



Patient Safety Alert

Wrong selection of orthopaedic fracture fixation plates

11 February 2019

Alert reference number: NHS/PSA/D/2019/001

Directive Alert

A variety of fracture fixation plates are used in orthopaedic surgery including dynamic compression plates (DC plates) and reconstruction plates. These plates have different properties, importantly their rigidity and strength, and are not interchangeable. We were made aware of seven cases where reconstruction plates were used when the intention was to use DC plates. The plate failed in two cases, the first following a fall and the second following rehabilitation physiotherapy. Both patients required further surgery.

Recent changes in the design of some reconstruction plates has made it easier to confuse types of plates that were once more visually distinct. In addition, some organisations use an instrument tray system, where multiple plates and screws are contained on the same tray, and this is replenished and re-sterilised after each operation. This creates a risk of confusing the types of plates both at the point the tray is replenished and when a plate is selected for use. Where individual, sterilised packs for each different type of plate are used, the risk of wrong selection is likely to be lower but still exists, especially if both types of plates have been made ready for use.

Since only a minority of orthopaedic procedures use reconstruction plates, storing them separately and fetching and opening them only when specifically required provides a stronger barrier to inadvertent wrong selection.

Although the seven incidents mentioned above were found by one organisation following a systematic review of patient records after the index cases occurred, the cases involved different surgeons, scrub teams and theatres and all the processes/procedures used were similar to those in many other organisations. The British Orthopaedic Association is concerned that other organisations may have inadvertently used the wrong type of fixation plate, putting patients at risk until their fractures have fully healed and potentially requiring them to undergo corrective treatment.

Actions

Who: All organisations providing NHS funded-care where orthopaedic surgery is undertaken to repair fractures

When: To commence immediately and actions completed by 10 May 2019

-  Identify a clinical lead within orthopaedics to prepare an action plan in response to this alert.
-  Identify all patients who have had a plate fitted since 01 February 2018 for treatment of long bone shaft fractures and undertake a retrospective review of patient X-rays to ensure the correct plate was fitted to stabilise shaft fractures of the humerus, forearm, femur or tibia (see Note A). If cases of unintended use of a reconstruction plate are identified:
 - a. agree an appropriate clinical plan of care
 - b. report each incident as a Never Event (see Note B).
-  Review processes within theatre and:
 - a. If continuing to use a tray system (see Note C), remove all reconstruction plates from this and purchase reconstruction plates as individual sterilised packs that are clearly identified, stored separately from DC plates, and opened only when needed.
 - b. If not using a tray system, ensure reconstruction plates in individual sterilised packs are clearly identified, stored separately from DC plates and opened only when needed.
 - c. Reflect any change in practice in the Local Safety Standard for Invasive Procedures (LocSIPP)¹ for the prevention of wrong implant/prothesis.
-  Communicate the key messages in this alert and your organisation's plan for managing those risks to all relevant medical, nursing and theatre staff.

Alert reference number: NHS/PSA/D/2019/001

Technical notes

Patient safety incident reporting

A review of the National Reporting and Learning System (NRLS) only identified the seven cases from the organisation concerned. However, it is believed that other organisations may not have identified the same error and as a result the issue could be under reported.

Notes:

- A. The list of fracture types and the time period is based on BOA's opinion of the fractures for which plate confusion could have clinical consequence for the patient.
- B. For details of reporting incidents as Never Events and undertaking Serious Incident investigation(s), see the Never Events list,² Duty of Candour guidance³ and Serious Incident framework.⁴ Note the advice in the Serious Incident framework as to when multiple incidents may be investigated within a single multi-incident investigation.
- C. The Medicines and Healthcare products Regulatory Agency (MHRA) has confirmed that manufacturers of orthopaedic plates must indicate if their products are single-use or reusable and CE mark them accordingly. For reusable devices, manufacturers must provide validated instructions for the decontamination and sterilisation of their product. The MHRA's guidance, Single-use medical devices: implications and consequences of reuse,⁵ provides more information.

References

1. National Safety Standards for Invasive Procedures, NHS England - <https://www.england.nhs.uk/wp-content/uploads/2015/09/natslips-safety-standards.pdf>
2. Never Events policy and framework, NHS Improvement - https://improvement.nhs.uk/documents/2265/Revised_Never_Events_policy_and_framework_FINAL.pdf
3. Serious Incident framework, NHS Improvement - <https://improvement.nhs.uk/resources/serious-incident-framework/>
4. Duty of Candour, CQC - <https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour>
5. Single-use medical devices: implications and consequences of reuse, MHRA – <https://www.gov.uk/government/publications/single-use-medical-devices-implications-and-consequences-of-re-use>

Stakeholder engagement

- British Orthopaedic Association
- Public Health England
- National Patient Safety Response Advisory Panel (for a list of members and organisations represented on the panel, see improvement.nhs.uk/resources/patient-safety-alerts/)

Advice for Central Alerting System officers and risk managers

This alert asks for a systematic approach to deciding how your organisation ensures that the correct type of fracture fixation plate is used in orthopaedic surgery to manage fractures. The approach needs co-ordinated implementation, not separate action by individual teams or departments. If you are unsure who should co-ordinate implementation of this alert, your clinical director for surgery or lead clinician for orthopaedic surgery will be able to identify the key individuals.

Acknowledgement

We are grateful to the trust that considered the potential for wider errors after identifying two cases and undertook such a comprehensive review of past cases. This diligence was instrumental in identifying the potential for national action to protect other patients who may have been affected elsewhere.