

The OSCAR 3 ultrasonic arthroplasty revision instrument for removing bone cement during prosthetic joint revision

Medtech innovation briefing

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Summary

The OSCAR 3 ultrasonic arthroplasty revision instrument is a tool to aid the removal of cement during operations to revise replacement joints. It would be used by orthopaedic surgeons, in combination with standard mechanical methods of cement removal.

Effectiveness	Adverse events and safety
<ul style="list-style-type: none">• Three clinical studies reporting on the use of the OSCAR were identified: 1 retrospective case series (n=17) and 2 case reports (both n=1). Also, 2 laboratory studies were identified where the safety of the device was investigated.• The retrospective case series reviewed 17 hip revision cases, 13 of which were performed with the OSCAR and 3 with standard care (1 case was excluded as cementless revision.)• The case series found that, compared with expected osteotomy length from pre-operative planning, the OSCAR was associated with significantly shorter osteotomies (mean reduction 7 cm, p=0.001) and shorter replacement prostheses (in 8/13 cases, p=0.006). There was no statistically significant reduction in osteotomy or prosthesis length in the standard care group compared with predicted results.• One case report described the successful removal of a large intrapelvic mass of cement from a woman aged 83 years having hip revision.• No efficacy studies were found for elbow, knee or shoulder revisions.	<ul style="list-style-type: none">• A single case report described an incident of thermal necrosis of bone caused by the OSCAR during elbow revision, resulting in post-operational radial nerve palsy and pathological fracture of the humerus.• No reports of adverse events using the OSCAR were found for shoulder, knee or hip revisions.

Cost and resource use	Technical factors
<ul style="list-style-type: none">• The 2014 costs of the OSCAR 3 include £22,550 for the generator, £4879 for the cement removal handset, £2466 for the cleaning system, and costs ranging from £103 to £154 for single-use probes and £108 to £346 for reusable probes. Annual maintenance charges also apply.• The OSCAR 3 system can be rented, with prices ranging from £886 for a single surgical procedure to £3309 for 1 month's use.• The use of the OSCAR 3 system would not be expected to impact on service provision before or after surgery.	<ul style="list-style-type: none">• One study found that high bone temperatures generated by the OSCAR in human bodies could be mitigated by using intermittent pulses of ultrasound and irrigating the area with chilled saline.• One measurement study showed that the release of potentially toxic chemicals during cement vaporisation with the OSCAR was well below occupational exposure standards.• One qualitative study using ex vivo femur samples found less bone loss with the OSCAR compared with cement removal by curettage. The researchers also attributed the presence of microscopic cracks in the bone to the use of ultrasound.

Introduction

In the UK, it is estimated that 8.5 million people are affected by joint pain caused by osteoarthritis (loss of cartilage and related degradation of surrounding bone), with around 400,000 people having rheumatoid arthritis (see NICE's technology appraisal guidance on [total hip replacement and resurfacing arthroplasty](#)). People with severe or ongoing pain, joint stiffness and resultant loss of quality of life may be referred for elective joint replacement, most commonly involving the hip or knee joint, and less commonly the elbow,

ankle, or shoulder joints (National Joint Registry 2013).

A variety of surgical techniques and prosthetic replacements are used in joint replacement surgery, and these may be fixed to the bone with or without the application of cement. Joint replacement surgery may involve total replacement of the joint or, alternatively, replacement of only the bone surface, known as resurfacing. The cement used for joint replacements is polymethylmethacrylate, to which an antibiotic is usually added to reduce the incidence of deep infections (National Joint Registry 2013). Cemented prostheses have the advantage of fixing the bone and prosthesis in place to allow quicker rehabilitation, and so they are preferred for older people (Rothman and Cohn 1990). The alternative option is to fix the prosthesis in place using cementless press-fit fixation. National data from 2012 shows the average age of people receiving cementless fixation was 65.2 years, whereas average age receiving cemented fixation was 73.1 years (National Joint Registry 2013). There is little evidence of superior outcomes using cementless fixation in the short- or longer-term (Abdulkarim et al. 2013).

In 2012, 76,448 hip replacements were done in the NHS in England, Wales, and Northern Ireland. Osteoarthritis was the underlying reason for 92% of hip replacements (National Joint Registry 2013), with the rest being for other indications such as fractured neck of femur due to falls (Moroni et al. 2014). Of all hip replacements in 2012, 33% were cemented, 43% were cementless, and the remainder used hybrid techniques or resurfacing procedures. Hip replacement hybrid techniques typically involve cementing of the femoral component only. In contrast, cement was used in 86% of the 90,842 knee replacements performed in 2012; most of these used high-viscosity polymethylmethacrylate cement loaded with antibiotics (National Joint Registry 2013).

Joint replacements may fail over time and need surgical revision. There were 10,040 revision hip replacements in 2012, most for aseptic loosening of the prosthesis causing unwanted prosthesis movement (44% of surgeries). Other indications included pain (25%), lysis (bone loss, 14%), dislocation or displacement (14%) and soft tissue reactions (15%), with fracture, infection, prosthesis wear, incorrect fittings or multiple causes listed as less common indications for hip revision. Cement was reapplied to 28% of femoral prostheses and 18% of acetabular prostheses. In the same period, there was 6009 knee revision procedures performed, again with aseptic loosening being the most common indication (48%) (National Joint Registry 2013).

An important element in the success of surgical revision of the hip, knee or other large joints is the safe and efficient removal of cement, where present, from the host bone

(Goldberg et al. 2007). Cement removal may be needed to detach well-fixed prostheses, and to allow for the insertion of longer or differently shaped prostheses. Traditional techniques for cement removal have included the use of drills, burrs, curettes and osteotomes. However, this mechanical removal can be difficult and time-consuming and carries the risk of bone perforation. To overcome some of these problems, the use of ultrasonic cement removal has been developed and this is reported to have the advantages of reducing surgery time and surgical complications (Goldberg et al. 2007).

Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the responsibility of healthcare professionals to check the regulatory status of any intended use of the technology in other indications and settings.

About the technology

The Orthosonics OSCAR 3 ultrasonic arthroplasty revision instrument helps the removal of polymethylmethacrylate bone cement during large joint revision procedures. The system uses ultrasound to soften the cement holding the implant in place. Bespoke probes are then deployed in sequence to collect and remove the softened cement from the host bone. The OSCAR 3 can also be used for cutting and removing bone in cementless press-fit prosthesis revision and when bone resection functionality is under development, but these functions are beyond the scope of this briefing.

The OSCAR 3 is the latest iteration of the OSCAR system. The first version of the technology was introduced to the UK between 1992 and 1993 and was analogue-based. This was superseded by the digital OSCAR II system which was phased in around 2000. The OSCAR 3 system was launched in 2009 and is described by the manufacturer as having enhanced digital components and increased efficiency compared with the OSCAR II.

CE marking

The OSCAR system was CE-marked as a Class IIb device to Orthosonics Ltd. in September 2002. The current certification for cemented and cementless arthroplasty including single-use probes is valid from February 2013 until February 2018.

Description

The OSCAR 3 consists of 3 main components:

- A portable, 2-channel ultrasound generator and control unit with illuminated liquid crystal display.
- A cement removal handset or an osteotome handset (for cementless revisions) connected via a cable encased in silicone rubber to either output channel of the generator. The osteotome handset produces reduced displacement amplitude and has a golden outer sleeve to differentiate it from the silver cement removal handset.
- A range of screw-threaded reusable or single-use probes and tools, which are attached to the appropriate handset using bespoke spanners. Cement removal probes have 5 mm threads and osteotome probes have 6 mm threads to ensure use with the correct handset.

The mains-powered ultrasound generator and control unit has 2 identical output channels, each operating at a specified frequency of 28 kilohertz and an output power of up to 150 Watts. Actual operating frequency ranges from 27.9 to 28.5 kilohertz depending on the resonant frequency of the attached handset. The generator automatically controls and adjusts delivered power in response to changing mechanical load during the cement removal procedure.

Probes can be single-use or reusable, and come in several shapes and sizes. Reusable bone cement removal tools, such as groover, scraper, piercer and acetabular probes, are included as part of the initial system. Optional additional tools include all single-use probes and:

- a slap hammer and single-use extraction probe to remove larger pieces of cement and the cement plug
- osteotome and hoe probes for cementless stem removal
- extension and reducer bars for reusable and single-use probes.

Probes are activated via a pushbutton hand switch on the main body of the handset or via an air-powered foot switch connected to a nozzle below the output socket. The probe is intended for intermittent operation (10 seconds on, 20 seconds off) with a maximum 'on time' of 30 seconds to avoid overheating. If the probe is operated for this maximum period,

it can be reactivated within seconds. A countdown timer starts when the handset is activated and an activation tone rises in pitch as the timer approaches zero. An alarm sounds if excessive force is applied to the handset. If the probe is pushed too deeply into the cement and allowed to remain in situ, the cement behind the tip can solidify and trap the probe. A special cement release mode must then be used to remove the probe.

Optional components include a wheeled trolley with probe attachment and foot switch storage, and a portable ultrasound cleaning system for reusable cement removal probes. After surgical use, the handset with the contaminated probe is connected to the system and inserted into a single-use cleaning cell. The probe is activated for a user-selectable 15- or 30-second cleaning cycle to remove traces of tissue and cement and can be repeated if necessary prior to normal hospital sterilising procedures.

Intended use

The OSCAR 3 is intended to be used for removing polymethylmethacrylate bone cement during joint revisions, and for cutting and removing bone in orthopaedic applications.

Setting and intended user

The OSCAR 3 is intended to be used in orthopaedic operating theatres by surgeons trained in standard orthopaedic surgical procedures and specifically trained in the use of ultrasonic surgical instruments.

Current NHS options

Current cement removal methods used during revision arthroplasty procedures comprise mechanical techniques using specifically designed hand instruments or pneumatic power tools. These are usually used in conjunction with the OSCAR 3.

NICE is aware of the following CE-marked device that appears to fulfil a similar function to the OSCAR 3:

- Ultra-Drive 3 Ultrasonic Revision System (Biomet Orthopedics).

Costs and use of the technology

The OSCAR 3 consists of several essential or optional elements, depending on the clinical procedure that is to be performed. The [NHS Supply Chain](#) catalogue lists 63 OSCAR products. The manufacturer of the OSCAR 3, Orthosonics, has provided a list of prices valid in 2014 which include (excluding VAT):

- OSCAR 3 generator: £22,549.79
- OSCAR 3 cement removal handset: £4879.11
- OSCAR 3 cleaning system: £2465.82
- OSCAR 3 reusable probes and tools: from £108.15 to £346.08 with an expected life of 6 to 9 months or 30 to 50 operations
- OSCAR 3 single-use probes and tools: from £103.00 to £154.50.

The OSCAR 3 system should be serviced annually. This includes visual checks of probes, handsets and cables; performance testing against system specifications; and medical standard electrical safety testing. The warranty cover for year 1 is free and is £3000 for year 2, rising to £6000 for year 6 onwards. The warranty covers any breakdown and an annual maintenance service.

The OSCAR 3 system is also available to rent directly from the manufacturer. Prices quoted by the manufacturer, which include reusable but not single-use tools or the cleaning system, are:

- single use – £885.80
- 1 week – £1449.21
- 2 weeks – £2595.60
- 3 weeks – £2866.49
- 1 month – £3309.39.

It is not possible to estimate the cost associated with alternative manual cement extraction techniques because of the wide range of practices and tools employed.

Likely place in therapy

The OSCAR 3 system would be used in the revision of replacement joints. Introduction of the OSCAR 3 would not be expected to significantly change NHS patient pathways before or after the revision operation.

Specialist commentator comments

One specialist commentator advised that cement extraction during large joint revision is currently done through combined use of the OSCAR system and mechanical means. The main role of the OSCAR is to remove the cement mantle from the intramedullary canal of the femur during total hip replacement revision, and the femur or tibia during total knee replacement revision. This can prevent the need for osteotomy, protect the bone by avoiding perforation or fracture and speed up the procedure.

Another specialist commentator advised that ultrasonic cement removers such as the OSCAR system have become standard tools for cement removal alongside mechanical instruments, and that the OSCAR is most useful during hip revision for the removal of well-fixed distal femoral cement and cement plugs distal to the prosthesis. The use of the OSCAR system reduces both the risk of femoral perforation and the need for femoral osteotomy compared with the use of mechanical instruments alone. It also allows for use of shorter femoral prostheses, thus preserving distal femoral bone.

A third specialist commentator uses OSCAR in combination with cement chisels, drills and powered burrs. OSCAR applications include removing cement from the bones of patients with osteoporosis, where the risk of perforating the femoral cortex is great, and in femora with a thin layer of cement and a sloping edge that will not engage a chisel. Its use reduces the incidence of extended trochanteric osteotomy. A lack of controlled trials of OSCAR in the evidence base may be explained by ethical concerns over conducting an osteotomy in a control patient when the use of OSCAR would make it unnecessary. In addition, patient outcomes with OSCAR can be very operator dependent, requiring skill and practice to be used effectively.

Equality considerations

NICE is committed to promoting equality and eliminating unlawful discrimination. We aim to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women
- eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief, in the way we produce our guidance (these are protected characteristics under the Equality Act 2010).

The OSCAR 3 is likely to be used primarily, but not exclusively, in older people because they are more likely to need large joint revisions involving cement removal. Older people are protected under the Equality Act (2010).

Patient and carer perspective

Quick recovery times and a rapid return to full mobility are key quality-of-life issues, especially for older people. Surgical techniques that involve less invasive or traumatic revision surgery might help their recovery.

Evidence review

Clinical and technical evidence

Five studies concerning the use of the OSCAR system for bone cement removal were identified. Two of these were laboratory studies and did not involve use of the device on living people. Three of the studies were related to clinical use of the technology: 1 retrospective case series (Fletcher et al. 2000), 1 case report (Smith and Eyres 1999) and 1 case report with an additional cadaveric study (Goldberg et al. 2005). One laboratory study used theatre air samples to investigate the environmental safety of the technology (Shewale and Briggs 2005). One laboratory study performed on ex vivo femur bone sections used the OSCAR system as a qualitative comparator to yttrium-aluminium-garnet laser irradiation (Birnbaum and Gutknecht 2010). Publication dates suggest that all of these studies used earlier versions of the OSCAR rather than the OSCAR 3, but as the core functionality of the device has not changed from previous versions, these studies were still considered to be relevant to this briefing.

The retrospective case series by Fletcher et al. (2000) investigated the potential for the first generation OSCAR system to preserve bone compared with mechanical cement

removal (by allowing for an altered surgical approach), which would result in shorter replacement prostheses. The theatre records of 16 hip revision operations were analysed. The preoperative radiographs were used to undertake 'sham planning', whereby the proposed osteotomy length and consequent prosthesis replacement using conventional cement removal were estimated. These estimations were compared with the actual osteotomy shortenings and prostheses used following cement removal with the OSCAR or by mechanical means. Significantly shorter osteotomies and prostheses were needed for patients who had cement removed with the OSCAR compared with the sham predictions. A summary of the study and results is reported in table 1.

The case report by Smith and Eyres (1999) described the removal of a large quantity of cement from the pelvic cavity of a woman aged 83 years having hip revision. The intrapelvic cement mass was progressively removed using the OSCAR and the patient was reported to have responded well postoperatively, but no other clinical data were stated. A summary is reported in table 2.

The case report by Goldberg et al. (2005) described the use of the OSCAR on a woman aged 69 years having revision arthroplasty of the elbow. Although the bone cement was successfully removed, postoperatively it became apparent that the device had caused thermal necrosis of the bone. Following this case, the authors investigated the potential for the OSCAR to induce heat damage in bone using 6 human cadavers. The authors reported that the device had the potential to cause damage to the bone and the radial nerve. However, this effect could be mitigated through the use of intermittent ultrasound and frequent irrigation of the area with chilled saline solution, as well as avoiding the application of a tourniquet. A summary of the study is reported in table 3.

The laboratory study by Shewale and Briggs (2005) used gas chromatography-mass spectroscopy to analyse the fumes released by 4 types of bone cement when treated with the OSCAR. The potentially toxic gases styrene and methylmethacrylate were detected. However, the concentrations of these chemicals remained within safe limits set by occupational exposure standards.

The primary focus of the laboratory study by Birnbaum and Gutknecht (2010) was to investigate the effectiveness of yttrium-aluminium-garnet laser irradiation for removing cement from sagittal sections of an ex vivo human femur bone. The OSCAR system and manual cement extraction through curettage were included as comparators in this study. The researchers found the OSCAR caused less bone loss than curettage. The researchers also attributed the presence of microscopic cracks in the bone to the use of ultrasound.

The results of the laboratory studies by Shewale and Briggs (2005) and Birnbaum and Gutneckht (2010) have not been included in tables 1–3.

Table 1 Summary of the retrospective case series by Fletcher et al. (2000)

Study component	Description
Objectives/ hypotheses	To observe whether ultrasound cement removal enables bone preservation and consequent use of shorter prostheses.
Study design	Retrospective case series incorporating sham planning control.
Setting	Northwick Park Hospital, Middlesex. Date of operations not stated
Inclusion/ exclusion criteria	Selection criteria and method not stated. All patients had hip revision procedures that used a Wagner SL stem implant transfemoral prosthesis. Inclusion: indications for hip revision were proximal endosteolysis (n=10); type II periprosthetic fracture (n=3); non-union of type III periprosthetic fracture (n=1); femoral component stem failure (n=2). Exclusion: 1 revision was excluded as it was for aseptic loosening in an uncemented hip.
Primary outcomes	Length of osteotomy performed (actual versus estimated). Prosthesis size used (actual versus estimated).
Statistical methods	Wilcoxon signed-rank test
Participants	Theatre records of patients undergoing hip revision procedures using Wagner SL stem implant transfemoral prostheses.

Results	<p>Length of osteotomy performed: hip revision cases performed with the OSCAR (n=13), mean reduction of osteotomy 7 cm (range 2 cm to 13 cm), p=0.001.</p> <p>Hip revision cases performed with standard care (n=3), one case with 3 cm reduction, 2 cases with no reduction.</p> <p>Prosthesis size used: hip revision cases performed with the OSCAR (n=13), 5 cases performed with planned prostheses, 3 cases used prostheses 1 size smaller (4 cm shorter) and 5 cases used prostheses 2 sizes smaller (8 cm shorter), p=0.006.</p> <p>Hip revision cases performed with standard care (n=3) were all performed with planned prostheses.</p>
Conclusions	<p>The authors concluded that the use of the OSCAR in combination with a transfemoral approach has the potential to preserve bone stock and allow for the use of shorter prostheses.</p>

Table 2 Summary of the Smith and Eyres (1999) case report

Study component	Description
Objectives/ hypotheses	To review a single patient who had undergone the removal of a massive intrapelvic cement deposit using the OSCAR system.
Study design	Case report
Setting	Orthopaedic surgery
Inclusion/ exclusion criteria	Not applicable
Primary outcomes	Not applicable
Statistical methods	Not applicable

Participants	n=1; a woman aged 83 years presenting with cement penetration of the medial wall of the acetabulum with malposition of the acetabular component resulting in limb shortening.
Description	Following removal of the femoral and acetabular prostheses, the OSCAR was successfully employed to remove the large intrapelvic mass of cement. The acetabulum was remodelled without complications, and the patient did well postoperatively.
Conclusions	Ultrasonic cement removal instruments were used to safely extract a massive body of intrapelvic cement without the use of excessive force in the form of blows to the cement or traction on the cement mass.

Table 3 Summary of the Goldberg et al. (2005) case report and follow-up study

Study component	Description
Objectives/ hypotheses	To describe a patient who developed radial nerve palsy and a pathologic humeral fracture as a consequence of ultrasonic cement removal because of an infection at the site of a total elbow arthroplasty.
Study design	Case report
Setting	Orthopaedic surgery
Inclusion/ exclusion criteria	Not applicable
Primary outcomes	Not applicable
Statistical methods	Not applicable
Participants	n=1; a woman aged 69 years presenting with persistent drainage and progressive osteolysis following a total elbow arthroplasty 2 years previously.

Description	<p>The OSCAR was used to remove cement from both the humeral and ulnar canals. During ulnar cement removal, the lateral cortex was perforated causing minimal soft-tissue trauma; humeral cement removal was uneventful.</p> <p>Postoperatively, the patient developed proximal radial nerve palsy and a pathological fracture of the humerus.</p> <p>Additional surgery was performed to stabilise the humerus; during this surgery widespread muscle necrosis was observed. Biopsy confirmed necrosis of the muscle, cortical bone and nerve tissue. However, there was no evidence that cement removal had caused any perforation of the canal.</p> <p>Follow-up at 10 weeks after this surgery showed that the fixation had failed, resulting in comminution and recurrent instability of the distal humerus and elbow. The radial nerve palsy was still present at follow-up 9 months after surgery.</p>
Follow-up study	<p>A follow-up study using ex vivo human material from 6 cadavers showed the OSCAR has the potential to cause thermal injury and necrosis during cement removal. This risk can be reduced through the use of intermittent ultrasound, application of cold saline and avoiding use of a tourniquet.</p>

Recent and ongoing studies

No ongoing or in-development trials of the OSCAR 3 were identified.

Costs and resource consequences

No published evidence on resource consequences for the OSCAR 3 was identified.

The manufacturer stated that as of July 2014, approximately 130 centres and 200 surgeons are using the OSCAR system in the UK. The model versions in use are unknown. It is unclear how many OSCAR systems are in use under rental agreements. As of April 2014, there were 160 NHS acute trusts in England. This would suggest that the OSCAR system is already well established as a surgical option for orthopaedic surgeons within the NHS.

The OSCAR system is usually used alongside existing mechanical techniques for

extracting cement from bone; therefore, implementation of the system would not replace existing mechanical methods. No other technologies would be needed to support the use of the OSCAR and service reorganisation would not be needed.

Strengths and limitations of the evidence

Published evidence to support the clinical effectiveness of the OSCAR cement removal system is lacking in both quantity and quality.

The retrospective case series by Fletcher et al. (2000) was the only available study that reported quantitative outcomes on the clinical effectiveness of using the OSCAR. The authors did not report their rationale or methodology for the selection of patients who were treated using the OSCAR (n=13) and those who were not (n=3), and patient characteristics were not fully described. This raised the potential for both selection and attrition bias. As there was no robust control group, the conclusion that treatment with the OSCAR led to improved bone preservation (and use of shorter prostheses) must be treated with caution. The rationale for the inclusion of outcomes reported was not described, and the study did not report on other potential clinical benefits of the OSCAR such as shorter surgery times, overall improved surgical outcomes, or patient-related outcome measures. Additionally, the study was relatively small, particularly with respect to the control group. However, it was explicitly stated that the OSCAR was not associated with specific adverse effects in these patients.

The case report by Smith and Eyres (1999) did not report any quantitative clinical outcomes, but did provide insight into the safe and effective application of the OSCAR in 1 problematic hip arthroplasty and reconstruction.

The case report by Goldberg et al. (2005) described a significant adverse effect associated with the use of the OSCAR but no quantitative data were reported. A follow-up technical study used human cadavers, and so did not provide evidence of clinical outcomes in living people.

The study by Shewale and Briggs (2005) did not report clinical or patient-relevant outcomes.

The OSCAR was not the primary focus of investigation in the study by Birnbaum and Gutknecht (2010), and quantitative clinical or patient-relevant outcomes were not reported.

Relevance to NICE guidance programmes

NICE has issued the following guidance in relation to osteoarthritis and hip joint replacement:

- [Mini-incision surgery for total knee replacement](#) (2010) NICE interventional procedure guidance 345
- [Minimally invasive total hip replacement](#) (2010) NICE interventional procedure guidance 363
- [Shoulder resurfacing arthroplasty](#) (2010) NICE interventional procedure guidance 354
- [Hip fracture: The management of hip fracture in adults](#) (2011) NICE guideline CG124
- [Quality standard for hip fracture](#) (2012) NICE quality standard 16
- [Osteoarthritis: Care and management in adults](#) (2014) NICE guideline CG177
- [Total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip \(review of technology appraisal guidance 2 and 44\)](#) (2014) NICE technology assessment 304

These clinical guidelines, quality standards, technical assessments and interventional procedure guidance relate to surgical replacement of the large joints, but do not specifically cover the management of large joint revisions, or the removal of bone cement.

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Shewale S, Briggs R (2005) Gas chromatography-mass spectroscopy analysis of emissions from cement when using ultrasonically driven tools. Acta Orthopaedica 76(5): 647–50

Smith P, Eyres K (1999) Safe removal of massive intrapelvic cement using ultrasonic instruments. Journal of Arthroplasty 14(2): 235–8

Search strategy and evidence selection

Search strategy

The strategy reflects the nature of the MIB assessments as rapid evidence reviews; the search strategy was pragmatic in order to retrieve a volume of records manageable within the timescales of the project. The strategy was developed for MEDLINE (Ovid interface).

The search comprised 2 concepts:

- The intervention. Search lines 1 to 5. This is captured by text words and subject headings to denote ultrasonics; this appears to be the key aspect of OSCAR 3 which distinguishes it from other devices for prosthesis revision.
- The population. Search lines 6 to 11. This concept captures cement removal and prosthesis revision using text words and subject headings.

Two additional, focused search lines (13 and 14) for the brand name of the device and ultrasonics in the context of hip, knee, shoulder or elbow prostheses were also used. These were designed to capture any records that may have been missed by the 2-concept approach.

As is standard in searches for MIB evaluations, non-English language publications were excluded from the search results (search line 19). The strategy also excluded studies published in dental journals (search line 17) in order to increase precision by excluding evidence on the removal of dental cement.

The strategy was limited to studies published from 1990 to current; this reflects the year Orthosonics was formed.

The final strategy was peer-reviewed by an independent information specialist. The MEDLINE strategy was translated appropriately for other databases.

The following databases were searched:

- Cochrane Central Register of Controlled Trials (Cochrane Library, Wiley)
- Cochrane Database of Systematic Reviews (Cochrane Library, Wiley)
- Database of Abstracts of Reviews of Effects (Cochrane Library, Wiley)
- Embase (OvidSP)
- Health Technology Assessment Database (Cochrane Library, Wiley)
- MEDLINE and MEDLINE in Process (OvidSP)
- NHS Economic Evaluation Database (Cochrane Library, Wiley).

Evidence selection

A total of 1437 records were retrieved from the literature search. After de-duplication, 920 remained. An initial 140 records were excluded at first pass as obviously irrelevant topics. This left 780 records remaining for assessment.

Records were sifted independently by 2 researchers. Any disagreements were discussed and, if agreement was not reached, were settled by a third independent arbiter. The first sift removed 759 records based on the following exclusion criteria:

- articles of poor relevance against search terms
- publication types that were out of scope
- non-English language studies
- conference abstracts
- review articles and protocols (for example, Cochrane review protocols).

Full articles were retrieved for the remaining 21 studies with full text assessment undertaken at second sift to identify relevant primary research addressing the specific use of the medical technology, within the defined indication under review. As it was immediately apparent that there was a paucity of data concerning the technology, all primary studies that included the term OSCAR were included and considered on an individual basis. This included in vitro studies, ex vivo studies, and studies in animals. In the second sift, 16 papers were therefore excluded because they did not concern the OSCAR system. Of the excluded papers at this sift, 1 concerned a dental ultrasound system, 4 concerned the Ultra-Drive 3 Ultrasonic Revision System (Biomet Orthopedics), 3 concerned an older system developed by Osseous Technologies and 8 concerned prototype ultrasound systems or the system was not specified. Only 1 excluded study, by Gardiner et al. (1993), had outcomes relevant to patients and healthcare services.

About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers, and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and **are not formal NICE guidance**.

Development of this briefing

This briefing was developed for NICE by Newcastle and York External Assessment Centre. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality assured and approved for publication.

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