EQ5D-5L and the SF-36v2 questionnaire at home at months 1, 3 and 6 months, in addition to their standard treatment pathway. A follow-up yearly X-ray together with an appointment with their consultants was also made to see if surgery would be required due to curve progression. Both groups of participants were asked to complete and return all documents to the first author's University in a prepaid envelope. If individuals decided they did not want to participate in the trial or if they decided to have surgical treatment, they were followed up at 12 months by their consultant with an X-ray to assess if any curve progression was apparent.

If patients chose to enter the trial, they were told that they could withdraw at any stage without giving a reason and it would not affect their future treatment. Participants were then provided with a participant information sheet and offered the opportunity to discuss the study with their consultant or a member of the research team. If patients agreed to participate in the trial, the consultants obtained signed consent. These completed forms were then passed on to the researcher who contacted the individual to verify they were still interested in participating in the trial (with at least a 24-hour gap after completing the slip). Once the patients confirmed they were still interested in participating, it was at this stage of the trial that they were informed which group they had been randomised into. At this point if the participants decided not to participate in the trial, it was explained they would follow the standard NHS treatment pathway. Each participant was also informed that if they did participate, all data they provided would be kept confidential and anonymised.

3.11 Sample size

A sample size of 102 for this study was originally calculated based on literature from previous back pain studies. An attrition rate of 10% was also added to the sample size [40], meaning a total sample size of 112 participants was required. Due to recruitment issues, this number of participants was not achieved. In total only 15 participants were recruited to the study. However, as randomisation took place before the research team had the opportunity to meet and screen the potential participants, two participants who were included by the consultants did not meet the inclusion criteria and were therefore not eligible, ultimately resulting in only 13 participants being involved. Given the low sample size, it is important to establish that the appropriate analyses (and therefore appropriate conclusions) were applied to the data. Research [41] has shown that even with a sample size of two people in a series of fake t-tests, the Type 2 error that occurred did not surpass the acceptable value of 5%; this has also been confirmed in studies by [42, 43]. Therefore, the small numbers in this study should not have any effect on the validity of the results generated from the questionnaires, although of course the small study numbers must be recognised in the interpretation of the results, as it is possible that the participants may not form a typical cross section of patients with degenerative scoliosis.

3.12 Statistical analysis

All study data were anonymised and analysed using a two-way repeated measure analysis of variance in SPSS [44]. The two-way analysis of variance (ANOVA) was used as it allows the differences between group means and their treatment methods to be compared over several time points [45]. The treatment group was compared against the mean data from the control group for each of the three time points to determine whether any significant differences were present. In-group comparisons were also calculated for both groups to see if any significant in-group changes occurred.

Any missing data or data belonging to participants who withdrew from the study were analysed based on an intention-to-treat (ITT) basis. It was important to use ITT as the main problem researchers find when using an RCT study design is that participants do not always follow the instructions or they drop out of the trial [46]. The benefits of using ITT are that the analysis still reflects clinical situations and it gives unbiased estimations on the effectiveness of the proscribed treatment [47]. Furthermore, the use of ITT maintains the original sample size; if dropouts were excluded from the overall data set, a reduction of statistical power may occur.

3.13 Outcome measures

The primary outcome measure for this study was a change in the participants' ODI scores over the 6-month duration. Secondary outcome measures were any changes in the EQ5D-5L and SF-36v2 scores.

3.14 Results

3.14.1 Oswestry Disability Index

The baseline data in **Table 3** show that the treatment group had a higher mean ODI than the control group upon initial consultation, although this difference was not statistically significantly different. Furthermore, a greater standard deviation was also present which indicated that a larger variation from the mean score was present within the treatment group. After 3 months, the mean ODI calculated from the treatment group's data showed a reduction of 9% in the 'pain they feel today' from baseline, in comparison to a 6.25% increase from the control group, although the standard deviation remained similar for both groups.

At the 6-month stage of the trial, the treatment groups' mean ODI decreased by a further 1.6%; this indicated a decrease in pain. This is in contrast to the control group, who as a group had a mean ODI change from data collected between months 3 and 6 of the study of 19%. The scores represent an overall decrease of 10.6% from the treatment group over the 6-month trial compared to an overall increase of 25.25% over the course of the 6-month trial from the control group.

Group	Mean	Std Deviation	N	+/-
Treatment	52.50	16.39	8	-
ODI Score M0 Control	41.60	12.97	5	-
Treatment	47.75	5.66	8	-9%
ODI Score M3 Control	44.20	10.83	5	+6.25%
Treatment	47.0	14.12	8	-1.6%
ODI Score M6 Control	52.60	22.32	5	+19%

1M0 represents the baseline mean ODI scores, M3 represents month 3 mean scores and M6 represents month 6 mean ODI scores. The +/- column represents score changes between months. Treatment represents the treatment group and control represents the control group

Table 3.
Analysis of ODI scores over 6 months.

1M0 represents the baseline mean ODI scores, M3 represents month 3 mean scores and M6 represents month 6 mean ODI scores. The +/− column represents score changes between months. Treatment represents the treatment group and control represents the control group. Furthermore, there was no significant difference between the treatment and control group over the course of the 6-month study (see **Table 3**). Also, there was no significant difference or in-group interaction amongst the groups between the treatment time points.

3.14.2 EQ5D

The data presented in **Table 4** show that at baseline, the control group's reported health state appeared worse than the treatment group. As the score gets closer to 0, the closer the individual feels to a state of death. The control group had an initial TTO 22.2% higher than that of the treatment group even before receiving the brace, which means that they felt less well than those in the treatment group. The mean TTO data from month 3 showed that both groups' health state changed, with a 21.4% increase coming from the control group, and the treatment group's mean TTO score improved by 10.62%.

Data from the 6-month collection point presented a further increase for the treatment group with an improvement in score of 7.69% and with an overall increase in score of 18.31% over the duration of the study with regard to their TTO health state. Furthermore, although no change in score was found for the control group in the final 3 months, over the full duration of the study, a total improvement of 22.2% was calculated. From the EQ5D questionnaire, it was also found that over the course of the 6-month study period, no statistically significant differences were found between the groups' TTO scores or in-group interaction.

3.14.3 SF-36 mental health scores

The results from the initial month's questionnaires show that both groups of patients had similar mean scores in terms of their mental health (see **Table 5**). After 3 months in the brace, the treatment groups reported mental health score decreased by 8.26%. However, this change in reported mental health was smaller than that of the decrease calculated from the control group questionnaires whose mean score decreased by 11.84%. The results from the month 6 time point indicated that both

	Group	Mean	Std Deviation	N	+/-
TTO MO	Treatment	.35	.35	8	
	Control	.28	.14	5	
TTO M3	Treatment	.39	.18	8	10.62%
	Control	.34	.54	5	22.2%
TTO M6	Treatment	.42	.17	8	7.69%
	Control	.34	.49	5	0

Note: 1M0 represents the baseline mean scores, M3 represents month 3 mean scores and M6 represents month 6 mean TTO scores. The +/- column represents score changes between months. Treatment represents the treatment group and control represents the control group

Table 4.
EQ5D health states over 6 months.

	Group	Mean	Std Deviation	N	+/-
MHS M0	Treatment	45.38	11.60	8	
	Control	48.2	9.8	5	
MHA M3	Treatment	41.63	12.32	8	-8.26%
	Control	40.20	11.95	5	-11.84%
MHA M6	Treatment	46.50	12.54	8	+4.87%
	Control	42	10.61	5	6.94%

Note; [1]MHS M0 represents the baseline mean scores, M3 represents month 3 mean scores and M6 represents month 6 mean mental health scores. The +/- column represents score changes between months

Table 5.
SF-36 mental health scores.

groups' mental health increased between the months of 3 and 6. The treatment groups' mean scores increased by 4.87%, whilst the control group's score increased by 6.94%.

3.14.4 SF-36 physical health scores

The initial month's mean SF-36 physical health scores show that the treatment group had an inferior physical health score of 25% compared to the control group, as the closer the score to 0, the lower the individuals' physical health. Data collected from 3 months into the study show that wearing brace for 3 months leads to the treatment group having an increase in their scores of 16.95%. This was in comparison to the control group, whose scores showed signs of their physical health decreasing by 3.31%. The scores calculated from data collected between the months of 3 and 6 show the treatment group's mean physical health decreased by 3.67%.

	Group	Mean	Std Deviation	N	+/-
PHS M0	Treatment	22.63	5.18	8	
	Control	30.20	10.01	5	
PHS M3	Treatment	27.25	3.69	8	+16.95%
	Control	29.20	6.14	5	-3.31%
PHS M6	Treatment	26.25	4.65	8	-3.67
	Control	31.80	9.18	5	+8.18

Note; [1]PHSM0 represents the baseline mean scores, M3 represents month 3 mean scores and M6 represents month 6 mean physical health scores.

Table 6.
SF36 physical health scores.

The results also demonstrated that no significant differences or group interactions were found between the treatment group's physical health score and the control group's physical health score at 6 months (**Table 6**).

4. Discussion

4.1 Aims of the study

The primary aim of this study was to obtain both patients' quantitative experiences of living with scoliosis together with developing an understanding of the pain they experienced and their quality of life. The secondary aims of this study were to investigate the effects the soft brace had on adults with degenerative scoliosis. Another aim of the study was to compare the questionnaire results from the treatment group against the questionnaire results from adults who did not receive the soft brace.

4.2 Summary of main results

The study inclusion and exclusion criteria were designed to recruit individuals who were at the end of the non-operative treatment pathway. For these participants the next stage of treatment would be surgery. However, as discussed previously, due to the complications and difficulties of the procedure, the need for a surgery should if possible be delayed or avoided especially in those patients who have additional underlying health conditions such as irritable bowel syndrome (IBS) and arthritis. These dangers are further highlighted as the complication rates of surgery in older adults range from 20% to as high as 80% [48].

The anthropometric data of nine patients (8 female, 1 male) in the treatment group and six (all female) in the control group were as follows: the female patients in the treatment group had an average weight of 75.3 kg with an average height of 155.4 cm; the one male participant had a height of 165.2 cm and weight of 84.7 kg. This is in comparison to the six female participants recruited into the control group, who had an average weight of 77.6 kg and average height of 153.8 cm. In comparison to the average healthy individual who has an ODI score of 10.19 [49], the mean ODI score of the individuals in this trial was 47. Moreover, the mean ODI score of 47 was also substantially higher than the minimum ODI score of 32 outlined in the initial study inclusion criteria. In comparison the control group showed an 8.18% increase in ODI in comparison to the data collected between the initial month and month 3.

The results further demonstrated that there were no significant differences or interactions between the treatment group's physical health score and the control group's. The average healthy individual has an ODI score of 10.19 [49], whilst the mean benchmark ODI score of the individuals in this trial was 47. Moreover, the mean ODI score of 47 was also substantially higher than the minimum ODI score of 32 outlined in the initial study inclusion criteria. In addition to a higher mean ODI score than the average healthy individual, participants also had a lower mean score in terms of SF-36 MH and SF-36 PH than the average healthy individual. A healthy individual's SF-36 MHS score is on average 50.17 and PHS 50.1 [50].

The mean baseline mental and physical health scores of the patients in this trial were 45.5 and 26.4, respectively. Additionally, a mean health TTO score of the average healthy individual is 0.94 [51] compared to the mean TTO score of 0.32 obtained from those in this trial. Furthermore, the inclusion criteria required participants' Cobb angle to be a minimum of 20. The average Cobb angle measurement of patients in this trial was 43° (+/−12), again highlighting the severity of the degenerative scoliosis our participants had. The questionnaire data showed that over the course

of 6 months, patients treated with a soft brace had a reduction in their ODI score regarding the 'pain they felt today'. However, no significant differences or interactions were observed over the 6 months of the trial. In addition to the change in the ODI scores, changes in the TTO and mental and physical health scores were also calculated from the treatment group's data. However, again no significant differences were found between questionnaire scores.

Like the treatment group, participants in the control group also showed no significant changes over the course of the 6-month study period. Furthermore, as seen in the tables above, the participants in the control group had a lower baseline ODI, EQ5D and SF-36 scores than the average healthy individual. It was difficult to compare the results of this study to previous work as little research has compared braced patients with patients who received no or standard NHS treatment. Furthermore, although several studies have been published [9, 52], these investigated the effectiveness of bracing on adolescents which has a different aetiology to adult scoliosis.

5. Discussion

In this study, the treatment group's data showed no significant difference in changes over the duration of the trial for all questionnaires. This contrasts with research [53, 54] which found a significant difference between the effectiveness of a surgical approach and a non-operative method of treatment. Research from Grubb et al. (1994) [53] examined the effectiveness of a surgery on 28 adults with idiopathic scoliosis and 25 adults with degenerative scoliosis. In comparison to the 10.6% change in scores over the 6-month treatment period for the present study [53], Grubb et al. found that patients who had degenerative scoliosis and were treated operatively reported a decrease in their pain scores of 70% whilst patients with adult adolescent scoliosis reported an 80% reduction. Furthermore, both sets of patients reported improvements in their health-related quality of life in addition to improvements in standing and walking over the 2–7 year follow-up period.

Li et al. [54] compared self-reported outcome scores from patients treated operatively to those treated non-operatively. They found that patients who received operative treatment reported significantly better self-outcome scores in the EQ5D VAS and SRS-22, but not in the ODI or the SF-12. Although the results from our quantitative work showed no significant difference over time for braced patients, discussions between patients and clinicians gave insight into the benefits of the brace. Patients spoke about how the brace reduced their pain, allowing their participation in new activities or longer participation in activities that they could already carry out. Some participants discussed how for the previous few weeks their pain levels were low, but when the time came to complete the questionnaires, they were having a 'bad week', due to their scoliosis pain or pain from other underlying health conditions. With a small sample size, the effect of 'bad weeks' would have a substantial effect on the results obtained, with potentially a Type 2 error where actual differences between groups may not have been detected. Furthermore, from the questionnaire results, it would appear that the questionnaires may not have been sensitive enough to assess small changes for patients who received the brace.

6. Conclusions

In conclusion this small pilot study has demonstrated that a soft brace has a potential as a treatment for degenerative scoliosis. In interviews, patients who were

given the brace reported an improved quality of life, although such improvements were not detected in the questionnaire data. A larger, sufficiently powered, quantitative study is required to provide a clearer understanding of the effect of a soft brace on pain and quality of life for older people with degenerative scoliosis.

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