A unique case of a radius shaft fracture with proximal radio-ulnar joint dislocation

S Maqungo MBChB(Natal), FCOrtho(SA), MMed(UCT)
Consultant, Orthopaedic Trauma Surgeon
W Nkomo MBChB(UCT)
Medical Officer
Orthopaedic Trauma Service, Groote Schuur Hospital, University of Cape Town, Cape Town

Correspondence:
Dr S Maqungo
4 Granula Place
7441 Sunset Beach
E-mail: sithombo@msn.com
Tel: +27 (0) 21 4045108
Fax: 0866922718

Abstract

We present a previously undescribed lesion of a fractured proximal radius associated with a proximal radio-ulnar joint dislocation. Compression plating was performed via the Thompson approach and closed reduction of the proximal radio-ulnar joint (PRUJ) was attained. At one-year follow-up he had united fully and regained full use of his arm. Clinicians need to be aware of this possible variation when confronted with proximal radius fracture.

Key words: Galeazzi fracture, proximal radio-ulnar joint dislocation, Monteggia fracture

Introduction

Displaced diaphyseal forearm fractures in adults associated with dislocation of either the proximal or distal radio-ulnar joints are inherently unstable, and plate fixation plus joint reduction of these injuries is the current gold standard. These injury combinations are respectively known by their eponymous names: Monteggia and Galeazzi fractures[1-3]

We present a unique case of a fractured proximal radius with associated proximal radio-ulnar joint dislocation. To our knowledge this injury pattern has not been described before.

Ethics approval was obtained from our institution and the patient consented to the study.

Case summary

We treated a 21-year-old male patient who was involved in a motor vehicle accident as a driver. He sustained blunt chest trauma with rib fractures but no head or intra-abdominal injuries. His right forearm was neurovascularly intact and he had no open wounds. He had no tenderness over the distal radio-ulnar joint so an Essex-Lopresti lesion was excluded.[4]

Radiographs (*Figures 1a and 1b*) revealed a displaced transverse fracture in the proximal third of the right radius with an associated posterior dislocation of the right proximal radio-ulnar joint (PRUJ).

Compression plating via the Thompson approach was performed and closed reduction of the PRUJ was attained; this was stable throughout the forearm and elbow range of movement arc.[5] The elbow joint was stable with no apparent ligament injury.

At one-year follow-up he had united fully and had a full range of movement of the forearm and elbow (*Figures 2a and 2b*). The calcification noted at the proximal aspect of the forearm may represent localised injury to the interosseous membrane but this patient did not have an Essex-Lopresti injury clinically.

Compression plating via the Thompson approach was performed and closed reduction of the PRUJ was attained

Figure 1a and b. Anteroposterior and lateral radiograph showing a proximal radius fracture and dislocation of the proximal radio-ulnar joint

At one-year follow-up he had united fully and had a full range of movement of the forearm and elbow

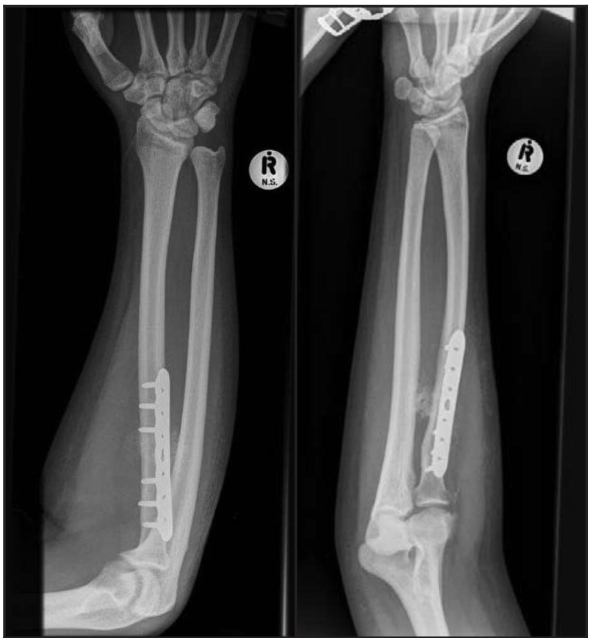

Figure 2a and b. Anteroposterior and lateral radiograph of the forearm at one-year follow-up showing a well-united fracture

Conclusion

Missed PRUJ dislocations may result in disabling complications such as limited forearm and elbow range of movement, chronic pain and chronic PRUJ instability. A vigilant eye for dislocation of both the proximal and distal radio-ulnar joints dislocation should be maintained when dealing with displaced diaphyseal radius fractures.

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The shelf life of sterile medical devices

TA du Plessis, MSc(Physics), DSc(Chem)
Gammatron (Pty) Ltd, Modimolle, Limpopo

Reprint requests:
Dr TA du Plessis
PO Box 1271
Kokanje 0515
Email: gammatron@mweb.co.za

Abstract

The issues of the shelf life of sterile medical devices and the concept of end-product sterility testing of a sample of devices to prove the sterility of a batch of sterile devices are discussed against the background of the probabilistic approach to sterility and sterilisation. The particular role that the sterilisation technique and the packaging materials used play in maintaining sterility are discussed against the background that sterility and the maintenance thereof is event- and not time-related, and the implications thereof on the shelf life of sterile medical devices.

Key words: sterile medical devices, sterility maintenance, shelf life

Introduction

Manufacturers of sterile medical devices often give an expiry ('use by') date on the package, generally five years from the date of sterilisation. The question arises as to what limits the duration of the sterility of such devices? Why is the shelf life limited by manufacturers, and if so, why specifically five years and not three or ten years – probably relating to the accelerated or real-time testing of the packaging material? This becomes particularly relevant in the case of medical implants such as prostheses. If the implant is specified by the manufacturer to have a shelf life of five years prior to implantation, how does this relate to the *in vivo* performance of the device? It should be clearly pointed out that in this discussion the emphasis is put on the sterility of the implant and not on the mechano-clinical performance of such a device.

In order to get perspective on this issue, it is necessary that we clearly understand the underlying principles of the particular sterilisation technique and the associated packaging of sterile medical devices.

The concepts of sterile, sterilisation and sterility assurance levels

In many authoritative books in the field of sterilisation, the concept sterile is referred to as a state completely free of any viable microorganisms, and sterilisation is defined as the process which will destroy all viable microorganisms.[1-3]

What limits the duration of the sterility of sterile medical devices?

These concepts are thus used in the *absolute* sense where no viable microorganisms exist.

However, an inherent problem is that it is *impossible in practice to prove either the complete absence or the destruction of these microorganisms*.[4] This will be discussed in more detail later.

The fact that the destruction of microorganisms through physical (radiation and steam) and chemical (ethylene oxide) sterilisation methods shows an *exponential dependence* on the various process parameters, clearly implies that the absence of microorganisms on a medical device following a properly validated sterilisation process can only be described in terms of a *probability function*.[4-5] This exponential nature of sterilisation means that, although the probability may reach a very low value, *it can never be lowered to a zero level in the absolute sense of the word*.[5-7]

This probabilistic approach to sterility leads to the concept of sterility levels – a view which no doubt may have little room in the 'classical' approach to sterility. Such a probabilistic approach also implies the existence of certain 'sterility assurance levels' (SALs) – a concept that plays an important role in this field and is being used to quantify the level or probability of sterility achieved through a certain sterilisation process.[8]

The SAL indicates the expected probability of finding a viable microorganism on a medical device after subjecting such a device to an acceptable and properly validated sterilisation process in which all process specifications are strictly adhered to, and is usually expressed as an exponential function – 10^{-n}.[6] The use of SALs improves the understanding of the efficacy of a sterilisation process and its practical significance.

Field of application as a determinant of the required Sterility Assurance Level (SAL)

The Association for the Advancement of Medical Instrumentation (AAMI) in the USA in the early seventies recognised that different SALs can be specified for medical devices, depending on the locality of their application.[9] In the ISO codes on sterilisation a similar distinction is made between two different medical device categories, depending on the intended field of application of such a device:

SAL 10^{-6}: surgically implanted devices
sterile fluid paths
other products transgressing natural tissue barriers;
implying that not more than one device in a *million* shall be non-sterile.

SAL 10^{-3}: topical products
mucosal devices
non-fluid path surfaces of sterile devices;
implying that not more than one device in a *thousand* shall be non-sterile.

With this approach, the contamination risk to the patient is the determining factor in selecting an SAL for a particular device. Those devices that are of an invasive nature will require a lower SAL than those that are non-invasive. Both categories will still be considered and classified as 'sterile' and appropriately labelled as such.

End-product sterility testing

The probabilistic approach to sterility and sterilisation has led to the concept and common practice of end-product sterility testing as proof of efficiency of a sterilisation process after completion. However, sterilisation is internationally recognised as an example of a process for which the efficacy cannot be verified by retrospective inspection and testing of the end product.[6] This implies that sterility testing of the end product cannot be applied to verify a SAL of smaller than about 10^{-2}, because the number of devices required as a representative sample for the sterility testing becomes both impractical and uneconomical. To perform end product sterility testing to uniquely 'prove' an SAL of 10^{-6} will require the sterility testing of one million devices. To further complicate matters, it is accepted that the inherent limitations of sterility testing typically leads to 'false positives' at a level of about 10^{-3}, which prevents end-product sterility testing to low SAL values.[10-11]

It clearly follows that end-product sterility testing of a few medical devices following sterilisation to 'demonstrate' or 'prove' that the entire batch is sterile, without a proper prior process validation, is without scientific foundation and can lead to erroneous conclusions with regard to the sterility of the batch as a whole.

However, it should be pointed out that the use of dosimeters (radiation) or biological indicators (steam and ethylene oxide) with a known accuracy and properly calibrated to monitor a properly validated sterilisation process, is completely acceptable and indeed essential, but they are employed to monitor the process parameters and not to prove the sterility of the resulting product.

The impact of sterilisation technique and packaging on the maintenance of sterility

Based on the basics of sterility and sterilisation, we return to our initial question on the shelf life of sterile medical devices – thus the maintenance of sterility prior to implantation. The sterilisation technique employed obviously plays a very important role on the nature and type of packaging that can be used.[12,13]

In the case of ethylene oxide gas sterilisation (EtO), the packaging material for both the primary and secondary packaging has to be selected to permit penetration by the sterilising gas to sterilise the devices, and its later removal at the end of the cycle. For this reason the polymer laminate packaging commonly used for radiation sterilisation cannot be used for gas sterilisation.

In the case of radiation sterilisation the device is hermetically sealed in double laminate pouches (polyethylene/polyester) – in general with a double seal and in the case of polymeric orthopaedic prostheses blanketed under ultra-pure nitrogen gas – the latter to protect the device or its polymeric components from radiation oxidative degradation during the radiation sterilisation cycle and subsequent storage. Radiation sterilisation has the advantage that the packaging integrity of these laminate pouches is particularly high and the author is not aware of any of such laminate pouches having failed during storage prior to use.

Radiation sterilisation has the advantage that the packaging integrity of these laminate pouches is particularly high

Sterility as a property of a medical device is recognised as event-related and not time-related

Provided a properly validated sterilisation process is used, and the integrity of the packaging is maintained, there is no reason to limit the shelf life of a sterile medical device – especially so in the case of radiation sterilisation. This clearly underlines the concept that sterility as a property of a medical device is recognised as event-related and not time-related. Should the packaging of a sterile medical device be compromised, it could lose its sterility directly after sterilisation. Similarly, if the packaging integrity is not compromised, the device will remain sterile.

The entire concept of the shelf life of medical devices is clearly still a topic that is hotly debated as follows from the international literature on the Internet, with the role of the packaging materials and the sterilisation techniques employed being the major points of discussion. Accelerated ageing of the packaging materials and seals that are generally used by manufacturers to set the shelf life are topics with their own inherent uncertainties.

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