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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