CareFlex HydroTilit, SmartSeat, and SmartSeatPro: evaluation of pressure and comfort.

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Chapter 1: Background to the evaluation

The purpose of this study was to explore the use of WaterCell Technology® in the redistribution of pressure of adults with mobility problems who remain seated for extended periods of time and self-reported comfort and discomfort scores using three chairs: HydroTilt, SmartSeat, and SmartSeatPro.

The role of the company in the study was to deliver, set up, and collect the chairs for the duration of the study.

Ethical approval to conduct the study was sought and granted by the University of Salford Ethics committee (see appendices, for the letter of approval).

Chapter 2: Literature Review

Wounds impose a substantial health economic burden on the United Kingdom's (UK) National Health Service. Guest et al. (2015) conducted a retrospective cohort analysis of the records of patients in the Health Improvement Network (THIN) Database and reported the current cost at £5 billion. In 2014 NHS England reported that there were 27,000 people a month found to have a pressure ulcer and 6,000 pressure ulcers are newly acquired monthly in hospitals in England. The limitations are safety thermometer data only reports the incidence of pressure ulcers and fails to calculate the impact on quality of life and the necessary life changes this group of people are required to make. However a small qualitative study by Langemo et al. (2000) conveyed how each day the presence of a pressure ulcer had a dramatic impact on issues such as: psycho-spiritual living, function, and pain.

A pressure ulcer is defined as '… localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear. A number of contributing or confounding factors are also associated with pressure ulcers; the significance of these factors is yet to be elucidated.' (European Pressure Ulcer Advisory Panel [EPUAP] and National Pressure Ulcer Advisory Panel [NPUAP] and the Pan Pacific Pressure Injury Alliance [PPPIA] 2014, p.7). Pressure ulcers that develop from pressure only, occur when soft tissues are damaged or injured due to compression between two surfaces (Krouskop 1983; Schubert and Héraud 1994). Seminal work by Kosiak (1959) states that average interface pressures of 60 - 70 mm Hg for 1-2 hours may lead to soft tissue pressure injury. Common sites for pressure ulcers are bony prominences, such as the ischial tuberosities (buttocks), sacrum, elbows, and heels. People with limited mobility, who are in a seated position for long periods are particularly at risk, because their weight is borne over a smaller surface area than when lying, with consequent higher interface pressure in the gluteal region (Barbenel 1991, Defloor and Grypdonck 1999). It has been well documented that in neutral sitting i.e. sitting upright the majority of the body weight is borne over the area around the ischial tuberosities with 75% distributed over the buttocks and thighs, 19% feet, 2% arms and 4% back (Cook and Miller Polgar 1995). Clinical decision making is a multi-faceted process, evidence based guidelines for the treatment and prevention of pressure ulcers do exist (EPUAP, NPUAP, PPPIA 2014; National Institute of Health and Care

Excellence [NICE] 2014). However, the level of guidance for people whilst seated is significantly less detailed than that for people cared for in bed (Stockton, Gebhardt, and Clark 2009).

Whitehead and Trueman (2010) in their review of the literature suggest that cost efficiency savings can be made if healthcare professionals consider using pressure redistributing devices for those at risk of developing a pressure ulcer. There are over 200 pressure redistributing devices on the market for wheelchair users and people with reduced mobility who are often confined to their chairs (Ousey, 2005). These devices are commonly cushions and can be gel-filled or contain air pockets, memory foam, or flotation type cells or indeed, a combination of these (NICE, 2014; Stockton and Rithalia, 2008). Static seat chairs are another such device available commercially. NICE (2014) noted a lack of comparative data on the effectiveness of such seat cushions in reducing pressure and risk of pressure ulcers. This is supported by Stockton and Rithalia (2008) who state that there is little evidence available on the effectiveness of a range of pressure cushions to guide prescription. Geyer et al. (2003) and Crane and Hobson (2002) highlight that effectiveness of pressure redistributing products may also be due to a lack of end user collaboration in product design and evaluation. Indeed, end user collaboration in other fields such as ergonomics has proven to be successful (Rutter, Becka and Jenkins 1997). Stockton and Rithalia (2008) and Crane and Hobson (2002) found in their studies of wheelchair users and cushions, that the importance of perceived comfort/discomfort and pain on the ability to carry out functional activities ultimately can lead to ‘equipment abandonment’ (Crane and Hobson 2002, pg1).

Interface pressure mapping is now an accepted method used by researchers to evaluate seating pressure redistribution as interface pressures have been shown to be higher in wheelchair users than those who do not (Brienza et al. 2001). Lung et al. (2014) report on common measurements taken such as; average pressure, peak pressure, peak pressure index, peak pressure gradient, peak pressure ratio, and dispersion index.

In light of this evidence healthcare professionals involved in clinical decision making need to consider the individual's level of perceived comfort, aesthetics of the equipment, posture, and best practice guidance, as often concordance with the use of a pressure redistributing device is determined by these factors.

Further research is therefore needed to evaluate the effect any innovations in the management of pressure redistribution and the effect it may have on vulnerable bony areas alongside the individual's perception of comfort, posture, and ease of use.

Chapter 3: Methodology

Research Design

The purpose of the project is to evaluate the impact of WaterCell® Technology in three chairs and the effect on pressure redistribution and self-reported comfort and discomfort scores of adults with mobility problems who remain seated for extended periods of time.

The project objectives were to establish:

1. The pressure reducing qualities of WaterCell® Technology in the three CareFlex chairs.
2. Whether there is a link between self-reported comfort and discomfort scores of adults and the pressure redistribution qualities of the three CareFlex chairs.

A small mixed methods evaluation between subjects using a pre-test post-test comparative design using three commercially available static pressure redistributing chairs formed the basis of the study. Each chair uses the CareFlex WaterCell® Technology which the manufacturer states provides 'a reliable low pressure solution for people at medium to high risk of pressure damage' to their skin.

The ensuing variables were studied:

- Interface pressure measurements using XSensor® pressure measurement system. Three snapshot readings were taken recording gluteal surface area (cm^2), mean interface pressure across gluteal region (mmHg) and peak pressure at ischial tuberosities, greater trochanters and sacrum (mmHg).
- Physiological observations of respiratory rate, pulse rate, and blood pressure.
- Comfort and discomfort scores.
- Qualitative feedback from semi structured questionnaires and interviews.

<u>Recruitment</u>

Sample recruitment for participants into the research study included:

- Identified participants from a previous study who agreed to be consulted regarding future studies.

- Advertisement on the University, College and Schools Twitter, Facebook and webpages.
- Presentation to local user and carer groups.

Participants

Twelve participants were recruited to the study, using an inclusion and exclusion criteria. The sample population from the study group were drawn from volunteers in the local community who were adults with mobility problems and who remained seated for extended periods of time. The participants were screened using the following criteria:

Inclusion criteria:

- Participants must be over the age of 18
- Participants must have mobility problems and remain seated for extended periods of time each day.
- The participants meet the safe working load of the chair (weight).
- Living at home in the community
- May or may not have a previous pressure ulcer
- To be able to read and understand English to the level of the information sheet to be able to give informed consent.
- To be able to complete and record a daily basic skin inspection of their gluteal region, trochanters and sacrum.
- To be able to complete and record a comfort and discomfort score.
- To be available to participate in the study for 1 week during the months of September-December 2015.

Exclusion criteria:

- Participants under the age of 18.
- Participants without mobility problems.
- The participants who exceed the weight for the safe working load of the chair.
- Currently in hospital.
- Have a current pressure ulcer.

- Are unable to read and understand English to the level of the information sheet to be able to give informed consent.
- Are unable to complete and record a daily basic skin inspection of their gluteal region, trochanters and sacrum.
- Are unable to complete and record a daily comfort and discomfort score.
- Current users of CareFlex chairs.

Ethical Approval

Ethical approval to conduct the study was sought and granted by the University of Salford Ethics committee.

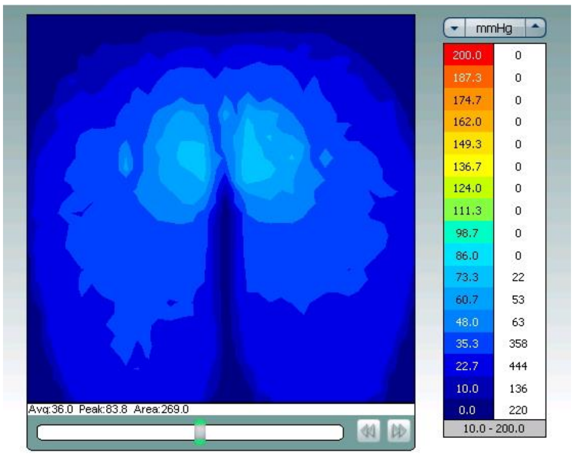
Procedure

Potential participants were given time to consider their involvement in the study. They were encouraged to discuss their involvement with their local healthcare practitioner, carer or family member. Participants were advised that they could withdraw from the study at any time without reason or prejudice. Withdrawal from the study would not affect their access to healthcare services and anonymity was guaranteed.

Once the participants had been recruited to the study applying the inclusion and exclusion criteria, a mutually agreed date was identified. A member of the research team telephoned the participant in their own home to explain the study and gain verbal consent. The consultation also allowed the participant to agree the week in which they would evaluate the chair for one week between the months of September-December 2015. The participant was then randomly allocated to one of the three CareFlex chairs to use and evaluate for one week. The researcher contacted the company to arrange delivery and set up of the chair, which was supervised by the researchers to limit external independent variables such as company influence. On the day of delivery of each chair and after consent forms were signed the researchers completed baseline demographic information (gender, age, weight, height, body mass index, and anthropometric measurements); measurements of blood pressure, pulse, and respiratory rate, and interface pressure measurements in their current chair. This was repeated when the randomly allocated CareFlex chair had been set up for the participant to use for the week of the study. This data was collected at day one and day seven after the participant had been seated for a minimum of fifteen minutes. At day seven a semi structured interview was undertaken which was recorded digitally. Verbal and written instructions were left with the participant on the use of the chair. This information included contact numbers of the researchers should the participant want to discontinue using the study chair or if they could not tolerate using it. A voucher to the value of £20 was given to each participant on completion of the study.

Data collection tools

Interface pressure measurements were collected using the XSensor® PX100 pressure measurement system from SUMED International. This is a dynamic system involving two grids of parallel conductive strips that offset perpendicular in orientation within a sensor mat. It is commonly used by clinicians to determine the suitability of wheelchair cushions and by researchers investigating support surfaces, risk factors for ulceration, and ulcer prevention protocols (Trewartha and Stiller 2011, Stinson et al. 2013). The mat is approximately one millimetre thick with a measurement grid of 450mm x 450mm. Containing 1296 sensing points. The sensor mat is linked to the XSensor PRO v6.0 software from SUMED International. Data recorded is represented as colour coded maps of pressure distribution as well as peak and mean pressure readings at specific time stages recorded in mmHg. Three snapshot readings were taken recording gluteal surface area (cm²), mean interface pressure across gluteal region (mmHg) and peak pressure at ischial tuberosities, greater trochanters and sacrum (mmHg).



- Clinical observations of respiratory rate, pulse rate, and blood pressure were collated to gauge physiological responses in relation to comfort and discomfort (See appendices)
- A validated comfort and discomfort rating questionnaire (Crane 2004) was completed by each participant to evaluate comfort/discomfort (see appendices).
- Skin inspection guide (NHS Midlands and East no date).
- A semi structured interview was digitally recorded (see appendices).

Data Analysis

Mean pressure across the gluteal region and peak pressure at ischial tuberosities were analysed using:

- SPSS v 22 to i) summarise the mean/standard deviation for the demographic data, peak pressure index and mean pressures and ii) compare peak pressure index and mean pressure across the three chairs using paired t-tests and analysis of variance (ANOVA) (iii) explore if there is a correlation between comfort and pressure redistribution.
- A detailed thematic analysis using a recognised Burnard's (2000) stepped analysis process was used to analyse the qualitative comments and feedback regarding self-reported comfort/discomfort. This stepped approach provides an opportunity to ensure a transparent and auditable account of the data analysis process.

Role of the company in the research

The company involved in the research was used to deliver, set up and collect the chairs for the duration of the study. The company representatives were not able to promote their products during the study, nor analyse any data. The only benefit perceived is that the findings will be used by the company for marketing purposes.

Chapter 4: Findings

The purpose of the project is to evaluate the impact of WaterCell® Technology in three chairs and the effect on pressure redistribution and self-reported comfort and discomfort scores of adults with mobility problems who remain seated for extended periods of time.

The project objectives were to establish:

1. The pressure reducing qualities of WaterCell® Technology in the three CareFlex chairs.
2. Whether there is an association between self-reported comfort and discomfort scores of adults and the pressure redistribution qualities of the three CareFlex chairs.
3. User opinions regarding the chair.

Quantitative Data

Demographics

The participants recruited ranged in gender, age, height, weight, and body mass index. Five were male, seven were female, and five of the group were wheelchair users. The chairs were randomly allocated to the participants (table one).

Table 1: Participant demographics

Participant Number	Gender	Age	Height cm	Weight kg	Wheelchair User	BMI	Type of Chair Allocated
1	F	72	157	88	no	35.7	HydroTilt
2	F	46	155.75	79	yes	24.4	SmartSeat
3	M	27	180	106	yes	32.7	SmartSeat Pro
4	F	73	152.4	55	no	23.7	SmartSeat
5	M	53	182	108	yes	32.6	SmartSeat
6	F	19	166	50	yes	18.1	SmartSeat Pro
7	M	81	177	102	no	32.5	HydroTilt
8	M	82	169	94	no	32.9	SmartSeat Pro
9	F	81	144	101	no	48.7	SmartSeat Pro
10	F	81	157	57	no	23.1	HydroTilt
11	M	59	177.8	80.6	yes	25.2	SmartSeat
12	F	84	157	44	no	19.5	HydroTilt

Observations and Discomfort Intensity Ratings

Observations of blood pressure, pulse rate, respiratory rate, and skin inspection were recorded at day one and day seven (see table two). There was a decrease in either systolic or diastolic blood pressure for 50% of the participants between day one and day seven. 33% of the participant's respiratory rate decreased from day one to day seven. Prior to the study commencing participant two reported a non-blanching erythema to left buttock, which remained constant throughout the study. Participant eight had a sore but intact sacrum on day one, by day seven this had resolved. Discomfort intensity rating was low for 100% of the participants and general discomfort assessment ranged from very low to medium (table 2)

Table 2: Observation and Discomfort Intensity rating

Participant Number	Observation	Baseline Chair	7 Days	Discomfort Intensity Rating	General Discomfort Assessment
1	BP	112/64	130/77	15	33
	Pulse	66	68		
	RR	12	14		
	Skin	intact	intact		
2	BP	112/78	126/81	14	36
	Pulse	71	81		
	RR	19	21		
	Skin	L Buttock non-blanching	L Buttock non-blanching		
3	BP	111/74	139/101	13	40
	Pulse	73	88		
	RR	13	15		
	Skin	intact	intact		

Table 2: Observation and Discomfort Intensity rating cont.

Participant Number	**Observation**	**Baseline Chair**	**7 Days**	**Discomfort Intensity Rating**	**General Discomfort Assessment**
4	BP	144/77	119/68	16	28
	Pulse	77	85		
	RR	13	17		
	Skin	intact	intact		
5	BP	171/93	169/87	11	49
	Pulse	67	68		
	RR	18	20		
	Skin	intact	intact		
6	BP	126/64	108/71	16	28
	Pulse	68	62		
	RR	18	15		
	Skin	intact	intact		
7	BP	114/53	119/61	21	43
	Pulse	59	60		
	RR	21	15		
	Skin	intact	intact		
8	BP	152/69	152/95	21	26
	Pulse	75	64		
	RR	18	17		
	Skin	Intact but sore	Intact no longer sore		

Table 2: Observation and Discomfort Intensity rating cont.

Participant Number	**Observation**	**Baseline Chair**	**7 Days**	**Discomfort Intensity Rating**	**General Discomfort Assessment**
9	BP	143/71	157/64	13	25
	Pulse	67	73		
	RR	17	18		
	Skin	intact	intact		
10	BP	150/62	154/52	49	15
	Pulse	74	83		
	RR	18	16		
	Skin	intact	intact		
11	BP	141/87	121/76	20	10
	Pulse	70	76		
	RR	20	20		
	Skin	intact	intact		
12	BP	115/63	128/72	8	30
	Pulse	80	83		
	RR	21	20		
	Skin	intact	intact		

Pressure reducing qualities of WaterCell Technology

Mean pressure across the gluteal region and peak pressure at ischial tuberosities were analysed using SPSS v 22 to:

- summarise the mean/standard deviation for the demographic data
- summarise the mean peak pressure index and average pressure across the three chairs
- compare peak pressure index and mean pressure across the three chairs using paired t-tests and analysis of variance (ANOVA)

- Explore if there is a correlation between comfort and pressure redistribution across the three chairs.

The mean/standard deviation for the demographic data

Descriptive statistics were calculated using IBM SPSS v22 for all participants for the following demographics: BMI, weight, height, and age. The results are found in table three.

Table 3: Descriptive statistics BMI, weight, height, and age.

	N	Mean	Std. Deviation
BMI	12	29.0917	8.49893
Weight in KGs	12	80.4167	23.34507
Height in CMs	12	164.6667	12.62273
Age	12	63.6667	23.05461
Valid N (listwise)	12		

Descriptive statistics were calculated using IBM SPSS v 22 to calculate the mean and standard deviation of the physiological observations (Mean arterial blood pressure, pulse rate, respiratory rate). There was a slight elevation in mean arterial blood pressure and pulse rate between day one and day seven. Respiratory rate stayed the same (see table four).

Table 4: Descriptive statistics: Physiological Observations.

	N	Mean	Std. Deviation
BP Day 1 in exp chair	12	91.4167	12.62363
BP day 7 in exp chair	12	95.3333	12.30176
Pulse Day 1 in exp chair	12	70.5833	5.68024
Pulse Day 7 days in exp chair	12	74.2500	9.74330
Resting Respiration Day 1 in exp chair	12	17.3333	3.08466
Resting respiration Day 7 in exp chair	12	17.3333	2.42462
Valid N (listwise)	12		

Peak and average pressure and peak pressure index

Descriptive statistics using IBM SPSS v22 were calculated in order to measure the average pressures at day one and day seven on the trial chairs. There was a slight increase in mean average pressure at day seven across the three chairs (see table five).

Table 5. Descriptive Statistics: Average Pressures

	N	Minimum	Maximum	Mean	Std. Deviation
Day 1 Average	12	32.60	50.30	42.0083	6.53570
Day 7 Average	12	32.10	54.00	44.0333	6.41282
Valid N (listwise)	12				

Descriptive statistics using IBM SPSS v22 were calculated in order to measure the peak pressure index at day one and day seven on the trial chairs. There was a slight increase in mean peak pressure index at day seven across the three chairs (see table six).

Table 6: Descriptive Statistics: PPI

	N	Minimum	Maximum	Mean	Std. Deviation
Day 1 PPI	12	64.30	194.80	134.2583	43.95983
Day 7 PPI	12	61.10	199.80	136.2833	35.30827
Valid N (listwise)	12				

Descriptive statistics were calculated using IBM SPSS v 22 to calculate the mean and standard deviation of the General Discomfort Assessment and Discomfort Intensity Rating across the three chairs (see table seven). Generally all three chairs had low GDA and DIR. The GDA mean was lower on the SmartSeatPro, however the DIR was lower on the Smartseat.

Table 7: Descriptive statistics of General Discomfort Assessment and Discomfort Intensity Rating

		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean Lower Bound	95% Confidence Interval for Mean Upper Bound	Minimum	Maximum
General Discomfort Assess	HydroTilt	4	38.75	8.808	4.404	24.73	52.77	30	49
	smartseat	4	33.25	12.366	6.183	13.57	52.93	20	49
	smartseat pro	4	29.75	6.946	3.473	18.70	40.80	25	40
	Total	12	33.92	9.539	2.754	27.86	39.98	20	49
Discomfort Intensity Rating (Average)	Hydrotilt	4	14.75	5.315	2.658	6.29	23.21	8	21
	smartseat	4	12.75	2.754	1.377	8.37	17.13	10	16
	smartseat pro	4	15.00	4.000	2.000	8.64	21.36	13	21
	Total	12	14.17	3.904	1.127	11.69	16.65	8	21

Descriptive statistics using IBM SPSS v22 were calculated in order to measure the mean peak pressure index and average peak pressure by chair type at day one and day seven on the trial chairs. The HydroTilt recorded the lowest mean peak pressure index and average pressure (see table eight).

Table 8: Descriptive statistics for Mean Peak Pressure Index and Average Pressure by chair type.

Chair		Day 1 PPI	Day 7 PPI	Day 1 Average	Day 7 Average
HydroTilt	Mean	94.1750	107.1500	36.8250	42.7000
	N	4	4	4	4
	Std. Deviation	35.74291	32.16877	3.79418	6.75722
SmartSeat	Mean	149.1250	133.6500	42.1000	42.0500
	N	4	4	4	4
	Std. Deviation	42.93028	17.89050	7.20833	7.20301
SmartSeat Pro	Mean	159.4750	168.0500	47.1000	47.3500
	N	4	4	4	4
	Std. Deviation	26.08414	27.01537	4.45720	5.56447
Total	Mean	134.2583	136.2833	42.0083	44.0333
	N	12	12	12	12
	Std. Deviation	43.95983	35.30827	6.53570	6.41282

Compare peak pressure index and average pressure across the three chairs using paired t-tests and analysis of variance (ANOVA)

Using IBM SPSS v22 analysis of variance (ANOVA), found a significant difference between the mean peak pressure index at day seven on the chairs and at day one it was approaching significance (table nine and ten) on the chairs, $P<.05$. A paired t-test found no significant differences.

Table 9: ANOVA Mean Peak Pressure Index across the three trial chairs.

		Sum of squares	**df**	**Mean square**	**F**	**Sig.**
Day 1 PPI	Between Groups	9854.287	2	4927.143	3.889	.061
	Within Groups	11402.843	9	1266.983		
	Total	21257.129	11			
Day 7 PPI	Between Groups	7459.227	2	3729.613	5.367	.029
	Within Groups	6254.190	9	694.910		
	Total	13713.417	11			

Table 10: Paired Samples t-Test Peak Pressure Index for participants

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference: Lower	Upper			
Pair 1	Day 1 PPI - Day 7 PPI	-2.02500	26.19178	7.56092	18.66646	14.61646	-.268	11	.794

Further exploration Using SPSS v22 a Tukey Post Hoc test showed there was a significant difference between type of chair and peak pressure index after seven days between the Hydrotilt and the SmartSeatPro (see table eleven) *p<.05*. The HydroTilt and SmartSeatPro was approaching significance at day one.

Table 11: Multiple Comparisons: peak pressure index by chair type.

Tukey HSD

Dependent Variable	(I) Chair	(J) Chair	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval Lower Bound	Upper Bound
Day 1 PPI	Hydrotilt	smartseat	-54.95000	25.16925	.128	-125.2227	15.3227
		smartseat pro	-65.30000	25.16925	.068	-135.5727	4.9727
	smartseat	Hydrotilt	54.95000	25.16925	.128	-15.3227	125.2227
		smartseat pro	-10.35000	25.16925	.912	-80.6227	59.9227
	smartseat pro	Hydrotilt	65.30000	25.16925	.068	-4.9727	135.5727
		smartseat	10.35000	25.16925	.912	-59.9227	80.6227
Day 7 PPI	Hydrotilt	smartseat	-26.50000	18.64014	.371	-78.5434	25.5434
		smartseat pro	-60.90000*	18.64014	.024	-112.9434	-8.8566
	smartseat	Hydrotilt	26.50000	18.64014	.371	-25.5434	78.5434
		smartseat pro	-34.40000	18.64014	.210	-86.4434	17.6434
	smartseat pro	Hydrotilt	60.90000*	18.64014	.024	8.8566	112.9434
		smartseat	34.40000	18.64014	.210	-17.6434	86.4434

*. The mean difference is significant at the 0.05 level.

Using IBM SPSS v22 paired samples t-test and analysis of variance (ANOVA) there were no significant differences between the average pressure (table twelve and thirteen) across the three chairs, however it was approaching significance on day one.

Table 12: ANOVA Average Pressure across the three trial chairs.

		Sum of Squares	df	Mean Square	F	Sig.
Day 1 Average	Between Groups	211.202	2	105.601	3.674	.068
	Within Groups	258.667	9	28.741		
	Total	469.869	11			
Day 7 Average	Between Groups	66.847	2	33.423	.780	.487
	Within Groups	385.520	9	42.836		
	Total	452.367	11			

Table 13: Paired Samples t-Test Average Pressure for participants.

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	Day 1 Average - Seven Days Average	-2.02500	5.20684	1.50308	-5.33327	1.28327	-1.347	11	.205

Table 14: Multiple Comparisons: Average Pressure by chair type
Tukey HSD

Dependent Variable	(I) Chair	(J) Chair	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval Lower Bound	Upper Bound
Day 1 Average	Hydrotilt	Smartseat	-5.27500	3.79083	.385	-15.8590	5.3090
		Smartseat pro	-10.27500	3.79083	.057	-20.8590	.3090
	Smartseat	Hydrotilt	5.27500	3.79083	.385	-5.3090	15.8590
		Smartseat pro	-5.00000	3.79083	.420	-15.5840	5.5840
	Smartseat pro	Hydrotilt	10.27500	3.79083	.057	-.3090	20.8590
		Smartseat	5.00000	3.79083	.420	-5.5840	15.5840
7 Days Average	Hydrotilt	Smartseat	.65000	4.62793	.989	-12.2712	13.5712
		Smartseat pro	-4.65000	4.62793	.592	-17.5712	8.2712
	Smartseat	Hydrotilt	-.65000	4.62793	.989	-13.5712	12.2712
		Smartseat pro	-5.30000	4.62793	.512	-18.2212	7.6212
	Smartseat pro	Hydrotilt	4.65000	4.62793	.592	-8.2712	17.5712
		Smartseat	5.30000	4.62793	.512	-7.6212	18.2212

Using SPSS v22 a Tukey Post Hoc test showed there was no significant difference between type of chair and average pressure (see table fourteen). However day one average pressures were approaching significance between the HydroTilt and SmartSeat Pro.

Explore if there is a correlation between comfort and pressure redistribution.

Using SPSS v22 to calculate if there was a relationship between the discomfort intensity rating score and peak pressure index (table fifteen) and average pressure index (table fifteen). There was no correlation found between discomfort and pressure redistribution

		General Discomfort Assess	Discomfort Intensity Rating (Average)	Seven days PPI	Seven Days Av	Seven Days Area
General Discomfort Assess	Pearson Correlation	1	.130	-.071	-.152	.093
	Sig. (2-tailed)		.688	.827	.637	.773
	N	12	12	12	12	12
Discomfort Intensity Rating (Average)	Pearson Correlation	.130	1	.481	-.078	.002
	Sig. (2-tailed)	.688		.113	.809	.995
	N	12	12	12	12	12
Day 7 PPI	Pearson Correlation	-.071	.481	1	.351	.288
	Sig. (2-tailed)	.827	.113		.264	.364
	N	12	12	12	12	12
Day 7 Average	Pearson Correlation	-.152	-.078	.351	1	.283
	Sig. (2-tailed)	.637	.809	.264		.373
	N	12	12	12	12	12
Day 7 Area	Pearson Correlation	.093	.002	.288	.283	1
	Sig. (2-tailed)	.773	.995	.364	.373	
	N	12	12	12	12	12

Qualitative data

A detailed thematic analysis using a recognised Burnard's (2000) stepped analysis process was used to analyse the qualitative comments and feedback regarding self-reported comfort/discomfort. This stepped approach provides an opportunity to ensure a transparent and auditable account of the data analysis process.

Recurring themes from qualitative interviews were found to be: *Comfort/discomfort, Occupations, Function, Aesthetics, and Posture*

Comfort/Discomfort

92% of participants reported the chairs as comfortable. It was hard for the participants to express what comfort meant, however, from the interviews comfort was associated with: falling asleep in the chair, the chair being at the right temperature, having a positive effect, posture and stirring memories.

50% of participants fell asleep in the chair, this occurred on day one and throughout the week.

"It's got to be comfortable because I've dropped off to sleep twice and I feel nice and comfortable and relaxed" (participant 8).

Other participants stated that the chair was the right temperature getting neither too warm nor cold,

"It never gets too hot and I think it's that that makes it as comfortable as it is." (Participant 1).

One participant felt that the chair had a positive effect on him as soon as he sat in it

"It was like my whole body had had a transformation really because the comfort is good." (Participant 5).

This participant also reported that this was the first time he had sat properly in a chair for eight/nine years.

Another participant felt that sitting in the chair had stirred earlier memories before her injury,

"I'd forgotten what it felt like to sit somewhere comfortably." **(**Participant 2).

One participant reported the chair as uncomfortable,

"I didn't feel quite comfortable. Not sort of comfortable as I do sitting in this. I felt more restricted in it really" (Participant 12)**.**

Occupations

80% of participants reported being able to carry out activities and leisure pursuits such as watching television, reading and pursuing hobbies whilst seated in the chair. One participant reported being able to do things that she would not have normally been able to do and for longer periods of time than sitting in anything else,

"I can sit and read, I've sat here and knitted, I've sewn, I've done all sorts of little bits and I've been able to sort of read for at least an hour." (Participant 2).

This participant also reported sitting properly in a chair for the first time in three years.

Chair Function

The operation of the chair was reported by 75% of the participants who felt that the chair was difficult to adjust if they wanted to and would need to rely on someone else to do this. Examples given were; removal of armrest for sideways transfers, being unable to fully extend the footrest, and tilting the chair back. However, one participant reported favourably that she could adjust the leg rest herself,

"I also like the fact that I can put this foot rest wherever I want…… I do think that's a smashing point on it that I can lower that if I want to." (Participant 1)

Most respondents reported the chair would be greatly improved if it had a powered facility in this study e.g. tilt in space, leg raise, and recline. The researchers are aware that the company does manufacture a powered version of the chairs. This information was relayed to the participants who responded very positively towards it.

50% of the participants questioned the purpose of the headrest cushion. On sitting in the trial chair 25% moved the cushion out of the way immediately and the other 25% for example participant 9 who reported that after trying the cushion he abandoned using it

"….because when you put your head on it, it's pushing you away from the rest of it". (Participant 7)

Aesthetics:

The participants differed in their opinions of the fabric. 25% gave positive feedback such as:

"I just love this fabric. This material whatever it is. I do like that, it's so comfortable" (Participant 1).

25% of the participants stated that they would prefer the chair to match their existing seating.

50% of the participants reported negative comments such as:

"*A different colour would be nice. I come through our living room door and I think 'oh who is that'. I think there's somebody there but there isn't obviously. I don't know really. No I don't think it's pleasant to look at but there again it's not meant to be living in my living room is it?* (Participant 9).

The wheels on the chairs in terms of manoeuvrability were favoured by 17% of the participants, however, one felt that the chair would be more aesthetically pleasing if they could be hidden by an apron or fringe of fabric

"like a skirt or something round the bottom of the chair just to cover them up" (Participant 10).

50% of the participants stated that the chair had a clinical/nursing home appearance and this could be off putting in their own homes,

"It looks a bit clinical to be honest. I think it would be alright say in a nursing home or a ward. But in somebody's house it looks a bit clinical and off putting really" (Participant 9).

One participant reported how the aesthetics affected her mood

"Well I felt depressed in it" **and** ***"I think it's a depressing chair. It wants to be something brighter"*** (Participant 12).

The size of the chair was reported by 33% of the participants to be too big and bulky

"It looks bulky to me. It looks very, very big and bulky, you know, which isn't … doesn't look too endearing, you know." (Participant 11)

Posture:

92% of the participants made comments related to posture. This ranged from full body support to specific areas being identified such as shoulders, feet, legs and back.

Full body support

67% commented on how the trial chair provided full support*,*

"I feel like I'm sitting better than I normally would which is enabling me to do things more comfortably" (Participant 6)

and ***"I've probably got a much better posture sitting in the chair, it's…I've had my altered posture for three years so it's taken some time to get used to…"*** (Participant 2)

Specific body area support

There were specific comments from the participants in relation to lumbar support. 25% of the participants reported being able to sit in the chair without using their usual additional back support as they do in their own chair (extra cushions, hot water bottle),

"It just supports that part of my back that hurts all the time" (Participant 1).

However 25% of participants reported still needing to use an additional cushion in the lumbar region of the chair as they felt it offered limited support, which could be attributed to previous medical history/pathology of these participants. 17% reported that they felt that the chair offered support in their shoulders which was visibly noticeable by the researchers. 50% of the participants commented on the armrests of the chair with 17% stating that they offered support whilst 33% reported them as being "bulky". 17% of the participants commented that the footplate was supportive enabling them to sit comfortably. Finally 17% of participants reported their legs being supported in the trial chair.

Chapter 5: Discussion and limitations

Discussion

The purpose of the project is to evaluate the impact of WaterCell® Technology in three chairs and the effect on pressure redistribution and self-reported comfort/discomfort scores of adults with mobility problems who remain seated for extended periods of time.

The project objectives were to establish:

1. The pressure reducing qualities of WaterCell® technology in the three CareFlex chairs.
2. Whether there is a link between self-reported comfort/discomfort scores of adults and the pressure redistribution qualities of the three CareFlex chairs

It is acknowledged by Stockton, Gebhardt, and Clark (2009) that the level of evidence in the management of people who are at risk of pressure ulcer development whilst seated is sparce. This is supported in the recent publications of best practice guidelines such as those developed by EPUAP, NPUAP, PPPIA (2014) and NICE (2014) whereby the two reports highlight the need for further research in this field. Well informed research on seating should involve key stakeholders including the end user. This is well documented by leading authors in the clinical arena who draw attention to equipment abandonment if seating is found to be uncomfortable and aesthetically displeasing (Geyer et al. 2003; Crane and Hobson 2002). The automotive industry appears to be leading the way in developing car seat technology, based upon pressure redistribution and end user perceived comfort/discomfort (Kyung and Nussbaum 2007).

Evidence based practice is "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research" (Sackett et al. 1996). In order to deliver this, clinical decisions regarding seating need to consider many factors: pressure reducing qualities of the seating, the individuals' level of perceived comfort, aesthetics of the equipment, posture, and best practice guidance. Failure to recognise all of these factors may lead to inappropriate prescription of equipment and opposition by the end user in accepting the equipment (Shectman et al.2001).

1. The pressure reducing qualities of WaterCell® technology in the three CareFlex chairs.

As average interface pressures of 60 - 70 mm Hg for one to two hours may lead to soft tissue injury (Kosiak, 1959) it is imperative with new seating technology that manufacturers investigate the pressure redistributing qualities of the materials used at the design stage. Pressure redistribution is assessed through the process of pressure mapping. Familiar units of measurement include: average pressure, peak pressure, peak pressure index, peak pressure gradient, peak pressure ratio, and dispersion index (Lung et al. 2014). However after conducting a comprehensive search of the literature the researchers found that there are currently no studies that suggest an ideal peak pressure index, indicative of the pressure redistributing qualities of seating. Within this study pressure mapping was undertaken to assess both peak pressure index in the area of the ischial tuberosities and average pressure across the gluteal region whilst seated.

Average Pressure

From the twelve participants who trialled the three chair types the mean pressure was 42 to 44.03mmHg offering lower average interface pressures than those reported to cause potential injury (Kosiak, 1959). Comparing this study to others in the field a similar study which measured average pressures whilst seated are those reported by Kim and Chang (2013). They found when comparing average sitting pressures of a chair and two different types of cushion, with eighteen participants, the average pressures were similar across the conditions (60.95mmHg to 61.97mmHg). Differences however, in the two studies are that Kim and Chang used young healthy volunteers, whereas this study recruited from a diverse age group and disabled population. The two interface pressure mapping (IPM) systems used to collect the data were from different companies, nonetheless both record interface pressure. Kim and Chang (2013) recorded average pressure for seventy seconds whereas this evaluation recorded average pressure for five minutes.

Average pressure across the three trial chairs using WaterCell® Technology

The researchers also note that in this evaluation although there were no significant differences in the average pressure across the three trial chairs using paired t-tests and analysis of variance (ANOVA) the analysis shows that the HydroTilt and SmartSeat Pro was approaching significance on day 1. This would suggest that there is a difference between those two chairs in regards to average pressure redistribution.

Peak Pressure Index

The mean peak pressure index was 136.28mmHg across all three chairs using WaterCell® Technology. Peak pressure index studies are difficult to source in order to make assumptions of the pressure redistributing properties of WaterCell® technology. This is due to previous studies in seating either having a sample population drawn from the same group for example wheelchair user or non-wheelchair user (Burns et al. 1999); comparing cushions across groups, for example spinal cord injury patients and the elderly (Ferrarin et al. 2000); or a link to peak pressure readings, BMI, and surface values (Gil-Agudo et al. 2009). The peak pressure index findings from this small evaluation study compare in some aspects to findings by Gil- Agudo et al. (2009). In a comparative study of forty eight people with spinal cord injury the maximum peak pressure under the ischial tuberosities and peak entire pressure map (area) on four pressure redistributing cushions was analysed using XSensor® pressure mapping. Gil-Agudo et al. (2009) found maximum peak pressure under the ischial tuberosities to range from 102mmHg to 207.5mmHg, which are comparable to the findings in this study of 137.5mmHg to 138.35mmHg. Nevertheless a difference noted is the length of time peak pressures under the ischial tuberosities was measured. Gil-Agudo et al. (2009) recorded peak pressure index for 1.5 minutes whereas this evaluation recorded peak pressure index for five minutes.

Peak Pressure Index across the Three Trial Chairs Using WaterCell® Technology

In this evaluation there was a significant difference in the peak pressure index across two of the three trial chairs after seven days using ANOVA. It was also approaching significance on day one. This would suggest that the Hydrotilt offers lower peak pressure index under the ischial tuberosity than the SmartSeatPro. However a limitation to this is the small number of participant's trialling the two chairs.

2. Whether there is a link between self-reported comfort/ discomfort scores of adults and the pressure redistribution qualities of the three CareFlex chairs

There was no correlation found using SPSS v22 Pearson's Moment Correlation between comfort/discomfort intensity ratings and pressure redistribution across the three chairs. Comfort/discomfort is a major factor for people when they decide whether to use a pressure redistributing device or not (Stockton and Rithalia 2008). These findings would suggest that from the mean Discomfort Intensity Rating 14.17 and General Discomfort Assessment Scores 33.92, the three trial chairs were not reported to be uncomfortable and therefore found to be comfortable for the 12 participants. This is further supported by the qualitative data, which presents the individual participants perceptions of how comfortable they felt in the chairs. The GDA has a possible range of 13–91, with higher scores representing increased levels of discomfort. The DIS has a possible range of 8–99. A score of 8 indicates no discomfort in any part of the body and a score of 99 indicates a maximum amount of discomfort in eight body areas and in the body as a whole. This study is analogous to previous studies that have reported on the possibility of an association between pressure redistribution and comfort. The largest study using 100 subjects found no association between the two (Lee et al. 1993) and although we used small numbers the results are similar with the difference being that our study was with a disabled population using specialist armchairs and the Lee et al. (1993) study was with healthy volunteers using car seats.

In this study the researchers have found is that although the Hydrotilt offers the lowest interface and average pressures, it was not recorded as the most comfortable. The GDA mean was lowest on the SmartSeatPro, however the DIR was lowest on the SmartSeat. This therefore supports the findings of Stockton and Rithalia (2008) that comfort is not always linked to lowest pressures.

Qualitative Data

Recurring themes from qualitative interviews were found to be: *Comfort/discomfort, Occupations, Function, Aesthetics, and Posture*

Comfort/Discomfort

Comfort plays a major part in whether a piece of equipment is deemed acceptable and then utilised by the end user (Crane and Hobson, 2002). A search of the literature indicates that the concept of comfort is a difficult to define. Comfort according to Cambridge Dictionaries Online (2016) can be defined as a 'pleasant feeling of being relaxed and free from pain' or by Redfern (1976, p.211) as 'an abstract multidimensional concept that is difficult to define and measure'. In this study 92% of the participants reported the chairs as comfortable although all had difficulty quantifying what this meant. Pearson (2009) concurs with this stating that comfort is poorly understood and inconsistently evaluated. This study used a validated tool (Crane & Hobson 2002) to evaluate comfort and discomfort which was adapted by the researchers for suitability in this study. Themes and adjectives from the interviews linked with comfort were: falling asleep in the chair, the chair being at the right temperature, having a positive effect mentally, feeling snug, and stirring memories.

Occupations

A significant number of participants reported being able to carry out activities and leisure pursuits such as watching television, reading and pursuing hobbies whilst seated in the chair. A search of the literature has found no previous studies exploring the impact of specialist pressure redistributing chairs on occupation. One notable exception is Stockton, Gebhart, and Clarke (2009) who state that the ability to maintain occupations when seated is a key consideration.

Operation of the chair

The operation of the chair was reported by 75% of the participants who felt that the chair was difficult to adjust if they wanted to and would need to rely on someone else to do this. Examples given were; removal of armrest for sideways transfers, being unable to fully extend the footrest, and tilting the chair back. Most respondents reported the chair would be greatly improved if it had a powered facility in this study e.g. tilt in space, leg raise, and recline. The participants did however find that the wheels on the chair where useful in relation to manoeuvrability. The researchers are aware that the company does manufacture a powered version of the chairs. This information was relayed to the participants who responded very positively towards it. Pinney et al. (2010) reports that a chair should be easy for the user or caregiver to operate without the use of excessive moving and handling.

Aesthetics:

Aesthetics of a chair is an important consideration in regard to the users' motivation and satisfaction (Pinney et al. 2010). The participants differed in their opinions of the fabric, the colour, the composition of the material, size of the chair, and the visibility of the wheels. 50% of the participants however stated that the chair had a clinical/nursing home appearance and this could be off putting in their own homes. This affected one of the participants resulting in 'equipment abandonment'.

Posture:

The majority of participants made comments related to posture. This ranged from full body support to specific areas being identified such as shoulders, feet, legs and back. Most notable is the reports of improved posture from sitting in the chair. The Hydrotilt was not recorded as the most comfortable chair, from the findings comments from the participants were in relation to a lack of lumbar support. Conversely, two of the participants who used additional lumbar support in their own chair, did not need to use them, when sitting on the HydroTilt. Therefore person centred assessment is essential, taking in to consideration previous medical history/pathology. It is reported that good seating conditions can lead to improvements in respiratory function, oral intake, digestion, motor skills, expiratory volume and expiratory time which can benefit the user physiologically and socially (Pinney et al. 2010). Notably in this study three participants reported that when sitting in the trial chair, they experienced a change in the position of their shoulders from protraction to retraction, which aided respiration, posture, and feelings of well-being.

Limitations

As a largely self-selecting sample, the views of those participants who chose not to participate may well be considerably different from those that did. The sample size of the study can be considered as a limitation, with twelve participants. Testing for associations is more robust when the sample size is larger. However, the small sample size in this evaluation does not preclude testing for a relationship as the qualitative and quantitative data suggest that there could be an effect between the two. Another limitation is asking the participants to adopt a neutral seated position and remain still during the recording of interface pressure measurements. Confounding variables such as the amount of time participants sat in the trial chair once the researchers had left cannot be excluded. Caution is advised when interpreting pressure mapping results alone due to errors from hysteresis (lagging effect of the pressure mat) and creep (increase in pressure whilst force remains constant) plus any hammocking effect from the mat. The system used in this evaluation is reported by the company as demonstrating low values in both hysteresis and creep.

Chapter 6: Conclusion and recommendations

This chapter concludes the report and makes clear recommendations as to next steps and the way forward, taking into account what has been found in this study and the implications for future manufacturing of CareFlex chairs.

This project sought to evaluate the impact of WaterCell® Technology in three CareFlex chairs: HydroTilt, SmartSeat, and SmartSeatPro in relation to pressure redistribution and self-reported comfort/discomfort scores of adults with mobility problems who remain seated for extended periods of time. The small scale evaluation ran over a period of twelve weeks and was conducted in the homes of the twelve self-selecting participants. The participants were randomly allocated one of the three trial chairs and asked to evaluate the chair by regularly using it for a period of one week. Metrics collated at day one and day seven of the evaluation included: demographics, interface pressure (area, average, and peak pressure index), and physiological observations (blood pressure, pulse rate, and respiratory rate). At day seven self-reported comfort/discomfort ratings (GDA and DIR) were collected and explored using digitally recorded semi structured interviews.

Mixed methods were used to collect the data. The findings note that across the twelve participants the average pressure and peak pressure index were low across the three chairs, comparable with studies already published. The HydroTilt offered the lowest PPI across the three chairs, yet scored highest on GDA and DIR ratings. The SmartSeatPro had the lowest recorded GDA score across the three chairs, yet the highest PPI and average pressure.

The project objectives have been met. It was intended to establish:

1. The pressure redistributing qualities of WaterCell® Technology in the three CareFlex chairs.
2. Whether there is an association between self-reported comfort and discomfort scores of adults and the pressure redistribution qualities of the three Careflex chairs

The report provides evidence of how the above were achieved and examines the three types of chairs in collaboration with the end user and what could be improved in future design. The evidence obtained in the qualitative interviews suggests that CareFlex chairs are comfortable for the people intending to use them. This is a new concept for chair manufacturers. This type of study has not been completed before using a disabled population and CareFlex can state that the evidence from this small study suggests that the chairs are comfortable as stated by the users, instead of purporting them to be so without the evidence.

In this evaluation pressure redistribution was not collated with the chairs in tilt as it is a different study to the one above.

Recommendations:

1. The researchers will seek to publish the findings of the report in a peer reviewed journal.
2. The researchers will submit abstracts to relevant conferences for dissemination of the findings.
3. The researchers will seek to publish other papers that explore the findings from the study.
4. The researchers recommend that the company invite the twelve participants to a user/carer listening event to receive feedback on their views of the chairs with motorised actuation.
5. To continue the collaboration with end users in the design/ modification of CareFlex chairs, which would be a new approach in specialist seating, as far as the researchers are aware.
6. Further research exploring the differences in peak and mean pressures with varying degrees of tilt would possibly add further evidence to the effectiveness of CareFlex chairs.

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