Luedtke et al. Fluids and Barriers of the CNS 2015, 12(Suppl 1):P29
http://www.fluidsbarrierscns.com/content/12/S1/P29

FLUIDS AND BARRIERS OF THE CNS

POSTER PRESENTATION Open Access

Clinically relevant skull models and optical measurement method to evaluate programmable hydrocephalus valve tool kit usability

MA Luedtke[1*], AJ Dextradeur[1], TB Boden Jr[1], J Mowry[1], JV Pattisapu[1], JT Megerian[2]

From Hydrocephalus 2015
Banff, Canada. 18-21 September 2015

Introduction

Five simulated skull models were created to simulate typical clinical conditions experienced while programming implanted adjustable ventriculoperitoneal hydrocephalus shunt valves. These models were created with physician feedback and evaluated by 13 health care professionals. Based on tactile evaluations and qualitative feedback, three models were selected as most clinically relevant. An optical measurement and valve setting method were developed to characterize programming tool movements during valve programming procedure and usability testing that evaluated over 50 health care professionals that program hydrocephalus valves.

Methods

The skull models used a variety of synthetic tissues and thicknesses simulating a 3mm scalp thickness protruding valve model (such as younger or older patients with thin skin), a 7mm scalp thickness model (that characterizes 'average' patients) and a 10mm thick model (simulating post-surgical edema or tissue scarring over a valve implanted for years). Different colors of ultraviolet fluorescent invisible ink markers were used to draw dot pairs relative to the valve center. Precision drilled tool kits (precision machined pairs of holes) were developed to characterize angular offset in addition to actual offset from valve center. Models were covered in plastic wrap enabling the same models to be reused throughout usability studies minimizing error. Various cameras were used (video and still) with visible and ultraviolet light photography throughout usability testing.

Results

The printed grid overlays were on average 0.05mm +/- 0.35 mm offset compared to the drawing; The machined toolset hole centers were on average -0.03mm +/- 0.40 mm offset compared to the drawing; The markers dots were on average 0.15mm +/- 0.30 mm offset compared to the drawing; The valve center was on average 0.43mm +/- 0.22mm offset from the printed grid overlay and had a difference in angle of -0.26 +/- 1.37 degrees from the actual position of the valve. Real time valve setting was enabled with an endoscope placed underneath the programmable valve.

Conclusions

It is very important to accurately characterize human factors while developing medical devices. Clinically relevant models and these measurement methods enabled characterization of programmable hydrocephalus valve tool kit usability.

Authors' details
[1]Codman Neuro, Raynham, MA, USA. [2]Avanir Pharmaceuticals, Aliso Viejo, CA, USA.

Published: 18 September 2015

References

1. The 5th Chinese Neuro Trauma Forum - The South Neurosurgery Forum: 2013, (Guangzhou, China) Combined meeting podium presentation - Intracranial Pressure (ICP) Monitoring, Guidelines, Present and Future Patient Care.
2. Opal – Medical Devices Summit: 2013, (Boston, MA) Best Practice in Postmarket Surveillance: Panel discussion - Meet the regulatory requirements in safety monitoring (Track adverse events among a growing set of information, Collect current, accurate data with minimal "noise" ensuring important signals are not missed, Maintain a central repository with up-to-date, accurate and comprehensive information, Postmarket Surveillance Abroad: Effective Data Management and Regulatory Compliance.

* Correspondence: mluedtk@its.jnj.com
[1]Codman Neuro, Raynham, MA, USA
Full list of author information is available at the end of the article

BioMed Central

© 2015 Luedtke et al. This is an Open Access article distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/4.0), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited. The Creative Commons Public Domain Dedication waiver (http://creativecommons.org/publicdomain/zero/1.0/) applies to the data made available in this article, unless otherwise stated.

3. North American Neuromodulation Society:Michael A Luedtke, Jeyakumar Subbaroyan, Jeffery A. Murphy Anthony DiUbaldi, J Thomas Megerian 2012, Poster 130 - Neuromodulation of Healthy Median Nerve by Means of Stimulation with a Transdermal Amplitude Modulated Signal (TAMS).
4. Melissa Chu, Nikiforos Kollias, Luedtke AMichael: **Confocal Scanning Laser Microscopy: Applications for Imaging Dynamic Processes in Skin In Vivo, Laser Scanning, Theory and Applications.**Chau-Chang Wang 2011, ISBN: 978-953-307-205-0, InTech, Book Chapter link: http://www.intechopen.com/articles/show/title/confocal-scanning-laser-microscopy-applications-for-imaging-dynamic-processes-in-skin-in-vivo.
5. Fan C, Luedtke M A, *et al*: **"Characterization and quantification of wound-induced hair follicle neogenesis using in vivo confocal scanning laser microscopy.".** *Skin Research and Technology* 2011, **17(4)**:387-397.
6. Luedtke M A, Papazoglou E, *et al*: **"Wavelength effects on contrast observed with reflectance in vivo confocal laser scanning microscopy.".** *Skin Research and Technology* 2009, **15(4)**:482-488.
7. Stamatas GN, Nikolovski J, Luedtke MA, Kollias N, Wiegand BC: **"Infant Skin Microstructure Assessed In Vivo Differs from Adult Skin in Organization and at the Cellular Level.".** *Pediatric Dermatology* 2009, 2009.
8. Spencer J M, Kurtz E S: **"Approaches to Document the Efficacy and Safety of Microdermabrasion Procedure.".** *Dermatologic Surgery* 2006, **32(11)**:1353-1357.

doi:10.1186/2045-8118-12-S1-P29
Cite this article as: Luedtke *et al.*: **Clinically relevant skull models and optical measurement method to evaluate programmable hydrocephalus valve tool kit usability.** *Fluids and Barriers of the CNS* 2015 **12**(Suppl 1):P29.

Submit your next manuscript to BioMed Central and take full advantage of:

- **Convenient online submission**
- **Thorough peer review**
- **No space constraints or color figure charges**
- **Immediate publication on acceptance**
- **Inclusion in PubMed, CAS, Scopus and Google Scholar**
- **Research which is freely available for redistribution**

Submit your manuscript at
www.biomedcentral.com/submit

BioMed Central