Therapist's influence on the design of Invacare's Flo-Tech Solution Xtra

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The trend for inclusive design appears to becoming stronger, and an area that clinicians are urged to participate in. Combining clinical and technical expertise can often be a demanding challenge and this paper looks to show the results of how a modular postural cushion was designed and evaluated by Invacare Ltd. The Flo-Tech Solution Xtra modular system was conceived through joint collaboration between manufacturer and therapists following discussion and demand from NHS wheelchair services (WCS) in the UK. Concept, rationale and design of the cushion are discussed from a clinical perspective, which underpins the manufacturing process from conception through to the finished product. The seating system was designed to address the postural requirements primarily of the neurological population and consequently the cushion underwent clinical trial at the Royal Hospital of Neuro-Disability, Putney, London.

Seven subjects were identified as suitable for the evaluation by the postural team at Putney and three were trialed independently by Invacare Ltd. The main focus of this study was identifying and meeting the individual's therapeutic aims of posture and pressure through using the Solution Xtra. Even though the study size was small and the results subjective in nature, there was an overall favourable outcome of using the modular system as a seating intervention, and it was also rated highly by the clinicians involved.

Key words: Seating, posture, wheelchair cushions, inclusive design

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Special seating innovations have emerged from Europe and America since the 1970's addressing the problems of pressure sores, skeletal deformities and sitting instability (Woods and Watson, 2004). Over the years there have been significant changes in the design of mobility equipment through the development and manufacture of more sophisticated and clinically effective products (Collins, 2004).

Evaluation to support the clinical application of these products is common practice for occupational therapists (OTs), usually through the appraisal of a finished item, with little or no involvement at the primary stages of manufacture. Of late there seems to be a new initiative towards involving OTs at the elementary stages of design and development within healthcare (Walker and Fall, 2006).

Recently *Occupational Therapy News* dedicated an issue to 'inclusive design', highlighting the need for synergy of ideas between therapists, engineers and manufacturers, stating that good design rests on collaboration (Garner, 2006). However, this article emphasizes the design of products for activities of daily living rather than on products to help manage seating and posture.

The volume of wheelchair cushions available on the market is forever increasing, as the importance of postural control and its continued link with improved function and pressure care management continues to be apparent (White, 1999). Postural cushions and systems have a tendency to be expensive and often new cushions appear onto the market with limited clinical support and evaluation.

Manufacturers often try to blind the clinician with science through issuing confusing and misleading commercial literature, when attempting to convince them that a cushion is worthy of recognition within the market place and NHS portfolio. The inappropriate use of pressure mapping, a computerized device that measures the individual's interface pressures of the seated surface, being one notable method (Rithalia, 2005).

In order to increase understanding and collaborative working between the clinical and commercial sectors, Standards of Better Health (2005) acknowledged the need for therapists to be more business orientated. Also, the National Clinical Guidelines (British Society of Rehabilitation, 2004) underline the necessity for the effective and economical deployment of resources. Now more than ever, as products become cost driven to fit the market, therapeutic input is essential to ensure these manufactured goods are concurrent with clinical need.

This paper discusses the value of therapist involvement throughout the planning, manufacturing and evaluation stages of the Invacare Flo-Tech Solution Xtra, a modular seating cushion primarily designed for postural management of wheelchair users.

CONCEPT OF THE FLO-TECH SOLUTION XTRA MODULAR SYSTEM

The prescription of mobility devices is a vital part of occupational therapy intervention (Christiansen and Baum, 2005) and therefore OTs generally hold the greatest knowledge in regards to seating and posture. As a consequence Invacare Ltd selected this profession to work with the project, in advising on the clinical application of the Flo-Tech Solution Xtra and its current viability for the NHS market place.

The Invacare Flo-Tech cushion range has been well recognized over the years for their pressure reducing qualities through the properties identified by Rithalia (2005) as a contoured base of high quality foam with the option of a unique low viscosity memory gel. Even though initially used primarily within the acute setting, there has been a successful move of the cushions into NHS WCS, with the introduction of improved covers and increased number of sizes.

Existing in the Flo-Tech cushion range is the established Solution cushion, which is aimed at end user's that are at elevated risk of pressure ulcer development. This cushion compromises of a contoured foam base and a dual layer of patented gel sacs over the ischial and sacral area. Additional components to be added to this cushion to address postural needs were often requested from WCS. Further discussions with several therapists led to the requirement of a postural cushion with the following features:

- Allowance for accommodation or correction of common postural abnormalities
- Variation of postural management within one cushion
- A comfortable seated surface that allows for postural movement
- Pressure care management not to be affected
- For transfer method not to be impeded.

Through joint collaboration between Invacare and WCS therapists, the concept of the Flo-Tech Solution Xtra was devised. It was decided to create a modular system so that the seated base could be altered according to individual need (Turner, 2006).

RATIONALE FOR MANUFACTURING THE FLO-TECH SOLUTION XTRA

When creating a new product, it is important to establish a good supporting rationale to define the planning, design, manufacturing and evaluation stages of the development. Walker and Fall (2006) likened product design to a treatment plan, through identifying a need in the market and developing a solution to meet that need. Evidence suggests that uncorrected postural abnormality can have profound consequences for physiological function and also that musculoskeletal development can be directly influenced (Farley et al, 2003). Adaptive positioning systems can provide active maintenance or correction of posture and appropriate seating serves an important foundation for function (Swee Hong and Wheeble, 2005). It is imperative therefore that OTs have adequate choice and variation of products that can be adapted to the individual to meet these needs.

The Flo-Tech Solution Xtra was envisioned to address a number of common postural problems encountered in wheelchair seating through providing a bespoke stable base for the end user. Radar et al (1999), state that the goal of individualized seating is to provide stability, while Bull (2001) outlines the need for a balanced and upright position to be gained from the seated base to allow freedom of the trunk and upper limbs through optimal muscular function.

The seating problems identified to be addressed by the Solution Xtra modular system were:

Fixed and correctable positions:

- Pelvic tilt (posterior and anterior)
- Pelvic obliquity
- Pelvic rotation
- Reduced hip flexion (unilateral and bilateral)
- Hip abduction
- Hip adduction
- External and internal rotation
- Windsweeping

These were chosen in accordance to standard leg and pelvic patterns incurred through wheelchair seating as indicated by Engstrom (2002).

THE DESIGN OF THE FLO-TECH SOLUTION XTRA MODULAR SYSTEM

The resulting outcomes are laid out in respect to the integrated parts of the Flo-Tech Solution Xtra and the required changes needed to meet the clinical rationale.

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The base
It continued to be important that the base was anatomically contoured to increase the surface support for the end user in order to provide maximum pelvic stability and also to assist with correct pressure redistribution, especially when combined with the gel sac (Collins, 2001). The foam base provides a comfortable seating surface on solid seat bases and is appropriate for those that cannot tolerate too firm a surface on a canvas sling or if altered sensation is an issue. An optional rigidizer is an important option to enhance stability at the pelvis, hip and thighs where required (Batavia, 1998).

The base therefore remained unchanged in initial shape or foam composition, however, loop velcro was added to enable affixing of the component parts with the hook counterpart. Also as the foam can be cut without the need for resealing, then leg length discrepancies or reduced knee flexion can be accommodated.

The gel
Hybrid gel-foam combinations are a common choice of postural cushion, as a result of their good envelopment, pressure reduction and support properties (Cook and Hussey, 2002), yet the viscosity of the gel differs significantly from cushion to cushion. The Flo-Tech Solution Xtra contains a memory silicon gel, which is affected by gravity. The gel returns to its original position after each use allowing for accommodation of the user's postural movements during the day and is particularly important if factors such as hoisting cannot guarantee the repeated achievement of a desired position.

Migration of the gel into one position is avoided, and there is no need for regular manual redistribution, which reduces maintenance of the cushion. Transferring method, accommodation of sitting posture and position, and carer education are all areas indicated by White (1999) as factors to be addressed for effective assessment and prescription of wheelchair cushions.

THE COMPONENT PARTS

Bespoke component parts were developed to be placed on both the topside and underneath the cushion to vary the contouring of the seated base to range from mild to semi-aggressive postural management.

These component parts, even though created to be strong enough to maintain or correct position, were made of a forgiving foam composition to allow for spasms, involuntary movements and unavoidable mal-alignment from transfers, without compromising tissue integrity. It was also important that the parts allowed for side transfers by depressing adequately for the use of a transfer board as excessive shaping should not impede independent transfers (Batavia, 1998).

It was important that the component parts were interchangeable – no left or right pieces, to assist in making assessment, ordering and re-stocking less complex and frustrating for the therapist.

CUSHION COVER

Covers can alter the shear and comfort properties of the cushion (Moody, 1998), so therefore the cover required to be altered after component parts were added and also required to have adequate multi-way stretch to allow for immersion of the client on the seated base. The cover was made expandable via a unique second zip design and the zips were fixed with a weld in order to reduce the risk of fluid ingress, as well as adding a full length flap to conceal the zip. Material used for the cover itself is ingress resistant, waterproof, vapour permeable, fire retardant and multi-stretch as identified as ideal properties by Rithalia (2005).

CLINICAL EVALUATION

The Royal Hospital for Neuro-Disability (RHND) in Putney, London was approached to carry out trials with the Solution Xtra cushion and modular system as they are well renowned for their clinical expertise within the postural management sphere. Lead clinical specialist Jane Harding, from the in-house posture clinic led the trials. The trial data has been taken from the information supplied by RHND.

The posture team at Putney identified seven subjects and also three end users were independently trialed by Invacare across the country and the results formulated as one.

METHODOLOGY SUMMARY

A small controlled sample population was used to trial the cushion and chosen via clinical assessment from the postural management team with the following variables:

- Neurological diagnosis
- One or more of the mentioned positioning problems
- Currently using a positioning cushion.

The method used was a mixture of qualitative and quantitative data in the form of a questionnaire that highlighted the following:

- Clinical opinion of the cushion's positioning properties
- Clinical opinion of the cushion's pressure reducing properties
- End user's perception of comfort
- Clinician's rating of the cushion.

The cushion's were then used over a period of 12 weeks and reviewed regularly by the clinical team and the results were then recorded and a summary submitted to Invacare.

SUMMARY OF RESULTS

During the recruitment period ten end users were identified (seven users by RHND and three by Invacare Ltd's clinical specialist) for their suitability in this trial. All were assessed by a qualified therapist and their postural problems recorded. Following is a brief summary breakdown of the:

- Diagnosis distribution
- Postural problems encountered
- Solution Xtra component parts prescribed by the therapist
- Clinical rationale

Diagnosis distribution
As previously stated only neurological conditions were considered for the trial and the diagnosis of the end users who were identified as suitable for the trial are shown in *Table 1*.

Postural problems encountered
Following a thorough assessment of the end user's seated posture by a qualified professional, the clinical presentations were recorded (*Figure 1*).

Flo-Tech Solution Xtra component parts prescribed by the therapist

Sizes: The sizes varied from client to client and held no bearing on the outcome of the effectiveness of the cushion.
Composition: All prescribed cushions were made of the same basic compositions of the foam base, gel sac and extendable cover.
Component parts: As each cushion is modular and bespoke to the user, the component parts were chosen by need and the distribution of the prescribed parts is shown in *Figure 2*.

TABLE 1.
Diagnosis of distribution of identified end users

Diagnosis	Percentage
Brain injury	60%
Cerebral palsy	10%
Spinal muscular atrophy	10%
Spinal injury	10%
Retts syndrome	10%

From the data supplied the rigidizer was also used in 30% of the cases. As a result of the complexity of the client group at RHND, it is presumed that most end users are in powered or tilt-in-space chairs where there is a tendency to have a solid base surface and therefore no need for a rigidizer.

CLINICAL RATIONALE

Clinicians involved in the trail were requested to identify the suitability of the cushion in respect to the therapeutic aims set out to address the pressure and postural requirements of the end user.

The results were collated as shown in *Figure 3*, and where the therapeutic aims were not met the following reasons were given:

Posture
- The client required a firmer base with less contouring
- The client potentially required custom made seating.

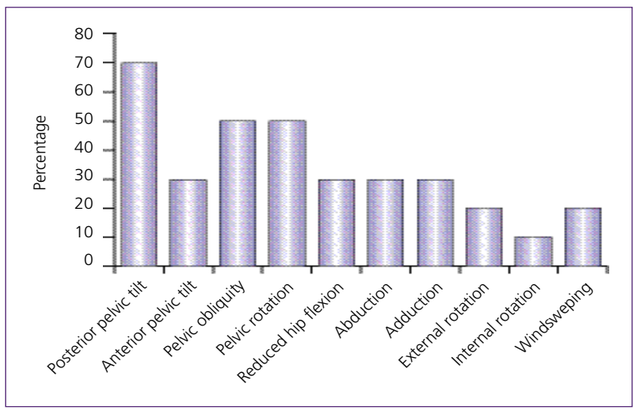
Pressure
- The client became unwell during trail and had increased risk of pressure care as a result of the lack of nutrition and existing tissue damage.

A comfort rating was requested from the end users in relation to their previous cushion. Even though comfort is difficult to define and the results in *Table 2* are subjective, the cushions had been used over a

TABLE 2.
End user perceptions of comfort

Diagnosis	Percentage
More Comfortable	40%
Same comfort	10%
Less comfrot	10%
No response	40%

Figure 1. Postural problems identified



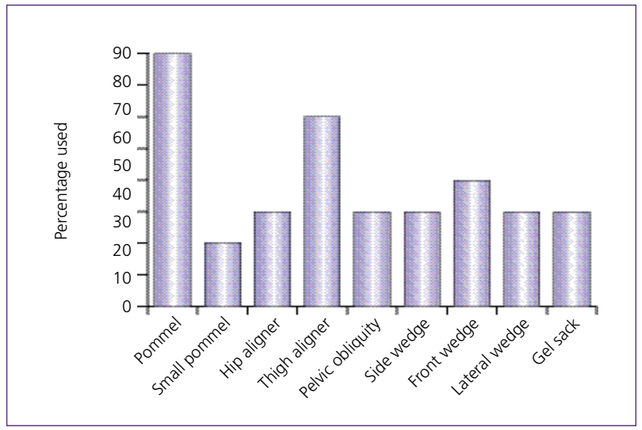


Figure 2. Component parts used

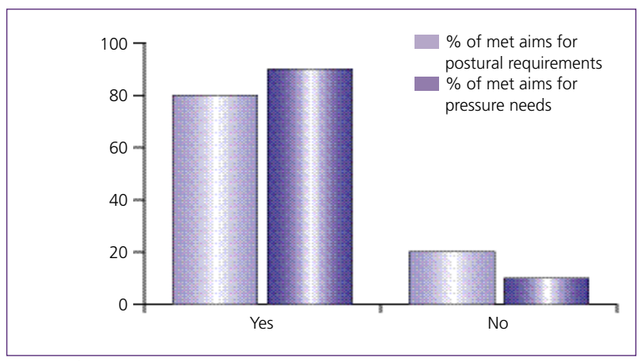


Figure 3. Therapeutic aims met

significant period of time to allow for user adjustment (Turner, 2006).

Where there was no response, the Client was unable to respond as a result of low awareness levels or because no data information was available.

Ninety per cent of the clinicians rated the cushion as either excellent or good, while 10% requested further clinical evaluation and pricing data.

DISCUSSION

From this brief study a number of issues arose that are worthy of discussion in respect to evaluating the Flo-Tech Solution Xtra.

Evaluation method

The clinician's own judgement of therapeutic met need of the clients and end user's perception of comfort has been the main focus for the evaluation, which does create potentially subjective data that is difficult to effectively analyse.

Pressure mapping was considered as a potential scientific study tool, however, as only one variable is recorded, the results can be misleading. When supporting posture, higher pressure may be exerted onto the seated base in specific areas and therefore may indicate less favourable results for pressure alone. Pressure readings do not always bear a true indication of improved posture and comfort. Consideration of therapeutic need is a more holistic viewpoint and represents a truer reflection of what is required in regards to cushion prescription.

It is felt that further research is required, however, wheelchair services often wish to independently create their own evaluation methods for clinical reasoning of cushions, and normally independent of the manufacturer. Evidence-based practice research should always be encouraged and the process of cushion evaluation should be more widespread and formulated into guidelines for each clinic, however, there are ongoing issues of resources and time constraints (Bennett et al, 2003).

Neurological conditions

The postural patterns identified for evaluation are primarily neurological implicated complications and hence this population was targeted. It was noted in Tuttiett's (1989) research, that the majority of wheelchair users have a neurological disorder and associated postural needs, hence the concentration on this clinical area.

Further evidence with regards to the effectiveness of each identified pattern could be beneficial, however, this cannot always be calculated as a result of other pre-disposing factors of each user. Also the available information supplied from the raw study data was inadequate in detail and not included.

The orthopaedic population was not completely discounted during the design of the Flo-Tech Solution Xtra as consideration was also given to how the cushion may be used within this client group. For example some users with below knee amputees may benefit from the increased contouring the components will provide, and where there are other implications such as reduced range of movement, the ability to cut the base for accommodation may be an advantage.

However, it is acknowledged that the existing trochanteric shelf may potentially be too contoured at present for some users with above knee amputations.

Cushion rating

Even though recognition is given of the small study sample, the findings indicate that the Flo-Tech Solution Xtra has been favourably received by the therapists who have seen and used the product. Possibly, this could be because of the active therapeutic involvement throughout its development and the clinical rationale which has increased the positive application of the cushion design.

Rating of the cushion showed that the clinician's felt it worthy of a place in their portfolio and that it sat well within the current market place. With the ever demanding need for evidence-based practice, there is no surprise that some clinicians were cautious in rating the cushion.

CONCLUSION

Inclusive design is set to become a precedence for manufacturers to follow in order to enhance good collaboration and create innovative products. This article has shown that where clinical application has been sought from the outset, the manufacture of a suitable wheelchair cushion produced favourable outcomes when shown to the UK WCS.

The Flo-Tech Solution Xtra Modular system aimed to fill the need in the market for an individualized postural seating system that could provide a range of postural management within one cushion and was flexible enough to allow for transfers and uncontrolled movements. Even though further research is required, initial results show that through the amalgamation of clinical rationale and technical expertise, these requirements have been met.

Therapists hold such vital skills which can revolutionize manufactured therapeutic equipment. Even though resistance to change and historical usage of previous products are always barriers to development, the identification of a clinical need, and a passionate desire to meet it, gives birth to inspiration. Manufacturers need to be continually open to critique from clinicians to ensure that their product lines reflect current clinical thinking. IJTR

Conflict of interest: none.

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KEY POINTS

- Addressing end user's postural requirements, mainly focusing on neurological implicated complications, with a modular seating system.
- Highlighting the need for joint collaboration between therapists and manufacturers when developing seating systems and cushions.
- Establishing a good supporting rationale for a design can facilitate the planning and evaluation of manufactured products.
- Evaluating the modular seating system through analysing therapeutic need, end user perception of comfort and the therapists clinical opinion.