A. Additive manufacturing (3D printing) for the provision of custom head supports

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Summary
This works demonstrates a viable technique for producing custom seating components, in this instance head supports, to inform how 3D printing could be utilised in the future. This project includes a survey of expert health professional opinions, a size and shape analysis, and mechanical testing of an additive manufacturing head support.

Aims & Objectives
Aim: Evaluate if an additive manufacturing-based workflow is a safe and viable method for the provision of custom head supports.
Objectives:

- Assess the need for custom head supports through a survey of clinicians working in specialist seating services.
- Analyse range of head shapes and sizes to inform design requirements.
- Assess the properties of an additive manufactured head support under static mechanical loading conditions.

Background
Additive manufacturing is enabling high degrees of design freedom, the opportunity to reduce component count and weight, enablement of close to point of care services, and reduced cost compared to alternative manufacturing methods (Wohler, 2018, Ngoa et al, 2018).

Additive manufacturing is therefore well suited for the production of highly personalised one-off products (Ford & Despeisse, 2016) and is already extensively used for patient-specific maxillofacial and dental implants, surgical guides, prosthetics and orthotics (Bibb et al, 2009, Van der Zel et al, 2009, Lunsford et al, 2016). There is currently limited published research regarding the use of additive manufacturing for wheelchair seating. It is hypothesised that additive manufactured parts can provide customisation in the shape of components and therefore parts can be more tailored to meet the individual requirements of service users with complex postural needs.

A questionnaire, distributed to professionals working with specialist seating, was used to explore the current custom headrests and additive manufacturing. Twenty-six responses were received. The majority of respondents had used a custom head support and most agreed that additive manufacturing could be useful. However, concerns regarding additive manufacturing were around its validation, the benefits it brings and the resources it requires.

A workflow, based around current processes for custom contoured seating, was developed using additive manufacturing to produce custom head supports. The workflow utilised 3-dimensional scanning and computer aided design methods. Static mechanical testing against a commercial equivalent head support was conducted to assess the safety of an additive manufactured head support produced based on the developed workflow. The head support was shaped based on a 3D head scan and was designed to provide left sided lateral support. The head support was manufactured from nylon. An aluminium block was embedded into the head support during manufacturing to enable the head support to interface with standard wheelchair bracketry.

Mechanical testing followed the protocol set out in ISO 16840-3:*2014 Wheelchair seating, Part 3: Determination of static, impact and repetitive load strengths for postural support devices*. Two different set-ups were used. The first applied a posterior force to the inner rear surface of the head support. The second represented a lateral force to the inner surface of the left lateral support. The second test was performed on a commercial equivalent head support and was repeated on two different additive manufactured head supports with different manufacturing properties.
The posterior force resulted in failure of the supporting bracketry before the custom head support. A similar magnitude of forces was applied laterally for the custom and commercial head support. When the load was removed, the custom recovered to its original shape while the commercial sustained plastic deformation.

3-dimensional head scans of 15 volunteers were compared using a mixture of 2D and 3D analysis tools to compare the variation in head shape sizes. The results demonstrated variation in head width, length and the shape of the occipital/sub-occipital. These measures were chosen as important for designing a custom head support.

Discussion

With the introduction of the new medical device regulations coming into force in May 2020, there is an increased need for standardised work processes to produce customised devices. Additive manufacturing can provide standardised manufacturing workflows for producing custom parts. This will enable complex user needs to be met with custom parts which are both safe and effective.
The testing performed provides some assurance that additive manufacturing can produce parts that mechanically perform under similar magnitudes of forces as a commercial head support. Moreover the recovery of the additive manufacturing head support back to its original shape, once the load was removed, could prove advantageous compared to the current commercial head support. The design flexibility facilitated by utilising additive manufacturing can enable more bespoke head supports which can be shaped to the individual requirements of the end user.

Further mechanical cyclic load testing should assess the mechanical properties of additive manufacturing under different loading conditions. This can help develop safe design and manufacturing parameters which can be utilised by a clinical service to implement additive manufacturing in a safe and effective manner . Recommendations will be provided on the future use of 3D printing for seating accessories, such as head supports. This work has successfully demonstrated the use of an ISO standard to inform the evaluation .

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B. A low-cost cushion for management of pressure ulcers

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Summary
A planar foam cushion with a hole cut in the area coinciding with a pressure ulcer provides excellent pressure relief compared to commercially available cushions and allows the user continued mobilisation. The cushion is low-cost and can be customised and issued in a single appointment.

Aims & Objectives
A pressure ulcer is usually located over an area of sustained high interface pressure, such as a bony prominence (1, 2). A method was investigated of cutting a hole in a simple foam cushion corresponding to an area of high interface pressure. The method aims to reduce or eliminate pressures over a pressure ulcer, allowing the wheelchair user to continue sitting with reduced risk to the affected area.

Background
A wheelchair user presented with a pressure ulcer over an ischial tuberosity from sitting on a commercially available cushion issued by the wheelchair service. Pressure mapping confirmed the presence of high interface pressure in this area. In order to find a suitable alternative product a healthy volunteer was pressure mapped on a range of cushions while sitting with an oblique pelvic position to replicate a high localised pressure over one ischial tuberosity. Published studies (1-4) have shown that some cushions perform better than others. A similar result was found in this study, but no cushion was able to acceptably reduce pressure in the at-risk area. However, it was found that a simple foam cushion with a hole cut into it at the location of the ischial tuberosity was able almost completely to eliminate pressure in that area.

Technique
A foam cushion made of 2” of CMHR 65 topped by 2” CMHR 40 is cut to match the size of the client’s current cushion. The client is pressure mapped while sitting on the foam cushion. A BodiTrak (Vista Medical) pressure mat was used in this study. The location of the high-pressure area is noted on a laptop display. The client is then hoisted from the cushion ensuring that the pressure mat is not accidentally moved in the process. The high-pressure area is located again manually, using the display as a guide and marked on the foam with a felt tip pen. A hole is then cut through the entire thickness of the cushion using a sharp knife and a Bosch foam cutter. When the client is placed back on the cushion the area where the hole is cut will show much reduced pressure. The hole may be modified slightly if it does not satisfactorily capture the entire area at risk. The cover from the original cushion can be used if it is loose enough to drape into the hole, or a custom cover can be made if necessary. A final check of the pressure is done with the cover on.

Results
Experience to date is that clients are able to use their wheelchairs for longer periods than when using their previous cushions while the pressure ulcer heals, due to the affected area being largely

free of interface pressure. One client has now used his cushion for three years with no recurrence of the pressure ulcer.

Discussion

This method has been used for three wheelchair users, all with different diagnoses, but all with high pressure over one ischial tuberosity. The advantages are that a cushion of this type is very low cost (under £10) and that it can be prepared in advance, then pressure mapped, modified and handed over at the same appointment.

While clients feel that they can use their wheelchairs for longer than would otherwise be the case, they are always cautioned to follow the advice of their tissue viability nurse or district nurse if the pressure ulcer is being actively treated.

Investigation may be needed to determine if transferring the weight to surrounding intact tissues creates a risk to the microcirculation and lymphatic drainage of the affected area compared to the usual advice of frequent weight shifts and the use of other pressure relieving interventions such as alternating pressure cushions (5, 6).

Further development of this technique could explore the efficacy of different density foams or shaping the cushion such as with a ramp. A custom carved foam cushion may also be suitable for further modification by the addition of a hole in the foam under an at-risk prominence such as an ischial tuberosity, coccyx or greater trochanter.

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