

Component Size Mismatch in Total Hip Arthroplasty: Identifying Risk Factors associated with this Surgical Never Event

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Abstract. This paper presents an evaluation into the causes of the surgical Never Event ‘*Component Size Mismatch*’ in total hip arthroplasty. A single-centre prospective service evaluation was conducted at specialist orthopaedic hospital in the UK. Hierarchical Task Analysis and Healthcare Failure Modes and Effects Analysis were used to analyse perioperative procedures and identify potential causes and interventions. Key vulnerabilities in the system included, but were not limited to, poor implant labelling, distractions, communication error, and a difficult working environment. Interventions to reduce this Never Event are proposed and could be tested in simulation environments.

Keywords. Arthroplasty; Component Size Mismatch; Never Event; Orthopaedic surgery.

1. Introduction

Despite having one of the highest incidence of surgical error (Neily et al, 2011) and litigation expenditure (Maed, 2014), orthopaedic surgery has received very little attention from the field of Human Factors and Ergonomics (HFE). Errors in orthopaedic surgery account for a significant proportion of surgical litigation claims in the UK, costing the NHS £490million between 2009-2013 (Maed, 2014). Many of these errors are deemed ‘Never Events’ by the NHS; defined as ‘*serious incidents which are wholly preventable, and have the potential to cause serious patient harm or death*’ (NHS, 2015). Compared to other surgical fields, the specific Never Event of ‘wrong implant/prosthesis’ has a high prevalence in orthopaedics, with 20 reported cases occurring in 2014/15 (NHS, 2015). The wrong implant/prosthesis occurs when, ‘*the implant/prosthesis placed in the patient is other than that specified in the surgical plan either prior to or during the procedure and the incident is detected at any time after the implant/prosthesis is placed in the patient*’ (NHS, 2015). One area where this problem has been identified as a significant risk is during total hip arthroplasty, where components of the hip prosthesis are mismatched according to size, known as Component Size Mismatch (CSM; Whittaker, 2014).

Total hip arthroplasty is a surgical procedure which involves the replacement of the hip joint with a prosthesis consisting of four main components (Figure 1). The acetabular cup, liner, and femoral head must all be matched for size to achieve faultless functioning of the prosthesis. If incorrectly matched the hip replacement can cause the patient unnecessary pain, poor function, additional operations, and increased risk of mortality (revision hip and knee surgery has a mortality rate of up to 2.5%) (NJR, 2012).

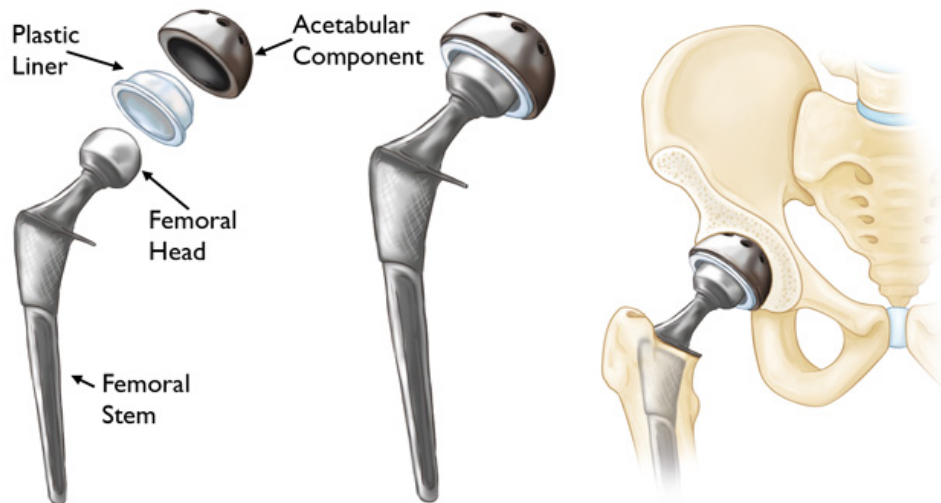


Figure 1. Total hip replacement (AAOS, 2015)

Data analysed from 1200 failed 'metal on metal' implants retrieved from 38 UK hospitals (2008-2013) found that 11 (0.92%) showed signs of CSM (Whittaker et al, 2014). Furthermore, the 2013 National Joint Registry (NJR) found that 62 out of 9676 (0.64%) revisions had taken place due to CSM of the head-acetabular socket (NJR, 2013). Recent advances in hip arthroplasty design and a greater focus on modularity in hip systems suggests that this prevalence may increase, and due to low detection rates the prevalence may be significantly higher than stated (Whittaker et al, 2014). There were 76,274 primary hip replacements in 2013, (increasing annually; NJR, 2013), so this problem presents a serious risk for patient safety, the NHS budget, and the reputations of hospitals, manufacturers, and surgeons. As far as we know, there have been no attempts to address the causes of CSM from an HFE perspective. This service evaluation aimed to evaluate and identify causes of CSM and propose interventions,

2. Methods

A qualitative prospective single-centre service evaluation was conducted using observations in the perioperative stages (preoperative, intraoperative, and postoperative) of 3 cases of total hip arthroplasty. A high-level Hierarchical Task Analysis (HTA) was used to map the perioperative system processes from the observations and discussions with Subject Matter Experts (SMEs). The HTA was used to conduct a Healthcare Failure Mode and Effects Analysis (HFMEA; DeRosier, 2002) to assess risk factors associated with CSM and develop potential interventions. Photographs of implants and packaging were collected from several manufacturers and analysed heuristically against current standards, guidelines, and literature.

Six participants were recruited as SMEs using purposive sampling based on their experience and roles within the procedure. They included two hip implant sales representatives (reps) with a client base of 36 hospitals bringing experience of working with a wide range of teams, and different types of organisational climates. Hip implant sales reps play a key role in training surgeons and staff to use the implants, and are often responsible for guiding the surgeon throughout the implantation process. Clinical staff included one orthopaedic consultant and orthopaedic registrar (combined experience of approx. 4000 operations), and one patient safety consultant with previous experience in reducing surgical error in obstetrics. The Stores manager (over 20 years of experience) was recruited to contribute in-depth knowledge of the procurement process of component selection, the preoperative preparation period, and the postoperative recording, reordering and management of implants.

Three total hip arthroplasty were observed with field notes recorded individually for each case by EP and the patient safety consultant; these were then collated for the development of the HTA and HFMEA. Photographs of the operating room (OR) and implant trolleys were taken to identify any environmental vulnerabilities/pressures. To reduce observer bias and ensure optimum patient safety, the theatre staff and practicing surgeons were not disturbed during the procedure. Two Multidisciplinary Team Meetings (MDTs) were also observed to understand the preoperative planning stage.

3. Results

The HTA (Figures 2 and 4) presents the key goals and tasks involved in component selection during the pre and intra-operative stages of total hip arthroplasty, and the recording and documentation of component sizes during the post-operative stage. The overall goal (0) was *Component Selection and Implantation*, with 4 sub-goals/stages: 1: *Ordering of implant*, 2: *OR prep*, 3: *Intra OP*, and 4: *Post OP*. Of these 4 sub goals/stages, the HFMEA discussions identified that whilst stages 1, 2, and 4 all had tasks which could lead to errors, the errors were not relevant to CSM, or were too undetectable or infrequent to warrant further HFMEA analysis. Only stage 3(during the Intra OP tasks) included errors specific to CSM.

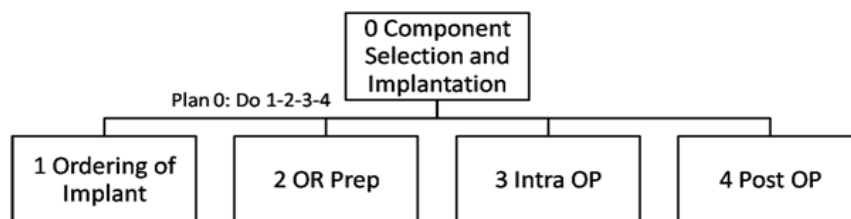
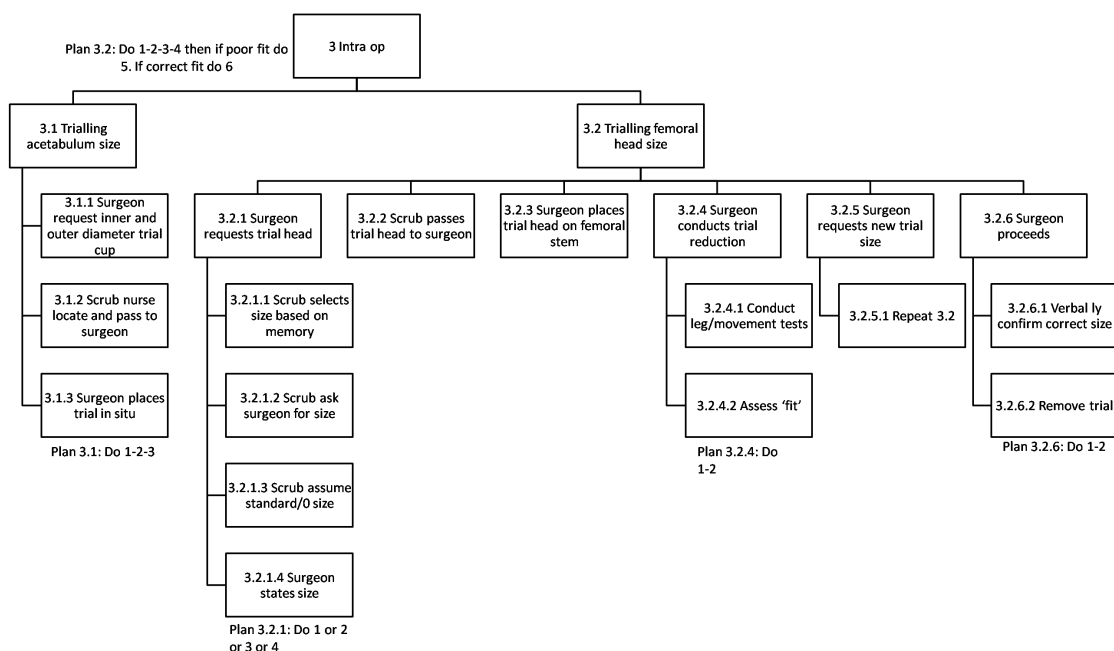


Figure 2.Highest level of HTA, showing four main stages of process.

Evaluation of the packaging for implants from 4 manufacturers found inconsistencies in the sizes of the text communicating the component sizes (Figure 3), with a range of 4mm between manufacturers, demonstrating a lack of standardisation.



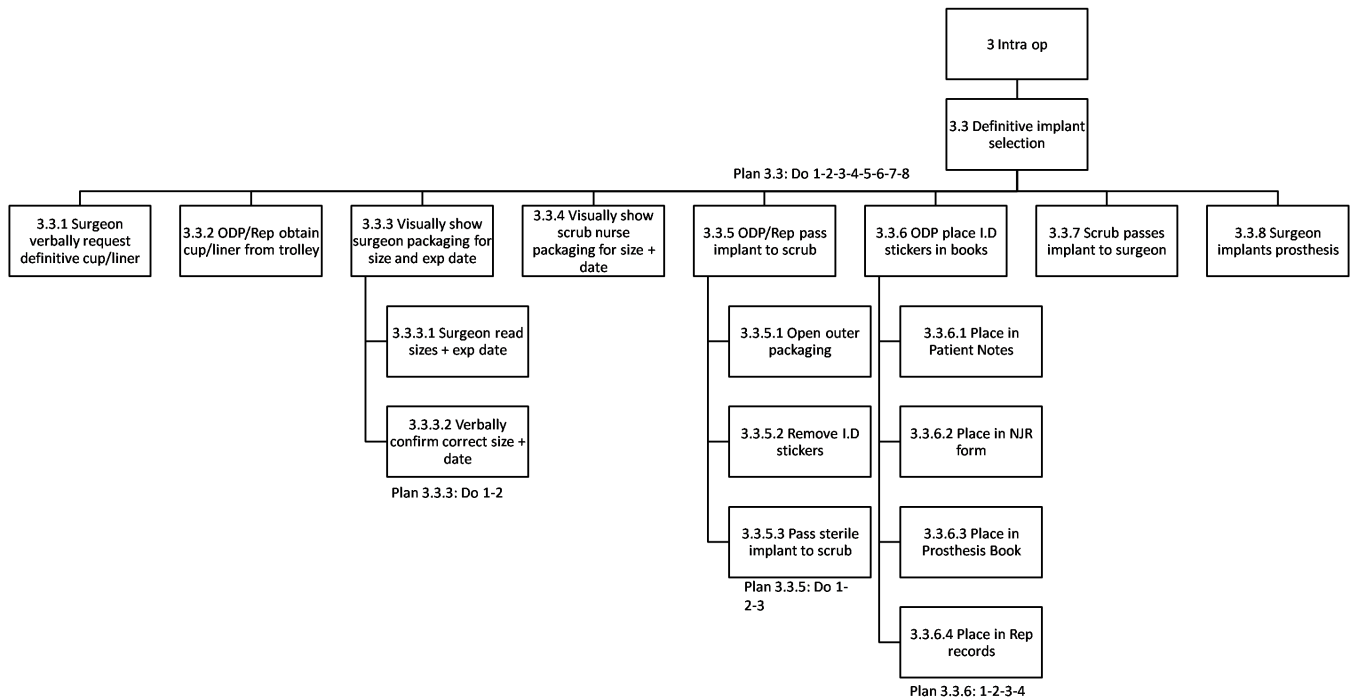


Figure 3. Examples of implant labelling from two manufacturers (manufacturer information removed)



Figure 4. Stage 3 of the HTA - Trialling acetabulum size, femoral stem head size, and Definitive implant selection.

The luminance under the lighting of the laminar flow canopy (used to filter air) appeared to be higher than the rest of the OR, resulting in a high contrast between areas (Figure 5). As the visual check of the implant size by the surgeon must be conducted outside of the laminar flow canopy in order to reduce infections, this difference in contrast has the potential to significantly reduce visual acuity (Foxwell and Stevens, 1955). The size of the sterile surgical flow canopy may require the surgeon to read text on the packaging from a distance of approximately 1.75m, and the HFMEA output raised reading labels from a distance as a potential cause to CSM, with label text size being too small to cater to this.



Figure 5. Example of luminance contrast within the OR.

ORs in the UK use a white board to record information. Observations found that the white board was an integral tool for temporary record keeping; it was used to document information including use (and number) of swabs, blades, and also patient allergies. However component sizes were not documented here and as the duration between trial selection and definitive implantation can be up to three hours the lack of written recording appeared to create a dependency (or single failure point) on staff memory.

Both the observations and HFMEA data found that communication within the OR is difficult and may contribute to CSM. The noise in an orthopaedic OR is often high due to electric or pneumatic power tools such as saws and drills, and music being played at high volumes. Additionally, staff are wearing surgical masks or 'space-suits' so their voices may be muffled and lips unreadable.

The HFMEA data found that distractions within the OR are frequent and may cause CSM. The observations also confirmed this, with an anaesthetist playing games on a smartphone, theatre staff taking phone calls, and a continuous flow of non-clinical conversation during component selection. Poorly organised implant trolleys could also contribute to CSM and observations noted that components were frequently placed in incorrect sections on implant trolleys. Finally, cognitive overload, fatigue, and lack of training/familiarisation with new/rarely used kits and equipment all appeared as potential CSM causes in the HFMEA.

4. Discussion and Conclusion

By conducting an HMFEA risk assessment this evaluation found that the processes involved in component selection during total hip arthroplasty contain many avenues for CSM to occur, but that these avenues are isolated within the intraoperative stage of the procedure. The evaluation supports much of the current research into surgical error, in that poor communication and labelling are key causes (Berman, 2004 & Catchpole et al, 2006). Reduction in CSM errors may be achieved by increasing the size of text on implant labels and creating standardised labels to eliminate inter-manufacturer variance.

A 'sterile cockpit' environment could also be introduced (Sumwalt, 1994) and recording the component sizes on the whiteboard would eliminate the dependency on memory and finally, it was suggested that training could be increased to improve familiarity with new/rarely used implant kits.

Overall, CSM is the result of system and process errors, and will continue to occur unless interventions are implemented. Future research could include cost-benefit analyses on the proposed interventions, and evaluation in simulated OR environments.

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