The use of individually wrapped presterilized small orthopaedic implants increase operating time: a prospective experimental study

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Summary

Objective There have been concerns about the potential increases in operating time associated with the use of individually wrapped presterilized small orthopaedic implants compared with our traditional method of screw banks. We set out to quantify this theory.

Design Prospective experimental study.

Setting Theatre.

Participants Orthopaedic Surgical Trainees and Theatre Scrub team.

Main outcome measure The time taken to complete the operation.

Results The use of prepacked and sterilized implants added 2 min 56 s to the use of a bank with a full complement of normal screws that required tapping and 3 min 58 s if self-tapping screws were used ($P < 0.001$).

Conclusion Using individually wrapped presterilized small orthopaedic implants increases operating time.

Introduction

Implants form an integral part of orthopaedic surgery and fracture fixation. Traditionally standard fixation sets are utilized in combination with banks of a selection of compatible (single use/implantable) plates and screws which are sterilized at central/local decontamination units. Unused items are reprocessed as reusable items.[1]

Currently there is a move away from such banks of implants, and a move towards the use of individually wrapped presterilized small orthopaedic implants. The precedent has been set by the Australian Standard 4187[2] in 1997 and followed by the Scottish Health Department in 2007.[3]

Such a move may have a number of advantages: the use of prepackaged itemized implants allows appropriate tracking of items by identification of manufacturer's batch or lot number recorded in the patient's notes.[1] The Scottish Health Department recognized inadequacies in the re-processing of unused implants due to reports of acquired organic and chemical residues during re-sterilization.[3] Added suggested benefits of individually packaged screws, therefore, may

Table 1
Description of the three simulated scenarios

Scenario	*Measured time (contributing time to overall procedure of scenario)*
Use of small AO fragment set with full complement of screws	Request of specific plate/screw, identification, verification of length (of screw), to handing over of plate or screw (on screwdriver) to surgeon when tapping completed
Use of small AO fragment set with full complement of self-tapping screws	Request of specific plate/screw, identification, verification of length (of screws), to handing over of plate or screw (on screwdriver) to surgeon (no tapping needed)
Use of small AO fragment set with use of individually prepacked and sterilized self-tapping plate and screws	Request of specific plate/screw, selection of correct package from implant tray, verification by surgeon of correct implant (plate or screw), opening of package and retrieval of sterile implant by scrub nurse, to handing over of plate or screw (on screwdriver) to surgeon

include a decrease in infection rate, decreased risk of inflammatory reaction to implants and avoidance of 'weakening' of implants due to repeated sterilization.[4]

However, the use of individually sterilized prepackaged implants has already raised concern among orthopaedic surgeons in view of perceived increases in operation times and the lack of clinical evidence with regard to reducing harm to the patient.[5] We have quantified such potential increases in operating time using simulated scenarios.

Methods

The contribution to the overall time needed for fixation of a long bone with a 6-Hole 3.5 mm DCP plate with six 3.5 mm cortical screws by each of three different instrumentation scenarios (Table 1) was measured. Four orthopaedic trainees carried out each of the simulated scenarios with the help of four different orthopaedic-trained scrub nurses and four different 'runners'. For all scenarios a 6-Hole 3.5 mm DCP plate was the requested plate implant. With regard to the selection of the six screws, a prewritten varied selection of screws (prepared by an independent surgeon) varying from 16 to 20 mm was given to the surgeon; the prewritten selection was not made available to the scrub nurse or runner in order to simulate a normal operating situation. For Scenario A, a predrilled dry-bone was used each time, so that the added time for tapping could be measured. With regard to Scenario C, implant trays are usually kept outside theatre, but the appropriate trays are brought just inside theatre during a procedure to optimize time of implant retrieval. A distance of 4 m (scrub nurse to implant tray) was selected, which was the approximate distance in a normal clinical scenario as measured in our theatres. Time (seconds) was measured using a digital stopwatch.

Statistical analysis was undertaken using SPSS 15.0 (2006)®, and the one-sided paired *t*-test was used to compare means between the groups, as our clinical experience was very suggestive of longer times for Scenario A compared with B, and Scenario C compared with both A and B. Statistical significance was taken at $P < 0.05$.

Results

The individual contributing times for the three scenarios for each of the four surgeons is shown in Table 2, as well as means ± SD (s). Scenario C added the longest time compared with both the more common Scenario A and Scenario B ($P < 0.001$ for both); Scenario A was quicker than B ($P < 0.001$). The use of prepacked and sterilized implants added 2 min 56 s to the use of a set with a full complement of normal screws that

Table 2
Contributing time to overall simulated procedure for each scenario for each orthopaedic trainee, and mean (SD) for each scenario (seconds)

	Scenario A (seconds)	*Scenario B (seconds)*	*Scenario C (seconds)*
Surgeon 1	50.7	110.3	292.6
Surgeon 2	52.3	106.5	284.3
Surgeon 3	49.3	112.3	303.2
Surgeon 4	54.5	122.1	276.8
Mean (SD) (seconds)	51.7 (2.2)	112.8 (6.7)	289.2 (11.3)

required tapping (more common scenario in our theatres) and 3 min 58 s if self-tapping screws were used.

Discussion

Surgical implants should be traceable and their sterility guaranteed for patient safety. General, cardiac, vascular surgical implantable items have been purchased presterilized and the batch number has been recorded in a patient's notes at the time of surgery.[1] Various orthopaedic prostheses such as joint replacements are already provided to us in such a fashion,[5] allowing the tracking of manufacturer or sterilization issues from production to patient.[2]

A move away from the traditional use of banks of small fixation implants (plates and screws) sterilized and re-processed at central/local decontamination units may have its merits. Legally, many such implants are classified as 'single use', according to the manufacturers, and should not be re-used following any contact with a patient. Infection and contamination of such sets during re-processing has been documented with inadequate cleaning resulting in retained or acquired organic and chemical residues on implants during re-processing. In addition, re-processed steel implants may cause inflammatory reactions in comparison to the use of pristine devices as a result of surface oxidation and weakening caused by the repeated processing.[1–3] Furthermore, any issues of failure of sterilization and metallurgical faults of presterilized individually wrapped items when identified by the manufacturer may be more easily dealt in view of easier traceability.[5]

We have confirmed previous concerns[5] that the use of individually wrapped presterilized small orthopaedic implants can add to operating time. Certainly, such delays have to be taken into account especially when implants are used in complex fracture fixation, especially when the use of a tourniquet may impose time constraints. Although we do not feel that the extent of the added operative time is a significant one, measures should be taken to minimize this. In our practice, such implants are stacked in an ordered manner (by ascending screw size and type) in individual trays that can be rolled as near to their point of need, therefore minimizing the time of retrieval. All theatre should be adequately trained to easily identify and retrieve the requested implant.

One may also argue that such delays may add to the time the wound is exposed and this may offset any benefits of the use of such implants with regard to reducing infection rates. Although we do not feel that such delays are of significance, we have to consider the evidence that the use of individually packaged screws is indeed a potential risk factor for post operative infection both because of the contamination of the packet exterior due to prolonged storage and the physical act of opening the packets in the vicinity of the operative field, as has been previously documented.[4,6]

The effects of the use of such implants on operative costs and theatre efficiency must also be taken into account. In our practice, the use of individually wrapped implants is more expensive than the use of implants from traditional banks. However, this compensates by the reduced costs of sterilization. For our simulated scenario of a 6-Hole DCP plate with six screws, the individually prepackaged implants would cost £4.32 (total) more, but this is well offset by the £36.18 added cost for sterilization of the implant bank. Although the added operating time may be too small to have any significant impact on the complex overall 'trauma list' efficiency and running costs, such delays should be taken into account as part of the Productive Operating Theatre Agenda.[7]

In conclusion, we have confirmed the concern for possible time delays with the move towards

the use of individually packaged presterilized small orthopaedic implants. This should be taken into account, in addition to potential effects on patient risks, and theatre costs and efficiency.

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