**OUTER HOUSE, COURT OF SESSION**

**[2019] CSOH 96**

**A306/15**

OPINION OF LORD TYRE

In the cause

JOHN HASTINGS

Pursuer

against

(FIRST) FINSBURY ORTHOPAEDICS LIMITED and (SECOND) STRYKER UK LIMITED

Defenders

**Pursuer: Milligan QC, C Murray, Connelly; Thompsons**
**Defender: Haldane QC, McBrearty QC, J Brown, E Campbell; Clyde & Co**

26 November 2019

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**Introduction**

[1] This is one of a number of actions raised in the Court of Session against manufacturers of hip replacement prostheses consisting of a metal acetabular cup or liner and a metal femoral head and stem: in other words, what has been termed a metal-on-metal total hip replacement, or "MoM THR" for short. It is the first such action in which a proof, albeit with a restricted scope, has been heard in the Scottish courts. Although the proof was concerned with a specific combination of acetabular and femoral components produced by particular manufacturers, it is envisaged that this opinion will be of relevance to actions concerning MoM THRs more generally.

***The pursuer***

[2] The pursuer is a former forestry worker, born in 1955, who had a history of arthritis affecting both hips. On 4 March 2009, when he was aged 54, he underwent a left sided MoM total hip replacement. The prosthesis used comprised a Mitch/Stryker Howmedica uncemented acetabular cup, manufactured by the first defender ("Finsbury"), and an Accolade V40 uncemented femoral stem with a large bearing (54 mm) MoM hip articulation, manufactured by the second defender ("Stryker"). The operation was carried out at the Golden Jubilee National Hospital. On 16 November 2009, the pursuer underwent a right sided MoM THR at the same hospital. The prosthesis used was the same as in his left sided implant. On 17 October 2012, he underwent revision of his left sided implant. The right sided implant has not been revised.

[3] The pursuer contends that he has suffered loss and damage as a consequence of the use of MoM THRs in his 2009 hip replacement operations. His case is not based upon allegations of fault or negligence, but rather on section 2 of the Consumer Protection Act

1987 which imposes no-fault liability on certain persons for damage caused wholly or partly by a defect in a product. The pursuer claims that the MoM THRs used in his operations were defective, in terms of section 3 of the 1987 Act, because their safety was not such as persons generally were entitled to expect. The preliminary proof that I heard was restricted to the question of whether certain propensities and risks inherent in MoM THR prostheses rendered the particular combination of components used in the pursuer's operations defective within the meaning of the 1987 Act. All matters specific to the pursuer, including issues of causation as well as quantification of loss, were excluded from the scope of the restricted proof.

***Evidence at the proof***

[4] At the proof, evidence of a factual nature was led from the following witnesses:

- Dr Alexander Siegmeth, consultant orthopaedic surgeon, who carried out the pursuer's THR operations in 2009 and the left sided revision surgery in 2012;
- Tom Baker, a senior product manager in relation to hip replacements for Stryker;
- Paul Pandiscio, project leader, hospital medical devices, for Johnson & Johnson, the parent company of Depuy International Limited ("Depuy"), which acquired Finsbury in December 2009;
- Sally Hunter, a self-employed regulatory consultant who had from 1995 until 2015 held the post of worldwide vice-president of regulatory affairs with Depuy.

In addition, witness statements provided by Nick Sheppard, director of quality and compliance for Depuy, and Mark Deane, staff reliability engineer for Stryker, were agreed to constitute their unchallenged evidence without the need for personal attendance. With the exception of Mr Pandiscio, a witness for the defenders who gave his evidence by video link

from the United States, there was no material challenge to the credibility or reliability of the factual witnesses and, subject to what is said below regarding Mr Pandiscio, I accept their evidence as credible and reliable.

[5] The expert witnesses gave their evidence in pairs: that is, each expert witness for the pursuer was followed by the counterpart expert for the defenders. The objective of this arrangement was to enable any disagreements between experts to be identified and addressed more immediately than if all of the pursuer's expert witnesses had given their evidence before any of the defenders' experts. I found this arrangement very helpful. In the event there was less disagreement between the experts than might have been expected. This may have been partly due to the procedural steps that had been taken prior to the proof to focus areas of dispute: each expert had had the opportunity to lodge a written report and a rebuttal report, and joint meetings of the pairs of experts had taken place, with their agreement or disagreement on particular issues having been recorded in joint statements prepared after those meetings.

[6] Expert evidence was led in relation to the following matters:

***Orthopaedic surgery***

- (For the pursuer) Professor Steffen Breusch, consultant orthopaedic surgeon, Edinburgh Royal Infirmary;
- (For the defenders) Professor Hemant Pandit, professor of orthopaedics and honorary consultant, Chapel Allerton Hospital, University of Leeds, and professor of orthopaedic surgery, NDORMS, University of Oxford.

***Biomechanics***

- (For the pursuer) Professor Harinderjit Singh (Richie) Gill, professor of health care engineering, University of Bath;

- (For the defenders) Dr Jenny Burke, biomedical engineering consultant.

***Immunology/toxicology***

- (For the pursuer) Dr John Duffus, director of Edinburgh Centre for Toxicology. Dr Duffus was unfortunately unable because of illness to attend the proof but had provided written reports and had contributed to a joint expert statement with Professor Kimber;
- (For the defenders) Professor Ian Kimber, emeritus professor of toxicology, University of Manchester.

***Histopathology***

- (For the pursuer) Dr Sonali Natu, consultant cellular pathologist, Teesside;
- (For the defenders) Dr Edward McCarthy, professor of pathology and orthopaedic surgery, Johns Hopkins Medical School and Hospitals, Baltimore, USA.

In addition, the defenders produced an expert report by Professor Robert Platt, professor of pharmacoepidemiology, McGill University, Montreal, Canada. His evidence was agreed to be unchallenged without the need for personal attendance.

***English litigation***

[7] Litigation concerning MoM THRs has taken place in other jurisdictions, notably in England and Wales. The case of *Gee and others* v *Depuy International Ltd* [2018] EWHC 1208 (QB) concerned claims by representative claimants in a group litigation founded upon the same statutory provision as the present case, but in relation to a different hip prosthesis system. As in this case the claimants in *Gee* contended that the prostheses supplied to them were defective within the meaning of section 3 of the 1987 Act, and that this had caused

personal injury for which the manufacturer was liable to compensate them. The common preliminary issue tried was whether or not the defendant was liable to the claimant, subject to any development risk defence. In contrast to the present case, the English trial encompassed issues of causation. Andrews J found in favour of the defendant, holding on grounds that were common to all of the cases and not dependent upon any issues of individual causation that the defendant was not liable to the claimants.

[8] The judgment of Andrews J included a large amount of background information regarding the nature and history of hip replacement surgery, and of certain pathological conditions observed either clinically or by histopathological examination in patients who received MoM prostheses. Much of this material was not controversial in *Gee*; nor is it controversial as between the parties to this action, who were able to enter into a lengthy joint minute of agreement in relation to these matters. The joint minute drew heavily upon Andrews J's judgment. At paragraphs 9 to 75 below, I set out an agreed factual background to the questions at issue between the parties. Much of this is based upon the joint minute which was based in turn on the exposition by Andrews J in *Gee*. For my part, I gratefully acknowledge that the availability of this exposition, and the parties' agreement of it, has significantly reduced the time that I have had to spend drafting my own background narrative. I have to some extent supplemented it with uncontroversial material in the expert reports and joint expert witness statements lodged in advance of the proof.

**Hip replacement surgery**

[9] The human hip is a ball and socket joint. Over time, it may become damaged and require replacement in consequence of natural wear and tear, which may be exacerbated and escalated by certain medical conditions, the most prevalent being osteoarthritis.

[10] Total hip arthroplasty, the reconstruction of the natural hip joint with an artificial prosthesis, has become a common operation. Approximately 100,000 such operations are performed annually in the UK. A successful total hip arthroplasty can make a huge difference to the patient's quality of life by improving their mobility and relieving them from debilitating pain.

[11] All prostheses used in this procedure will consist of three or four components: a femoral stem, made of metal, fitted into the centre of the femur (thigh bone), to which a ball-shaped replacement femoral head is attached; a cup which replaces the damaged acetabular socket in the pelvis; and in some prostheses a liner. Prostheses have a smaller head and acetabulum than the natural hip. The "bearing" in a total hip arthroplasty refers to the articulation between the femoral head component and the acetabular component. The latter will either be a monobloc cup, which articulates against the femoral head, or a modular cup with a liner inserted into it, whose surface articulates against the femoral head.

[12] A total hip arthroplasty is to be distinguished from a resurfacing arthroplasty, a procedure by which the native femoral head is retained, but reduced and re-shaped to receive a metal component which "resurfaces" it to produce a new integrated femoral head, which articulates against a monobloc acetabular cup.

[13] The original types of hip replacement prostheses were monobloc systems which were fixed in position by using bone cement. Over time, the product designers and manufacturers developed modular prostheses with separate cups and liners, and modular stems, allowing the surgeon to better reproduce each individual patient's anatomy. Modular stems and heads were well established components by the 1990s. Modular cup and liner combinations were developed around the late 1990s. By 2009 nearly all hip replacement prostheses in use in the UK consisted of modular components. Increasing

modularity is, however, associated with a potential for improper assembly and movement (whether micro or macro) between individual parts.

[14] In a total hip arthroplasty, the surgeon has a choice of bearing surface combinations. The femoral head will be made of metal or ceramic material. The liner may be made of polyethylene, ceramic or metal. Of these, polyethylene is the softest material, and therefore most prone to wear. There is a distinction between conventional polyethylene and cross-linked or highly cross-linked polyethylene ("XLPE" and "HXLPE" respectively). XLPE and HXLPE are more resistant to wear than conventional polyethylene and were developed more recently.

[15] The various combinations of articulation, using a modular acetabular component, are:

- A metal head with a liner made of polyethylene (MoP);
- A metal head with a metal liner (MoM);
- A metal head with a ceramic liner (MoC);
- A ceramic head with a polyethylene liner (CoP);
- A ceramic head with a ceramic liner (CoC).

Most metal heads are made of cobalt chromium ("CoCr") alloy.

[16] Implants may be fixed to the bone by means of bone cement ("cemented") or may be fixed by being press-fitted to the bone allowing fixation by a process of osseointegration ("uncemented"). Fixation is required for the stem and cup components. Both fixings may be cemented, both may be uncemented or a combination (hybrid) may be used.

[17] The stem is fixed to the head by means of a self-locking taper joint. The male taper, known as the trunnion, fits tightly into the cone of the femoral head, which is the female taper. As force is applied the male and female tapers lock together.

[18] A surgeon will select the implant that he considers is most suited to his patient, based on an assessment to include how much wear it might be expected to suffer, and the demands that are likely to be placed upon it in terms of the stability of the construct and its potential risk of dislocating. That assessment will in turn be based upon an assessment of the individual patient's characteristics including age, gender, weight and level of activity.

[19] Dislocation is a painful event which reduces the patient's confidence and may lead to a need for revision surgery – that is, surgery to replace all or some of the components used in the primary operation. It can cause damage to surrounding tissues with an ongoing impact on function, giving rise to a risk of further dislocation. The risk of dislocation is related to head size; the smaller the components, the greater the risk. The advantage of using a large femoral head (one with a diameter of at least 36mm) is that it brings increased stability to the joint by increasing the distance that the head must lift out in order to dislocate.

[20] All hip prostheses wear in use. If a patient lives long enough, they may need to undergo revision surgery. This is generally associated with an increased risk of complications and poorer outcomes. The actual incidence of negative outcomes will depend on many factors, including the nature and extent of the revision, the characteristics of the individual patient and the indication for revision in the individual case.

**Prosthesis development**

***Early development***

[21] In the 1950s, McKee and Watson-Farrar designed a stainless steel prosthesis, building upon a model which was originally used by Philip Wiles in 1938 at the Middlesex Hospital in London. However, it suffered from early loosening, and they revised their design to

utilise a CoCr alloy. At around the same time Sir John Charnley began to experiment with using a Teflon acetabular cup combined with a small head stainless steel monobloc femoral stem. This did not perform well, due to excessive wear, and the design was abandoned in 1961.

[22] In the early 1960s, Sir John Charnley published a new design which he termed the "low friction arthroplasty". This was a cemented implant with a MoP articulation. The stem of the Charnley prosthesis consisted of a monobloc of cobalt chrome steel with a small metal head, and the cup was a monobloc of conventional (ultra-high molecular weight) polyethylene. The Charnley hip was very successful and generally outperformed the various first-generation MoM designs that were being developed throughout the 1960s. The performance of the latter prostheses was very mixed, with poor patient outcomes and relatively high failure rates in the first years of clinical use. The reasons for the rate of failure of these older designs included flaws in the design and manufacturing processes, and problems with their fixation.

[23] Up to the early to mid-1990s, the Charnley hip was the prevailing articulation in use in the United Kingdom and it, or variants of it, are still in use today. However, its major drawback was the risk of failure due to osteolysis: that is, aseptic loosening caused by an adverse reaction to particulate debris in the body that was largely produced by wear to the polyethylene cup.

[24] During the early part of the 1970s, first-generation alumina ceramic was introduced as a bearing surface as a harder-wearing alternative to conventional polyethylene. Its early performance was very mixed. Problems arose from a relatively high fracture rate, as well as difficulties with aseptic loosening. The fracturing of a ceramic head or cup can cause very serious practical difficulties, in particular the difficulty in removing all the parts of the

shattered component, and the risk that any parts left behind might interfere with the revision prosthesis. There was also a problem of squeaking, possibly caused by edge loading of the ceramic bearing, which for some patients could be intolerable and lead to them requesting a revision.

[25] By around the middle of the 1970s most first-generation MoM bearings were no longer used, as it was perceived that they were outperformed by the MoP designs. However, work continued to develop a bearing surface that would prove to be more durable than conventional polyethylene. During the 1980s, second generation alumina CoC bearings were developed. Whilst the incidence of fracture decreased, they continued to suffer from aseptic loosening. A second generation of MoM bearings were developed in the latter half of the 1980s. The Swiss company, Sulzer, produced a design which used 28 mm and 32 mm femoral heads made from a CoCrMo alloy. At around the same time, the designers of MoP articulations experimented with structural cross-linking of polyethylene through gamma or beta-ray irradiation, and the use of antioxidant agents such as Vitamin E to stabilise the material, producing early examples of cross-linked polyethylene, which it was also hoped would be less likely to degrade over time. The abbreviation "MoCP" is often used, and is used in this opinion, to refer to metal on conventional polyethylene implants, ie those used before the development of metal on cross-linked polyethylene ("MoXLPE") or metal on highly cross-linked polyethylene ("MoHXLPE") articulations.

[26] The increased use of MoP designs, particularly the Charnley hip, led to an increased incidence of failure of such implants due to polyethylene wear osteolysis. Other modes of failure or complication of MoP prostheses existed, including dislocation, but by the mid-1990s aseptic loosening caused by osteolysis was widely recognised to be the predominant cause of failure, especially in younger or more active patients. The length of time before

such failure occurred would depend on multiple factors, including how active the patient was, and the nature of the activity, though there would be a degree of degradation in the body irrespective of activity. The patient's weight and body shape would also have an impact on the forces being applied to the prosthesis.

[27] Osteolysis in MoP implants would not usually develop until the prosthesis had been implanted for seven to ten years, though in some cases there is accelerated wear and osteolysis before five years. The incidence of failure due to osteolysis was a major focus at meetings of professional associations of surgeons at which the topic of polyethylene wear was regularly discussed. Patients with osteolysis were largely asymptomatic in the early years, and problems would only become apparent if they started to experience pain, or the prosthesis started to loosen. If the hip was not subject to periodic X-ray follow-up, and it was well fixed, the consequences of the adverse reaction to the polyethylene debris would not become manifest until the hip began to loosen and the patient began to suffer symptoms.

***Development of harder-wearing material combinations***

[28] During the 1990s, once earlier problems experienced with the fixation of the prosthesis appeared to have been largely overcome, the search for alternative harder-wearing material combinations of the articulating surfaces of total hip implants became the subject of more intense scientific study in the orthopaedic community. Designers of implants began to focus on improvements to wear rates, so as to reduce the volume of wear debris. This led to a move away from conventional MoP towards alternative articulations. A third generation of CoC implants were developed and introduced during the 1990s, but concerns about potential fracture remained, and the size of the components meant that these prostheses were unsuitable for patients with smaller anatomies.

[29] Also in the 1990s, MoM resurfacing prostheses were developed by Wagner and McMinn, using cemented and uncemented fixations. The advantage of the resurfacing technique was that it allowed for preservation of the femoral head and neck, with normal femoral loading, and reduced the risk of dislocation. That was one reason why hip resurfacing became a popular choice for younger and more active patients. Resurfacing arthroplasty started to be used in significant numbers in the mid-1990s. The "Birmingham" hip resurfacing was first used clinically in 1997.

[30] In 1995, a conference took place in Santa Monica, California, which was attended by leading scientists, clinicians, engineers, academicians, industry-based scientists and engineers, and government regulators involved with orthopaedics, to discuss the future of hip prostheses and specifically the issue of alternative bearing surfaces to conventional polyethylene, focusing on MoM bearings. The conference brought together people with clinical and scientific experience who had already undertaken research or had a specific interest in evaluating MoM bearing technology for total hip arthroplasty. The conference generated a "consensus statement" on the current state of knowledge in the industry, which was published in a leading orthopaedic journal, Clinical Orthopaedics and Related Research, in 1996.

[31] The consensus statement referred to the fact that retrieval analyses had indicated that in the absence of specific design flaws, such as excessive clearance, the long term wear rates of MoM hip prostheses were typically up to 20 times less than polyethylene wear rates. Despite noting that histological features seen with failed MoM components differed from those seen around MoP components, and express identification of the issues of metal ion and particle toxicity (and even potential carcinogenicity), the statement concluded that MoM

technology was a worthwhile subject of further research and development as an alternative articulation, to address the problem of polyethylene wear particle-induced osteolysis.

[32] The views of the orthopaedic community as to the need to improve on the longer term survivorship of MoP prostheses because of the problems of particle-induced osteolysis were reinforced by the data from the National Swedish Hip Arthroplasty Registry ("SHAR") published in a report, written in English, by Dr Malchau, one of the directors of the registry, in 2000[1]. SHAR, which was established in 1979, is the longest established national joint registry. The data referred to the entire patient cohort (169,419 primary procedures and 13,561 revisions) and it was the only available data at the time on long-term survivorship rates. The orthopaedic community's general view of survivorship of hip prostheses was largely informed by this registry. The SHAR data showed that younger and more active patients, particularly those aged under 55, were at greater risk of revision in all diagnostic groups.

[33] In the early years of the 21st century the received wisdom as to the likely survivorship of a hip prosthesis after a primary operation was based on the track record of MoP prostheses recorded in the Malchau report. The Swedish data indicated that the survival rate of MoP prostheses declined rapidly after ten years, especially in younger patients, a problem starkly illustrated by the graphs in the report. The rapid decline has been appropriately described as a "cliff edge" phenomenon. The Malchau report continued to drive the search for alternative, harder-wearing bearing surfaces.

[34] Prior to the early years of the 21st century, total hip arthroplasty was largely targeted at older patients (those aged 70 or over), with the purpose of restoring mobility around the

[1] H Malchau et al: "Prognosis of Total Hip Replacement – Update and Validation of Results from the Swedish National Hip Arthroplasty Register 1979-1998", 2000.

home and the locality, and significantly reducing pain. The prevailing MoP articulation worked reasonably well in such patients by providing improved function and pain relief. Their activity levels tended to be low, and so the demands on the prostheses were relatively modest. The standard advice given to such patients was that such a prosthesis might last 10 to 15 years. In practice, there would be those that failed earlier, including much earlier, and those that would last much longer. The experience of clinicians was that the wear of the hip would increase with higher levels of activity, which reduced the length of time the prosthesis might be expected to survive in a more active patient.

[35] There was a general reluctance in the orthopaedic community to proceed to replace the hip of a younger patient, because younger and more active patients appeared to be at greater risk of revision in all diagnostic groups. This was borne out by the data in the Malchau report. For younger patients who were sufficiently symptomatic, clinicians would still make the decision to replace, but they would generally try to keep the patient going with injections and/or physiotherapy until they fell within the elderly, less active group. At that time, in such cases, orthopaedic surgeons lacked confidence that they had an implant which was going to outlive the patient. Even today, most experienced arthroplasty surgeons would advocate conservative management of an arthritic hip for as long as possible if the patient's symptoms permit it.

[36] The major challenge for the orthopaedic community was to create an implant that was suitable for the younger, fitter patient who wanted to lead a more active life. They wished to develop prostheses to combat the problem of osteolysis and provide a greater range of motion whilst also reducing the incidence of dislocation. The larger sizes of femoral heads were developed to address the problem of dislocation and create greater stability.

[37] One advantage of using metal as the liner material was that it enabled a larger sized femoral head to be used in the prosthesis. The maximum size of components in the bearing of the prosthesis is limited by the strength of the materials comprising the liner. Stronger materials can be thinner, and so accommodate a large femoral head within the same size of acetabular cup. Metal liners allowed for the largest size heads with the thinnest liners.

***The trunnion***

[38] (This and the following four paragraphs are largely based upon the written report by Dr Burke; I do not understand this material to be controversial.) In a modular femoral component, the femoral head and femoral stem are connected with a self-locking taper joint. The male taper, known as the trunnion, fits tightly into the cone of the femoral head, which is the female taper. As force is applied the male and female tapers lock together.

[39] In the operating room, the surgeon will place the femoral head onto a dry trunnion by hand, often with a slight twist to engage the correct alignment, and then impact the head, using manufacturer-supplied instruments, to lock the taper joint. The exact impaction method, such as the force used and the number of blows, varies between surgeons. When the head is impacted on to the trunnion, the female taper generates compressive forces onto the male taper and this along with frictional forces between the two surfaces creates a locking mechanism that keeps the components together. The taper interface surfaces are deliberately manufactured with a slightly roughened surface so that the microscopic asperities of the surfaces deform on assembly, interlocking and adhering to each other. The trunnion of a hip stem is a highly toleranced connection for the femoral head. Trunnions are designed with a specific angle and depth of taper to engage with the femoral head.

[40] There is no standard design of trunnion, and therefore there are a large variety of trunnions supplied by different manufacturers. The differences between trunnions can often be small, but significant enough to mean that surgeons should not mix and match heads and stems from different companies, unless they are specifically designed to be compatible, as with the Mitch/Accolade combination. The variables between trunnions include trunnion length, trunnion width, taper angle, and surface roughness.

[41] Another design variable is material. The choice of material is a trade-off between strength and flexibility. Cemented stems perform best when the metal is stiff, which decreases stresses on the cement mantle. CoCr and stainless steel are the preferred materials for cemented stems. By contrast, uncemented stems need to be more flexible to transfer the loads through the stem into the bone to prevent stress shielding and bone resorption. Current uncemented stems are therefore manufactured from a titanium alloy, which is more flexible than stainless steel and CoCr but still has the required strength. Titanium cannot, however, be used as a bearing surface, because it is too soft. Designers do not place a titanium head on a titanium stem. The combination of a titanium stem and a CoCr femoral head is therefore standard practice for uncemented stems.

[42] Metal wear producing debris occurs at the trunnion interface. "Trunnionosis" is defined as wear of the femoral head–neck interface. However the term is often used inconsistently in the literature, describing fretting and corrosion found at the taper junction with no identified wear. Metal wear at the trunnion/head interface is normally a small percentage of the total metal wear; in a well-functioning MoM prosthesis, the majority of metal wear will be generated at the articulating surface, ie where the metal head articulates against the metal cup or liner. Despite the fact that a very large number of studies have attempted to identify the most influential design features affecting trunnion wear, there is

currently no scientific consensus as to which design feature, or combination of features, produces the lowest wear at the trunnion interface.

**Pathological conditions**

***Adverse Reaction to Metal Debris ("ARMD")***

[43] Adverse Reaction to Metal Debris ("ARMD") is an expression used by orthopaedic surgeons to describe changes that can occur in the soft tissues immediately adjacent to the implant (and less commonly, to the local bony tissues also). However, as with the term ARPD (adverse reaction to particulate debris) which does not distinguish between metal debris and other material debris, it is not used consistently among orthopaedic surgeons. Not all periprosthetic tissue changes can properly be described as adverse from a clinical perspective.

[44] All artificial hip prostheses, irrespective of the materials used, will produce particulate debris. This will not always be visible to the naked eye, or even under a microscope, as some particles will be sub-micron in size (nano particles). The debris is mainly the product of wear. Most of it will be generated at the bearing. Some wear debris may also be produced at the junctions of modular components. Debris may also be produced in consequence of the natural degradation of the materials used over time, or their reaction to fluids or chemicals in the body; for example, metal may corrode, plastics will oxidise.

[45] The nature of the debris will depend on the nature of the articulating surfaces. A MoP articulation will produce polyethylene debris, although it may also produce some metal debris. A MoM articulation will only produce metal debris. The amount of wear debris produced, even by the same design of prosthesis, will vary from patient to patient,

and will depend on such variable factors as how the implant has been fixed by the surgeon, the nature and amount of activity undertaken, and physical characteristics of the patient, including gender, weight and gait. The amount of debris produced may not be consistent over time.

[46] All patients will react to foreign materials in the body, but the nature and extent of the reaction to debris from a prosthesis may vary significantly from person to person. The fact that there is a biological reaction to particulate debris does not necessarily mean that the reaction is clinically adverse. The body's response to an implant may be beneficial, such as the reaction of bone to grow around a component to secure it (osseointegration), or it may be neutral in terms of benefit or disadvantage. Some reactions will cause bony and/or soft tissue destruction and/or aseptic loosening of the prosthesis, necessitating revision surgery. Occasionally there may be damage to the nerves and blood cells, and in extreme cases, muscle damage. In such cases the prospects of achieving a reasonable function after revision surgery are very poor.

[47] The immunological reaction to particulate debris may also lead to the formation of pseudotumours. In this specific context, that expression refers to the formation of a tumour-like mass in the tissues around an implant that is non-neoplastic and non-infective. Pseudotumours communicate with the hip joint and may be associated with soft tissue and/or bony periprosthetic damage. They may be solid or filled with fluid. They can present with pain or be asymptomatic. They may, or may not, have adverse clinical consequences for the patient; this may depend on the size and precise location of the pseudotumour.

[48] There is no agreed set of diagnostic criteria for ARMD, and orthopaedic surgeons have varied in their approaches to the diagnosis. Some surgeons rely on features or

presentations which are neutral or non-specific, or for which there is no scientific evidence that their presence has anything to do with ARMD. Examples are the colour or opacity of fluid drawn from the hip joint, or the presence of metal staining in the tissues (metallosis). The term metallosis refers to deposition and build up of metal debris in the soft tissues of the body. It is visible macroscopically at the time of surgery. Its presence is not diagnostic of adverse symptoms.

[49] Some orthopaedic surgeons have sought to draw clinical conclusions from the level of metal ions to be found in a patient's blood. Small amounts of Co and Cr are to be found in everyone's blood. There is ongoing scientific debate, and no scientific consensus, as to what constitutes a "normal" level of ions in a patient with implanted metal prostheses. There is no direct correlation between the level of metal ions in a patient's blood, and the existence or extent of any reaction to metallic debris. A patient with one or more metal implants would ordinarily be expected to have a higher level of metal ions in their blood than a patient who did not have such an implant. The presence of metal ions by themselves are not diagnostic of ARMD.

[50] The propensity of a given patient to suffer an adverse clinical reaction to particulate debris is unpredictable, and despite ongoing research, scientists have not yet worked out why one patient's body can tolerate a particular level of debris or its products (such as a given percentage of metal ions in the blood) without suffering any adverse effects, whereas another will suffer a very serious adverse reaction with the same, or lower, levels of debris in the body.

[51] ARMD is also an expression which is used by some histopathologists as a description of tissue changes that they can see macroscopically or microscopically. Since what they are describing is a biological reaction to foreign particles, in terms of inflammation and repair,

and they cannot determine whether it is clinically "adverse" or reasonably well tolerated by the patient, the use of the expression by histopathologists needs to be treated with caution. Histopathologists may refer to "*an* ARMD" rather than simply "ARMD" as a means of distinguishing between what they are describing and a clinical diagnosis.

[52] Since biopsies are very rarely, if ever, taken prior to revision surgery, the histopathology evidence will not be available until afterwards, when samples of excised tissue have been examined, and therefore can only serve to confirm (or not) a clinical diagnosis that has already been made, based on other evidence. A histopathologist cannot determine whether a patient has suffered from ARMD, in the clinical sense, but he can explain whether the macroscopic and microscopic findings are consistent with that diagnosis, and identify other possible explanations for those findings.

***Immune system responses***

[53] The human body will produce immune responses to wear debris from any form of prosthetic implant. The immunological reactions that debris can produce in a patient's body are fundamentally similar, although the specific reactions, outcomes and clinical consequences may vary in proportions between the different types of prostheses. The actual types of reaction and the actual consequences, such as soft tissue damage or bony damage, or the formation of pseudotumours, can occur across the entire range of prostheses.

[54] There are two categories of immune responses, innate and adaptive. Innate immunity is a more primitive, non-specific, immune system, that by a variety of means provides a first line of host defence before the adaptive immune response may become engaged. The innate immune system plays an important role in supporting adaptive immune responses. It is a complex response in which many factors come into play.

Adaptive immunity is a sophisticated and dedicated immune response that has the cardinal features of memory, specificity and the ability to distinguish between self and non-self, and to mount specific immune responses. There cannot be an adaptive immune response unless there has first been an innate immune response.

[55] All forms of foreign debris can trigger an innate immune response (although potentially involving different mechanisms). Macrophages play an important part in that response. They are cells which may be activated by a wide variety of stimuli, and they serve several important functions. Their presence is a signal of chronic inflammation, and therefore macrophages will be present to some extent in a patient who is already suffering from a chronic inflammatory disease such as osteoarthritis, irrespective of whether the patient has had a joint replacement. They are responsive to, and also produce, chemical mediators such as cytokines (proteins that, by their effect on lymphocytes and/or other cells regulate the nature, intensity and duration of the immune response).

[56] The products of activated macrophages attempt to eliminate perceived injurious agents or materials from the body, be they indigenous or foreign in nature. They do this by bringing the material into the macrophage cell and breaking it down (a process known as phagocytosis), so that in due course the harmful elements can be secreted from the body. If one cell cannot achieve this, for example because the particle is too large, it will recruit others. If need be, macrophages can fuse with each other to form multinucleated foreign body giant cells.

[57] Macrophages also play an important role in the adaptive immune response. In some individuals, macrophages will ingest and present antigens to T-cells (T lymphocytes) which will activate those cells and produce type IV hypersensitivity (delayed allergic reactivity). It

is potentially a much more complex reaction than with innate immunity, given the number of processes involved, and again will vary from person to person.

[58] An adaptive response is not necessarily more damaging or longer lasting than the innate response – it may be, but it depends on the individual. Some people are predisposed to suffer such a reaction, others may become sensitised over time. There is no reliable method for identifying those who are predisposed to mounting a cell-mediated hypersensitivity reaction to a MoM implant. A cellular reaction does not equate to a clinical consequence.

[59] There is a spectrum of innate foreign body macrophage response to all particles generated from a hip prosthesis, irrespective of the material used. There will always be some non-specific inflammation present in the tissues of any patient with an implanted device of any type, but it may not be significant in type or amount, and it may have no clinical consequences. The presence of macrophages, even in large numbers, may have no adverse clinical consequences for a patient.

[60] If wear particles cannot be completely broken down, they may remain in the macrophage (or giant cell) for the natural life of the cell. They may do so without causing any harm. However, in some cases the phagocytosed macrophages will release chemicals that can promote inflammation and osteolysis (the destruction of bone) by stimulating the formation of osteoclasts (cells whose sole function is to cause bone resorption) and consequential resorption of periprosthetic bone, eventually resulting in aseptic loosening of the prosthesis. This is a more common reaction to polyethylene debris than to metal debris. In other cases, the particle size, shape and/or chemical composition of the wear particles, or their products when broken down, may prove cytotoxic, that is, cause or accelerate the death

of the phagocytosed macrophages and other cells such as lymphocytes, which may in turn lead to soft tissue necrosis.

[61] All cells, including macrophages, have a limited lifespan and will die naturally. The presence of significant quantities of dead cells in tissue is a sign of pathology and a cause for concern, because it suggests that something is causing those cells to die. Sometimes the histopathologist can discern a layer of dead cells, or dying cells, next to a layer of normal cells, which may suggest a progressive necrotic process within that tissue. A histopathologist may express a view as to what may have caused it and over what period, but how that situation may evolve in the future is a matter for a clinician.

[62] The death of macrophages induced by metal or polymer particles is size and concentration dependent. The volume, dose and rate of generation of wear and wear debris produced by a prosthesis has an impact on its potential for inducing adverse biological reactions. In very broad terms, the greater the dose, and the greater the concentration in the tissue, the more likely there is to be a cytotoxic reaction (and vice versa), though tolerance levels will vary from patient to patient.

[63] The required dose to trigger a cytotoxic reaction to metal debris has not yet been estimated with any degree of accuracy. Experiments have been carried out and scientific research is ongoing, but it is extremely difficult, if not impossible, to replicate in a laboratory what goes on in the human body.

[64] Micron sized particles may drive an innate inflammatory response, but nano sized particles are more likely to drive an adaptive immune response. The likelihood of an adaptive immune response is higher with metal ions than with polyethylene or ceramic debris. With ceramic debris, the immunological response would be less extensive, and predominantly macrophage in nature.

[65] One feature of the adaptive response may be an aggregation of lymphocytes around small vessels in periprosthetic tissues (perivascular cuffing). Cuffing is not specific to the type IV hypersensitivity reaction or to MoM bearings, but where there is a type IV hypersensitivity reaction to metal debris, the lymphoid response may be far more pronounced. Perivascular lymphocytes and lymphoid aggregates, as well as a macrophage infiltrate, can be seen in a patient with osteoarthritis, although in such a patient the macrophage infiltrate is not as marked as in ARMD.

***Aseptic Lymphocytic Vasculitis-Associated Lesions ("ALVAL")***

[66] The term "ALVAL" was first coined by Dr Willert and others in a clinical study[2] published in the Journal of Bone and Joint Surgery in 2005, to describe a condition seen under the microscope in periprosthetic tissues: a lesion in which a distinct lymphocytic infiltration is present, with perivascular cuffing, accompanied by plasma cells, and visible metal debris, often inside macrophages but sometimes outside them. Other features they noted in some patients were drop-like inclusions in the cytoplasm of the macrophages, areas of cell necrosis, often large, and extensive fibrin exudation. Fibrin is a generic term for plasma protein and is a pink material which histopathologists see in the context of inflammation. It is commonly seen on the surface of the joint capsule in osteoarthritis and after joint replacement.

[67] ALVAL is a purely histological finding which takes account of the various features of the tissues observed under the microscope. The one essential feature of it is the distinct diffuse perivascular lymphocytic infiltration, and the extent to which some of the other

[2] HG Willert et al "Metal-on-metal bearings and hypersensitivity in patients with artificial hip joints: a clinical and histomorphological study", J Bone Joint Surg [Am] 2005; 87-A:28-36.

features mentioned in the Willert paper are present may contribute to a conclusion that ALVAL is present.

[68] Some clinicians have used the expression ALVAL as a synonym for ARMD (in the clinical sense). The fact that an ALVAL response may be seen by a histopathologist when examining tissue taken from a patient does not necessarily mean the patient has ARMD (in either sense). A significant lymphocytic infiltration may be consistent with the histological finding or the clinical diagnosis of ARMD, particularly if it is accompanied by significant tissue necrosis and the presence of metal debris in and around the dead or dying cells. The mere fact of an ALVAL reaction does not mean that there has been an adverse reaction in clinical terms. It depends on the nature and extent of the ALVAL response and any other relevant features.

[69] There can be ARMD (in both the clinical and histological sense) without ALVAL, but it is rare to find ARMD without a lymphocytic response. When one does, it is often associated with heavy necrosis, macrophage infiltrate, and a large pseudotumour.

[70] Tissue necrosis may be more extensive in "high ALVAL" cases. This is based on a scoring system for ALVAL that ranks the multiple features described in the Willert study. It was originally used as part of a study of the correlation between the incidence of ALVAL and the amount of prosthetic wear measured in explants from patients who had had revisions (not just of total hip arthroplasties but of resurfacing arthroplasties). A different scoring system for ALVAL, used for a similar purpose, but focusing on the lymphocytic infiltrate, was developed in Oxford by Grammatopoulos.

[71] Neither scoring system was intended to be, or should be used as, a diagnostic tool. Whichever system is used, there is likely to be broad agreement between histopathologists as to where in the spectrum the ALVAL phenomenon observed in the tissue lay.

***Histological findings consistent with a clinical diagnosis of ARMD***

[72] A macrophage response to metal wear particles is a relevant feature of ARMD (in the histological sense). Fibrin or a lymphocytic response (including a low-grade lymphocytic response) are non-specific to ARMD. Bone and/or soft tissue necrosis, macrophage response to wear particles, the formulation of granuloma (a distinctive pattern of chronic inflammation characterised by the presence of numerous macrophages), and lymphoid infiltrate are all histological features that can support the clinical diagnosis.

[73] The macrophage response probably reflects the innate response and the lymphocytic response the adaptive response. Therefore, if, in a case of ARMD, in the clinical sense, the histopathology reveals significant ALVAL, it can be deduced that the adaptive immune response and cell-mediated hypersensitivity caused or contributed to that condition. If there is ARMD without ALVAL it is most likely to be the patient's innate immune system that is driving the reaction, and the condition has probably been brought about by a quantity and concentration of metal or metal products sufficient to bring about a cytotoxic effect.

[74] As to the correlation between pseudotumours and tissue necrosis, almost all cases in which a very large amount of necrosis is found are associated radiologically and clinically with very large pseudotumours. Extensive tissue necrosis is commonly seen in a patient with ARMD and a pseudotumour, but has been found in some patients without a pseudotumour. Most patients implanted with MoM implants that have failed further to ARMD will generally have extensive necrosis, but not necessarily so. Whilst minimal necrosis can be seen in ARMD (in the histological sense), there is a spectrum of histological findings and it is more common to see more extensive necrosis. In cases of minimal necrosis

other strong features would be required to point towards a finding of ARMD because one of the critical features would be missing.

[75] The state of the synovial lining is not a histological feature that is seen in ARMD. The synovium is the tissue covering the inner part of the joint capsule. The synovial membrane lines the joint cavity except over the articular cartilage, and the membrane is covered by a synovial lining which is normally one or two cells in thickness. Beneath this there is connective tissue. If areas of the synovial lining are missing, that may be consistent with ALVAL, but it is also seen in many other settings. Therefore, the state of the synovial lining is of little or no assistance in determining whether there is ARMD.

**Introduction and subsequent withdrawal of the Mitch/Accolade THR product**

***Entry into market***

[76] As already narrated, large head MoM THRs were developed in the late 1990s and became popular in the early 2000s. At one stage during 2000-2010, MoM was the commonest bearing surface implanted, particularly in the young and active. Stryker manufactured a range of femoral stem products, including the Accolade TMZF stem which had been introduced in about 2001, but it wished to enter the market for provision of MoM THRs. Stryker accordingly entered into an agreement in 2005 with Finsbury for the development, manufacture and supply of a metal acetabular cup and femoral head that would be compatible with its Accolade stems. The consequence was the production by Finsbury of the Mitch range of products which, together with Stryker's Accolade stem, were marketed as the Mitch TRH [sic] system. This system was marketed to surgeons as a "clinically proven joint innovation", although it was acknowledged by Mr Baker in cross-examination that the words "clinically proven" could only be accurately regarded as

applicable to MoM THRs in general, and not to the Mitch/Accolade product in particular. It was never, for example, the subject of a randomised control trial or staged market introduction.

[77] The Mitch/Accolade product is fully described in the expert report of Dr Burke who, as one of those responsible for marketing it on behalf of the manufacturers, was well informed as to its features. The following are excerpts from her description. The Mitch TRH System was designed to replicate successful MoM hip resurfacing devices on the market at that time. The bearing surface dimensions and tolerances of the Mitch TRH modular head replicated the bearing surface of the Mitch TRH resurfacing head to ensure compatibility with the Mitch TRH cup. As well as being provided in size variants, the modular heads were provided in "offset" variants to allow for intra-operative restoration of the hip. The main difference between the Mitch TRH head and other large diameter MoM modular heads was that the under-surface of the head was closed in to avoid a cavity that could harbour low-grade infection or the accumulation of soft tissue/debris. The most common head size was 54mm (as in the pursuer's implants).

[78] The Mitch TRH modular head was specifically designed to be compatible with all Stryker V40 stems and was therefore manufactured with the female dimensions of the V40 taper. The most commonly used stem was the Accolade stem, which was Stryker's most used stem in the younger patient population. It was an uncemented stem designed for implantation without bone cement. It was commonly used in MoCP and CoC devices as well as MoM. The alternative stem with which the Mitch TRH was used was the Exeter stem, a cemented stem generally used in older patients with lower bone density. The Accolade femoral stem had a trapezoidal neck designed to allow for an improved range of motion. It was manufactured from a titanium alloy known as TMZF (titanium–

molybdenum–zirconium–iron). TMZF was a proprietary material developed by Stryker to have a Young's modulus (a measure of stiffness) that was lower than conventional titanium alloys.

[79] The Mitch/Accolade product became commercially available in the UK in 2006. It was supplied along with instructions for use ("IFU"). The section in English runs to two pages in very small point size; a text in more easily legible print size was helpfully provided by the pursuer for use at the proof. The IFU contained a section entitled "Possible Adverse Effects" which described a very wide range of such effects. It included the following passage:

> "Corrosion of metal implants leading to metallic ion release in the patient occurs, to some extent, with a well-fixed implant, but it will be increased if the implant is loose or articulation is metal on metal. The long-term effects of metal on metal articulations are not fully understood although they have been used for many years without reports of directly related clinical problems. There may however be some adverse reactions to metal particles, and metal ion release that may lead to cytotoxicity, genotoxicity, mutagenicity, hypersensitivity and carcinogenicity.
>
> While the expected life of total hip replacement components is difficult to estimate, it is finite. These components are made of foreign materials, which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physicochemical factors, which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
>
> Surgeons should warn patients of all the Possible Relevant Adverse Effects."

[80] The level of sales of the Mitch/Accolade product was never high in comparison with rival products. Mr Baker explained that this was because Stryker had come late to the market, after other products had become well established.

[81] After Finsbury was acquired by Depuy in 2009, it continued for a time to implement its contractual obligations to Stryker. The supply agreement was due to terminate in 2011. It was not renewed. According to Mr Pandiscio's evidence, this was because Depuy had no

desire to renew an agreement to manufacture and supply a product to a commercial competitor. I accept that this was part of the reason why manufacture and supply of the Mitch TRH system ceased in about 2011, but I do not accept that it was the predominant consideration. As the defenders' witnesses accepted, sales of MoM THRs generally had sharply declined by the end of the 2000s. Sales figures for the Mitch/Accolade product show that 973 were sold in 2008, 468 in 2009, 212 in 2010, and 29 in 2011.

***Expression of orthopaedic concerns***

[82] The reason for the general decline in MoM THR sales was that concerns had begun to be expressed among orthopaedic professionals about revision rates and potential difficulties in carrying out revision operations. One of the first papers to be published, in July 2008, was written by a team of clinicians and scientists, including Professor Pandit (as lead author) and Professor Gill, at the Nuffield Orthopaedic Centre, Oxford. This paper[3] reported an incidence of soft-tissue mass, which the authors described as a pseudotumour, in a group of patients (all female) experiencing problems after MoM hip resurfacing, ie not THR. The estimated incidence was approximately 1% of MoM resurfacing patients at five years. Further investigation was recommended. These observations were initially greeted with surprise and scepticism by the orthopaedic community. In 2009 the Nuffield team published a further paper (Grammatopoulos et al, including Professors Pandit and Gill)[4] reporting that revision surgery in a group of MoM resurfacing patients with symptomatic pseudotumours had a poor outcome because of the associated soft tissue destruction. A

[3] H Pandit et al "Pseudo-tumours associated with metal-on-metal hip resurfacings", J Bone Joint Surg [Br] 2008.90-B:847-51.
[4] G Grammatopoulos et al "Hip resurfacings revised for inflammatory pseudotumour have a poor outcome", J Bone Joint Surg [Br] 2009.91-B:1019-1024.

further paper (Mahendra, 2009)[5] by the Nuffield team, written primarily from a histopathological perspective, described necrosis and inflammation in periprosthetic soft tissues in failed second generation MoM resurfacing arthroplasties, in response to the deposition of CoCr wear particles. ARMD was first reported at a national orthopaedic conference in 2008-2009, and awareness of it increased during the next two to five years as a consequence of the publication of scientific papers in peer reviewed journals. An expert committee set up by the Medicines and Healthcare Products Regulatory Agency ("MHRA") in April 2010 further developed awareness amongst clinicians, patients and others.

[83] In 2012, public concern regarding the safety of MoM implants was increased by the broadcasting of the results of an investigation by the British Medical Journal and BBC Newsnight. An article published in February 2012 by the BMJ's features editor proclaimed, somewhat sensationally:

> "Hundreds of thousands of patients around the world may have been exposed to toxic substances after being implanted with poorly regulated and potentially dangerous hip devices, a BMJ/BBC Newsnight investigation reveals this week. Despite the fact that these risks have been known and well documented for decades, patients have been kept in the dark about their participation in what has effectively been a large uncontrolled experiment."

***Medical device alerts***

[84] The first medical device alert ("MDA") in relation to MoM hip replacements was issued by the MHRA in April 2010. The alert stated *inter alia* as follows:

> "**Problem**
>
> The majority of patients implanted with MoM hip replacements have well functioning hips and are thought to be at a low risk of developing serious problems.

[5] G Mahendra et al "Necrotic and inflammatory changes in metal-on-metal resurfacing hip arthroplasties", Acta Orthop 2009;80:653-9.

> A small number of patients implanted with these hips may, however, develop progressive soft tissue reactions to the wear debris associated with MoM articulations. The debris can cause soft tissue necrosis and adversely affect the results of revision surgery. Early revision of poorly performing MoM hip replacements should give a better revision outcome."

The action required of orthopaedic professionals by the MDA alert was to "put systems in place for the follow-up of patients implanted with MoM hip replacements including, where appropriate, blood metal ion measurements and cross sectional imaging".

[85] Revised MDAs were issued on 2 April 2012 (for the Mitch/Accolade product in particular) and on 25 June 2012 (for all MoM hip replacements). The problem identified in the April MDA was the same. The action required in the June MDA now differed depending upon whether the hip replacement had been a resurfacing, a THR with an acetabular head diameter of less than 36mm, or a THR with a head diameter of 36mm or more. Within the latter category, the action required depended upon whether or not the patient was symptomatic, but one recommendation common to both symptomatic and asymptomatic patients was for annual follow-up for the life of the implant.

[86] On 26 April 2012, a few weeks after the issuing of the revised MDA for the Mitch/Accolade product, an "urgent" field safety notice ("FSN") was issued by Depuy and Stryker regarding the product. According to Ms Hunter, a FSN is a communication from the manufacturer identifying that a product may not be performing as intended by the manufacturer, and explaining the actions to be taken by customers to reduce the specified risks. The problem identified was that review of post-market surveillance data suggested a higher than expected revision rate for the product. The action to be taken was stated tersely: "Do not implant [the Mitch/Accolade product]". As regards patients who had received implants, recipients of the notice were referred to their local orthopaedic association for

detailed information related to the treatment of patients with MoM articulations. In the UK context I take this to be a reference to the then current MDA.

[87] A useful summary of the thinking of orthopaedic professionals as at 2013 is provided in a review article[6] by Mellon, Liddle and Pandit. Having narrated the history of hip replacement surgery, the authors made the following observations (in section 3.3) concerning MoM hip replacements:

> "Metal-on-metal (MoM) hip replacement became very popular in the middle part of the last decade. It promised to be a low wearing bearing surface, with the added distinction of allowing hip resurfacing, where, rather than cutting the femoral neck and inserting a stem into the femur, the femoral head is resurfaced with a metal cap. Metal-on-metal hip resurfacing arthroplasty (MoMHRA) promised improved mechanical performance, less bone resection and, if necessary, easier revision surgery.
>
> However, whilst there is evidence that MoMHRA works well in young active men, the failure rates of MoMHRA in women and of metal-on-metal THR in both sexes are significantly higher than expected. Average failure rates at seven years are 11.8% for MoMHRA and 13.6% for metal-on-metal THR, although failure rates vary with the brand used (one brand of MoM THR was reported to have a failure rate of 22% at five years). This compares with rates of 3.3% – 4.9% for hip implants made of other materials. This high failure rate appears to be due to the pro-inflammatory effects of submicron wear particles; the effects of long-term exposure to these particles is largely unknown. In addition to the high failure rate, the mode of failure is a major concern. These failures typically involve soft tissue and bone disruption which can be massive, leading to severe functional impairment and extremely challenging revision surgery. These reactions have been referred to by a number of terms such as adverse reaction to metal debris (ARMD), aseptic lymphocytic vasculitis associated lesions (ALVAL), adverse local tissue reaction (ALTR) and pseudotumour."

[88] Since 2012, the implantation of MoM THRs has stopped altogether, although some MoM hip resurfacings continue to be performed on patients, including the tennis player Andy Murray, for whom this is considered by surgeons to be the appropriate option.

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[6] 2 SJ Mellon et al "Hip replacement: landmark surgery in modern medical history", Maturitas 2013 Jul; 75 (3): 221-226.

**The question for determination at the proof**

[89] Against the foregoing background, the question for determination at the proof was agreed by the parties to be as follows:

> "Does the admitted inherent propensity of metal on metal hip prostheses to shed metal debris through wear in use (including trunnion wear), and the admitted risk that some patients may suffer an adverse reaction to such metal debris that may necessitate early revision, render the product* less safe than persons generally were entitled to expect and thus defective within the meaning of the 1987 Act, taking account of all of the circumstances, including the following particular circumstances relied upon by the pursuer:
>
> 1. The knowledge reasonably to be expected of the body of orthopaedic surgeons responsible for advising patients as to the choice of prosthesis, pre and post supply;
>
> 2. The sufficiency of disclosure of the likelihood and severity of such risks of the product within the literature supplied in relation to the product, including the Instructions for Use; in particular, having regard to point 1;
>
> 3. Advice and warnings issued by the relevant regulatory authorities post supply;
>
> 4. Advice and warnings issued by the manufacturers and suppliers post supply;
>
> 5. The combination of a titanium alloy stem and a cobalt chromium head;
>
> 6. The date of supply of the product;
>
> 7. The fact that the product is no longer supplied?"

* "The product" is identified as being the combination of Mitch acetabular cup and femoral head and Accolade stem.

**The law**

***Consumer Protection Act 1987***

[90] Section 2(1) of the Consumer Protection Act 1987 provides that "where any damage is caused wholly or partly by a defect in a product, every person to whom subsection (2) below applies shall be liable for the damage". Among the persons listed in subsection (2) is

the producer of the product, defined in section 1(2) to mean, *inter alia*, the person who manufactured it. Section 3 then provides as follows:

> "(1) Subject to the following provisions of this section, there is a defect in a product for the purposes of this Part if the safety of the product is not such as persons generally are entitled to expect; and for those purposes 'safety' , in relation to a product, shall include safety with respect to products comprised in that product and safety in the context of risks of damage to property, as well as in the context of risks of death or personal injury.
>
> (2) In determining for the purposes of subsection (1) above what persons generally are entitled to expect in relation to a product all the circumstances shall be taken into account, including—
>
> > (a) the manner in which, and purposes for which, the product has been marketed, its get-up, the use of any mark in relation to the product and any instructions for, or warnings with respect to, doing or refraining from doing anything with or in relation to the product;
> >
> > (b) what might reasonably be expected to be done with or in relation to the product; and
> >
> > (c) the time when the product was supplied by its producer to another;
>
> and nothing in this section shall require a defect to be inferred from the fact alone that the safety of a product which is supplied after that time is greater than the safety of the product in question."

[91] It is common ground between the parties that the question whether there is a defect in a product falls to be determined as at the date of supply by its producer of the product said to have been defective. The practical effect of that consensus in the present case is that the question whether there was a defect in the prostheses implanted in the pursuer falls to be determined as at 2009, when he received the implants, and not, for example, at an earlier date when MoM THRs generally or the Mitch/Accolade product in particular came on to the market. (I note in passing that the trial in *Gee* proceeded on the basis that it was common ground that the level of safety that the public was entitled to expect had to be evaluated at the time when the product was first put on the market by the producer, which in the case of

both the prosthesis at issue in *Gee* and the Mitch/Accolade product was 2002. I was informed, however, that *Gee* proceeded on this basis because it was agreed that nothing turned on whether the time of supply was taken to be the date when the product was first put on the market or, alternatively, any of the various dates on which prostheses were supplied to the claimants.)

[92] Under section 4(1)(e), it is a defence for the producer to show that the state of scientific and technical knowledge at the time when the product was supplied was not such that a producer of products of the same description as the product in question might be expected to have discovered the defect if it had existed in his products while they were under his control. This is known as the "state of the art" defence. The defenders have reserved their position in relation to it, but it did not fall within the restricted scope of the proof before me.

***Council Directive 85/374/EEC***

[93] The 1987 Act implemented the UK's obligations under Council Directive 85/374/EEC "on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products". It is unnecessary to set out any of the provisions of the directive itself, because it has not been suggested that there is any conflict between them and the implementing legislation. It is, however, worth noting one or two of the recitals:

> "…Whereas approximation of the laws of the Member States concerning the liability of the producer for damage caused by the defectiveness of his products is necessary because the existing divergences may distort competition and affect the movement of goods within the common market and entail a differing degree of protection of the consumer against damage caused by a defective product to his health or property;

> Whereas liability without fault on the part of the producer is the sole means of adequately solving the problem, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production;
>
> …
>
> Whereas, to protect the physical well-being and property of the consumer, the defectiveness of the product should be determined by reference not to its fitness for use but to the lack of the safety which the public at large is entitled to expect…
>
> Whereas a fair apportionment of risk between the injured person and the producer implies that the producer should be able to free himself from liability if he furnishes proof as to the existence of certain exonerating circumstances…"

[94] The parties were in disagreement as to the principal purpose or purposes of the 1987 Act. On behalf of the pursuers it was submitted that the principal objective of the Act was, as its name implies, consumer protection. Reference was made to a statement to that effect by the Lord Advocate (Lord Cameron of Lochbroom) when introducing the bill for its second reading in the House of Lords (HL Deb, 8 December 1986, vol 482, column 1003). The Act, it was submitted, should be interpreted on the basis that its overriding objective is to provide effective protection for the consumer.

[95] On behalf of the defenders it was submitted that the Directive which the Act implemented had had a variety of purposes, of which consumer protection was only one. Reference was made to statements to that effect in a number of decisions of the European Court of Justice, including *Commission* v *France* [2002] ECR I-3827. The Directive had sought to balance the interests of the consumer and the producer by harmonising the level of protection afforded to consumers across member states: *Sanchez* v *Medicina Asturiana SA* [2002] ECR I-3905 at paragraph 26.

[96] In my opinion there is no justification for construing either the Directive or the Act in a manner more favourable to the consumer than to the producer. As the Advocate General

(Szpunar) observed in *Novo Nordisk Pharma GmbH* v *S* (Case C-310/13; EU:C:2014:1825) at paragraphs 16- 20:

> "16. According to the first recital in the preamble thereto, Directive 85/374 was adopted, as regards EU law, in order to prevent distortion of competition, adverse effects on the movement of goods within the common market, and differences in the level of consumer protection against damage caused by defective products. According to that recital, those adverse phenomena come about because of divergences in the laws of the Member States concerning the liability of producers for damage caused by the defectiveness of their products.
>
> …
>
> 19. To my mind, it is clear that, in order to attain those objectives, account has to be taken of the various interests that may come into play in this connection. As the Court has found, 'the limits set by the [EU] legislature to the scope of ... Directive [85/374] are the result of a complex balancing of different interests. As is clear from the first and ninth recitals in the preamble to the Directive, those interests include guaranteeing that competition will not be distorted, facilitating trade within the common market, consumer protection and ensuring the sound administration of justice'. I believe it possible to apply that finding not only to the scope of the directive but also to the rights and obligations arising from it.
>
> 20. This leads to the conclusion that consumer protection in general, and the attainment of the highest level of protection in particular, is not the only — or even the principal — objective of Directive 85/374. It is only one out of a number of considerations of equal weight which enter into the balance that the legislature sought to strike by means of that legal act."

[97] In *Gee*, Andrews J expressed the view at paragraph 73 that "…whilst the effective protection of consumers is a key objective of the Directive, it is not the main or overriding objective. It has equal status with the other objectives." On the basis of the authorities cited, I respectfully agree, and I reject the pursuer's submission to the contrary. It is undoubtedly true that, at least in the United Kingdom, the protection of consumers was materially enhanced by the introduction of no-fault liability. But that was only one of the objectives of the Directive and, notwithstanding the words used by the Lord Advocate when introducing the bill, the European case law is quite clear that when approaching the task of interpreting the Act, the court is not entitled to give it priority over the others.

[98] That analysis is reinforced by the judgment of the Court of Justice in *W* v *Sanofi Pasteur* [2017] 4 WLR 171, a reference by the French Cour de Cassation for a preliminary ruling, in which the question was whether article 4 of the Directive (which requires the injured person to prove the damage, the defect, and the causal relationship between the two) precluded a system of evidential presumptions by which the existence of a causal relationship between a defect attributed to a vaccine and injury sustained would always be held established if certain indications were present. The Court ruled that national rules of evidence may not undermine the apportionment of the burden of proof prescribed by the Directive, nor (at paragraph 27) "the effectiveness of the system of liability provided for under [the Directive] or the objectives pursued by the EU legislature by means of that system".

***Court of Justice case law on the Directive***

[99] The case of *Boston Scientific Medizintechnik GmbH* v *AOK Sachsen-Anhalt — Die Gesundheitskasse* [2015] 3 CMLR 173, a reference by the German Federal Court of Justice for a preliminary ruling, concerned a defect discovered in pacemakers which could lead to premature battery depletion, resulting in loss of telemetry and/or loss of pacing output without warning. As a consequence, the supplier recommended physicians to consider replacing such pacemakers for the patients affected. Following that recommendation, the pacemakers previously implanted in two patients who had medical insurance cover with AOK were replaced by other pacemakers provided free of charge by the manufacturer. The insurance company sought reimbursement of the costs of implantation of the original pacemakers. There was no evidence as to whether the devices implanted in those two

particular patients were faulty, and the question was whether those devices were defective in terms of the Directive. The Court observed (at paragraphs 37-40):

> "37 …A product is defective when it does not provide the safety which a person is entitled to expect, taking all the circumstances into account, including the presentation of the product, the use to which it could reasonably be expected that it would be put and the time when the product was put into circulation. Moreover, according to the sixth recital in the preamble to [the] Directive, that assessment must be carried out having regard to the reasonable expectations of the public at large.
>
> 38 The safety which the public at large is entitled to expect, in accordance with that provision, must therefore be assessed by taking into account, inter alia, the intended purpose, the objective characteristics and properties of the product in question and the specific requirements of the group of users for whom the product is intended.
>
> 39 With regard to medical devices such as the pacemakers and implantable cardioverter defibrillators at issue in the main proceedings, it is clear that, in the light of their function and the particularly vulnerable situation of patients using such devices, the safety requirements for those devices which such patients are entitled to expect are particularly high.
>
> 40 Moreover, as observed, in essence, by the Advocate General at paragraph 30 of his Opinion, the potential lack of safety which would give rise to liability on the part of the producer under Directive 85/374 stems, for products such as those at issue in the main proceedings, from the abnormal potential for damage which those products might cause to the person concerned.
>
> 41 Accordingly, where it is found that such products belonging to the same group or forming part of the same production series have a potential defect, it is possible to classify as defective all the products in that group or series, without there being any need to show that the product in question is defective. "

The question whether the product at issue in the present case was defective must likewise be approached on the basis of the reasonable expectations of the public at large, taking into account *inter alia* the intended purpose, the objective characteristics and properties of the product, and the specific requirements of the group of users for whom the product was intended.

***English case law on the 1987 Act***

[100] There have been surprisingly few cases in England and Wales in which the statutory test in section 3 of the 1987 Act has been subjected to analysis. Counsel's submissions in the present case focused on three first-instance judgments, two of which were concerned with MoM total hip replacements. I propose to extract from those cases the propositions of a general nature which I have found to be of assistance in my own analysis.

A v National Blood Authority

[101] In *A* v *National Blood Authority* [2001] 3 All ER 289, the claimants had been infected with Hepatitis C through blood transfusions which had used blood from infected donors. They brought a claim for damages under the 1987 Act against the authorities responsible for production of blood and blood products. In a lengthy and complex judgment, Burton J held *inter alia* (i) that for the purposes of the Directive and the Act, products could be categorised either as "standard" products, which are and perform as the producer intends, or "non-standard" products, which are different from the standard product because they are deficient or inferior in terms of safety, and where it is the harmful characteristic present in the non-standard product, but not in the standard product, which has caused the damage; (ii) that "avoidability" was *not* one of the circumstances to be taken into account under section 3 of the Act, even in respect of a harmful characteristic in a standard product, as the purpose of the legislation was to exclude consideration of fault or negligence; and (iii) that the test is not that of an absolute level of safety: the requisite degree or level of safety is not what is actually expected by the public at large, but rather what they are entitled to expect. On this latter point it was common ground in *A* v *NBA* that the expression "legitimate expectation" could be used in preference to "entitled expectation", so long as it was recognised that the former expression did not carry its administrative law connotations.

[102] *A* v *NBA* was concerned with what Burton J characterised as a non-standard product. As regards standard products, Burton J proposed the following approach:

> "If a standard product is unsafe, it is likely to be so as a result of alleged error in design, or at any rate as a result of an allegedly flawed system. The harmful characteristic must be identified, if necessary with the assistance of experts. The question of presentation/time/circumstances of supply/social acceptability etc will arise as above. The sole question will be safety for the foreseeable use. If there are any comparable products on the market, then it will obviously be relevant to compare the offending product with those other products, so as to identify, compare and contrast the relevant features."

Wilkes v Depuy International Ltd

[103] In *Wilkes* v *Depuy International Ltd* [2017] All ER 589, the claimant had undergone a MoM THR using components manufactured by the defendants which included a steel femoral shaft called a C-Stem. The stem fractured and in the course of revision surgery there was evidence of metallosis around the joint. A trial was ordered of the preliminary issue of whether, having regard to the failure of the C-Stem by fracture, the manufacturer was liable to the claimant under section 3 of the 1987 Act. That question was answered by Hickinbottom J in the negative. In so doing, Hickinbottom J stated a number of propositions which, for my part, I regard as uncontroversial:

- The Directive and the Act focus not on the acts or omissions of those involved in production, but rather upon the condition or state of the product itself (para 63);
- The condition of the product required by the Directive and the Act is not put in terms of fitness for purpose or efficacy, but rather in terms of safety and only in terms of safety, the hallmark of defect being a lack of safety (para 64);
- Safety is inherently and necessarily a relative concept. In the case of a medical or medicinal product, there cannot be a sensible expectation that it is entirely risk-free. Potential benefits have to be balanced against risks (para 65);

- The test for safety requires an objective approach. The level of safety is not assessed by reference to actual expectations of an actual or even a notional group of individuals. Section 3 is concerned with what persons generally are entitled to expect as a matter of law (para 69);
- It follows that in considering whether a product suffered from a defect, the court must assess the appropriate level of safety, exercising its judgment, and taking into account the information and the circumstances before it, whether or not an actual or notional patient or patients, or indeed other members of the public, would in fact have considered each of those factors and all of that information (para 72);
- although a claimant must prove causation in the sense of showing a causal link between the defect and damage, he is not required to prove the cause of that lack of safety or why the product failed (para 73).

[104] At paragraph 71, Hickinbottom J accepted a submission that Burton J's use of the expression "legitimate expectation" as a substitute for entitled expectation was an unnecessary and unhelpful gloss on the Act. I respectfully agree; the statutory language does not in my view require any such gloss. On the question whether "avoidability" was a relevant consideration in application of the statutory test, Hickinbottom J observed (para 85):

> "I accept that, in considering avoidability, there is a danger of unduly focusing upon the acts and omissions of the designer/producer of the product, rather than the product itself. However, I consider that whether, and the ease with which and extent to which, a risk might be avoided, may, in appropriate cases, be a circumstance that is relevant to the question of level of safety and therefore defect under the Act; although, in respect of a medicinal product such as a prosthesis, I consider a detailed consideration of the discrete question of whether a particular risk is or is not 'avoidable' is unlikely to be fruitful."

Again I respectfully agree. As Hickinbottom J put it at paragraph 89, "…the ease and extent to which a risk can be eliminated or mitigated may be a circumstance that bears upon the issue of the level of safety that the public generally is entitled to expect".

[105] Hickinbottom J then addressed the standard/non-standard dichotomy adopted by Burton J in *A* v *NBA*, and expressed the following view (para 94):

> "…The categorisation of defects into 'standard'/'non-standard', as a classification, is unnecessary and undesirable. It is not, of course, a classification deriving from the Directive or Act. In my judgment, whether a particular product is within the producer's specification, and is compliant with relevant standards… may be relevant circumstances in relation to whether the level of safety is that to which persons generally are entitled to expect; but to raise the distinction to a rigid categorisation is positively unhelpful and potentially dangerous. "

This criticism of the dichotomy has itself been the subject of adverse academic comment. For example, Professor Donal Nolan (at [2018] 134 LQR 176) observed that within the above dictum there is acknowledgment that the question whether a particular product is within the producer's specification may be a relevant circumstance. For my part, I accept that there is nothing in the Directive or the Act to invite the imposition of a rigid categorisation, but it seems to me that it is almost inevitable that in the course of identifying whether or not a product is defective, as statutorily defined, there will be some focus on whether or not the particular product at issue in the case was or was not within the producer's design specification.

[106] At paragraphs 99 to 108, Hickinbottom J considered the relevance of, firstly, regulatory approval and, secondly, warnings and other IFU. As regards the first of these, he observed that although regulatory approval is not an automatic defence under the Act, such approval may be evidence that the level of safety of the product was that which persons generally were entitled to expect. As regards warnings and IFU, he noted that in the case of

medical products these will usually be addressed not to the patient/consumer but to a learned intermediary. He observed (para 108):

> "…The fact that there is a learned intermediary does not provide a complete or automatic defence for a producer of a medicinal product. However, particularly in respect of a product such as a prosthesis (in respect of which there is no obligation upon a producer to give any information direct to the patient), it seems to me unarguable that the fact that there is a learned intermediary (who has chosen a particular prosthesis for a particular patient and has available, not only his general professional knowledge, but also the specific IFU including warnings) is other than a relevant circumstance for the purposes of section 3 of the Act. That, again, appears to be the unanimous view of academic writers…"

Gee and others v Depuy International Ltd

[107] The third of the English cases was *Gee*, to which I have already referred. The judgment of Andrews J contains a detailed legal analysis including, at paragraphs 139-178, a discussion of legally relevant circumstances. To some extent, this discussion draws upon the judgments of Burton J in *A* v *NBA* and Hickinbottom J in *Wilkes*. For the purposes of this opinion I do not find it necessary to conduct an analysis of the judgment in *Gee*, except in so far as the pursuer in the present action took issue with it. Instead, I can state briefly that there is nothing in those paragraphs with which I have any material disagreement. In particular, I respectfully agree with Andrews J (and with Hickinbottom J) that the Directive and the Act require a flexible approach to the question of what may or may not be relevant circumstances, rather than any imposition of rules or rigid categorisations. In relation to the issue of whether a distinction falls to be made between standard and non-standard products, I agree with and adopt the following observations (para 160):

> "…The Court is entitled to have regard to all circumstances which may have a bearing on the assessment of the safety of the product; that those circumstances may differ, depending on the product and the nature of the complaint about it; and that there is nothing in the Directive that compels the Court to disregard a circumstance which plainly has a bearing on the level of safety which the public was entitled to expect in a given case, either because the product is 'non-standard' or because the

> regime is one of non-fault based liability. The Court simply needs to be vigilant not to let notions of negligence or other irrelevant considerations creep into that assessment."

It follows that I also agree that consideration of benefits of a medical or pharmaceutical product need not necessarily be confined to safety benefits; whether it is appropriate to weigh the benefits of a new product against known risks will depend upon the circumstances of a particular case.

[108] One of the criticisms directed by the pursuer against the decision in *Gee* was that it misinterpreted the purpose of the Directive and the Act, and failed to acknowledge that the principal objective was protection of the consumer. I have already explained why I reject that argument. At one stage in the pursuer's submissions it was suggested that *Gee* subordinated the importance of consumer protection. I can find nothing in the judgment to support that characterisation: it is simply not treated as carrying greater weight than the other objectives.

[109] It was further submitted on behalf of the pursuer that *Gee* failed to recognise the policy principles underlying the imposition of strict liability. Reference was made to the decision of the Supreme Court of New Jersey in *Beshada* v *Johns Melville Prods Corp* (1982) 90 NJ 191, in which it was emphasised that one of the most important reasons for applying strict liability was that the cost of injuries caused by a product are best allocated by manufacturers and distributors, by insuring their risks and incorporating the cost of insurance into the product price. This was equally applicable to unknown as to known risks. These policy considerations, it was contended, reinforced the proposition that consumer protection should be regarded as the main objective of the legislation. In my view this argument also falls foul of the clear statements in the recitals to the Directive and the judgments of the Court of Justice, to which I have already referred, that consumer protection

is only one of the objectives of the Directive, and hence of the Act. It would in my opinion be an error of law if I were to attribute any greater weight to consumer protection than to the other explicit objectives of the Directive. I therefore regard these criticisms of *Gee* as unfounded.

[110] The pursuer's other criticisms of *Gee* focused upon the approach taken by Andrews J to definition of the test of entitled expectation, and to the significance to be attached to the fact that the product has been withdrawn from the market. I address these criticisms later in my opinion.

***Application of the legal principles to the present case***

[111] At paragraph 89 above, I set out the question for determination at the restricted proof. The parties were ultimately in agreement that answering this question required a two-stage process:

- Firstly, what was the "entitled expectation" of persons generally in respect of the safety of the Mitch/Accolade product?
- Secondly, did the product fail to meet the entitled expectation?

[112] It is necessary to recall at this stage that the question for determination is expressly restricted to the Mitch/Accolade product. In terms of Burton J's standard/non-standard categorisation, the present case is a standard case: there was no suggestion that the prostheses supplied to the pursuer did not fall within the manufacturer's specification. However, much of the evidence led at the proof concerned MoM THRs generally, and there was also much discussion of the consequences of use of large head MoM THRs as a sub-category of product. None of the expert witnesses professed familiarity with the Mitch/Accolade product itself. In answering the question for determination, I must do so in

relation to the particular product with which this action is concerned. It will then be for others to assess the significance of my opinion in relation to other MoM THR products which are the subject of litigation in this jurisdiction.

**What was the entitled expectation?**

[113] When addressing the question of what persons generally were entitled to expect in relation to the safety of the Mitch/Accolade MoM THR, it is important to bear in mind that "safety" in this context is a legal concept and not a medical term of art. In their joint statement, Professors Breusch and Pandit observed that the concept of safety in relation to a hip implant was not one with which they were familiar as orthopaedic surgeons; the criterion that they recognised was "clinical efficacy", which as Professor Breusch explained in his evidence to the court meant using an implant that had a proven track record. It follows that it is for the court, rather than for the orthopaedic surgeons, to decide what, as a matter of law, was the entitled expectation in relation to the "safety" of the Mitch/Accolade product.

[114] Professors Breusch and Pandit were asked to consider, in their joint statement, the question of what, if any, expectation relating to performance and/or adverse health consequences a hip surgeon would be entitled to have in relation to a hip implant (a) generally, and (b) in relation to a MoM implant in 2009. In response, they noted that a hip implant should offer potential benefits to patients (and surgeons) which *could* include some or all of the following:

- Implantation via a straightforward and reproducible surgical procedure;
- A return to near normal function;
- A low rate of dislocation and other complications;

- A lower bearing wear rate and associated improved survivorship;
- The potential for straightforward revision surgery, when required;
- Predictable and surgically manageable mode of failure.

It was not contended that this response should of itself be taken to represent the entitled expectation of persons generally, or even the actual expectation of orthopaedic professionals, at the time of supply of the pursuer's prostheses. It is clearly aspirational in a number of respects, not least in that one of the potential benefits of a MoM implant was improved survivorship. Nevertheless it seems to me to provide a useful starting point in assessing entitled expectation in relation to a particular MoM product that was being promoted for use in 2009.

[115] I have already narrated the background to the development of third-generation MoM prostheses in general, and to the introduction of the Mitch/Accolade product in particular. An important aspect of that background is that large head MoM THRs were developed with particular regard to the problems posed by young and/or active patients requiring some form of hip replacement. Survivorship of conventional MoP implants was significantly lower for such patients than it was for older or inactive patients, the most common causes of failure being dislocation and stem fracture. It should be borne in mind, as is common ground, that age was not the only issue here: there was not merely a need to identify materials suitable for patients with a longer life expectancy at the time of original surgery; there was also a desire to address low survivorship of implants provided to older but active patients who wished to continue to pursue a lifestyle that would subject their prosthesis to additional stresses. A significant percentage of MoM THRs were in fact carried out on patients aged over 55.

[116] It is also relevant, in relation to entitled expectation, to recognise that the MoM THRs supplied during the period in question did not have the benefit of 10-year outcome data, which is considered the minimum benchmark by the UK-based Orthopaedic Data Evaluation Panel (ODEP). The shared view of Professors Breusch and Pandit was that any device without published 10-year data should be treated with caution, and that "staged market" introduction with close surveillance of any new device, prior to widespread use and marketing, should be the norm. In his oral evidence, Professor Pandit explained that before using a device which did not have 10-year outcome data he would familiarise himself with its perceived advantages and give the patient a choice, having informed the patient of the possible advantages, the absence of 10-year data, and the fact that he would normally use a different device. For his part, Professor Breusch's approach, which he readily accepted was conservative, was to decline to use any product unless it had acceptable 10-year data.

[117] I do not regard these factors – nor was it suggested that they should be regarded – as lowering the entitled expectation in relation to MoM implants below the level of entitled expectation in relation to other products with the requisite period of outcome data to support their use. They do, however, tend to suggest that the objective assessment required by section 3 of the 1987 Act should not conclude that there was an entitled expectation in 2009 that either MoM implants generally or the Mitch/Accolade product in particular would have a significantly *improved* survivorship as compared with MoCP implants then in common use. It seems clear that that was the hope, and perhaps even the belief, of many of the orthopaedic professionals who carried out MoM implant procedures during the 2000s: Professor Breusch, for example, agreed that at the time of introduction of third-generation MoM implants, the perceived benefits included a better long term outcome, a reduced risk of dislocation, and an increased range of movement. That does not, however, represent the

statutory test against which the existence or otherwise of a defect in the product must be measured.

[118] Against that background, the parties proposed apparently differing formulations of entitled expectation. The pursuer submitted that the entitled expectation in relation to the safety of the Mitch/Accolade product was that it was at least as good as the non-MoM products that would otherwise have been recommended by the surgeon for implantation. The defenders submitted that the entitled expectation was that the performance of the Mitch/Accolade product would not be materially worse than the products that it was intended to replace. This latter formulation accords with what appears to have been the position adopted by the claimants in *Gee*: at paragraph 247, Andrews J noted their case as being that at the time of the launch of the Pinnacle product at issue in that action, it carried with it "a materially increased risk of failure/early revision than relevant comparator implants" (because of the propensity to cause ARMD), and therefore fell below the standard of safety that the public generally were entitled to expect. It was not, therefore, regarded as enough for the claimants to demonstrate that revision rates for the Pinnacle product were higher than for the comparator; they had to establish that they were very much higher, and that that constituted a reliable measure of failure to meet entitled expectation.

[119] I have to say that I do not, for my part, see any persuasive reason why a THR patient should have to establish that revision rates were "very much" higher in order to establish that the product had a defect that met the statutory test in section 3. That appears to me to impose an unnecessary burden on the claimant. In the end I understood senior counsel for the defenders to accept that in the defenders' formulation the word "materially" could be read as meaning "not *de minimis*", and with that acceptance it seems to me that the formulations of the parties in the present case are largely reconciled: the entitled expectation

in relation to the Mitch/Accolade product can accordingly be stated as being that, subject to *de minimis* considerations, its level of safety would not be worse, when measured by appropriate criteria, than existing non-MoM products that would otherwise have been used. I shall return, when addressing the question whether the entitled expectation was met, to consider what the criteria ought to be.

[120] In assessing the entitled expectation in relation to the Mitch/Accolade product, I have attached little weight to the IFU supplied with it. Regulation 8 of the Medical Devices Regulations 2002 prohibits the supply of a medical device unless it meets the essential requirements set out in Annex I to EC Directive 93/42. One of those requirements, in paragraph 13 of Annex I, is that the device be accompanied by "the information needed to use it safely". Paragraph 13 is detailed and prescriptive. Although Ms Hunter's evidence was that IFUs are intended to be read by surgeons undertaking implantation operations, I am sceptical as to whether the instructions in this case had (or were expected to have) any real practical value. I have already observed that the IFU with the Mitch/Accolade product were in very small point size so as to be virtually illegible. As can be seen from the excerpt at paragraph 79 above, the instructions in relation to possible adverse effects were in highly general and heavily qualified terms. Professors Breusch and Pandit agreed in their joint statement that orthopaedic surgeons would not generally read IFUs in detail. It seems to me on the basis of the orthopaedic evidence that the quoted passage in the IFU would have added little, if anything, to the knowledge of any surgeon qualified to carry out a hip replacement operation, and accordingly that the IFU would have had no significant effect on entitled expectation in relation to this product.

**Did the product fail to meet the entitled expectation?**

*Introduction*

[121] I take as a starting point the following observation in the joint statement of Professors Breusch and Pandit: "The majority of patients with MoM implants are pain free and are able to enjoy activities of daily living with excellent outcome. The pain relief and functional improvement achieved with MoM or MoCP or MoHXLPE are similar". That statement does not of itself resolve the question before the court because it leaves a number of issues unaddressed, and in particular:

- Whether the "majority" with satisfactory or excellent outcome is smaller for MoM THRs than it is for comparable products;
- Whether, in relation to the minority, the unsatisfactory outcome is materially worse than for the minority who fail to achieve such an outcome with comparable products, for example in relation to survivorship of the implant or success of revision surgery;
- Whether there is any feature of the Mitch/Accolade product, either by itself or as a member of a category such as large head MoM THRs, which renders the statement inapplicable, or less applicable, to it.

If any of those questions were to be answered in the affirmative, that could indicate that entitled expectation in relation to the product had not been met. I turn therefore to address those issues.

*The pursuer's argument based upon withdrawal of MoM THRs from the market*

[122] The argument for the pursuer is founded strongly upon the fact that in the wake of the orthopaedic concerns and MDAs to which I have already referred, surgeons stopped recommending MoM THRs and they disappeared from the market. Nothing has changed in

that regard since 2012. In a 2016 paper[7], Matharu et al observed that "…the unacceptably high failure rates of stemmed MoM THA's are undisputed, with these devices no longer implanted worldwide" (although it should be noted that the primary references cited in support of this observation were published in around 2011-12). As Professors Breusch and Pandit put it in their joint statement, "In 2019, there is universal agreement that large head MoM THRs are no longer used (and are no longer available)". One consequence of this is that evidence as to whether or not MoM THRs are defective (according to the statutory definition) is less readily available than if they had continued to be supplied and implanted for a longer period of time; I return to this later. The point for present purposes is that by about 2012 there had emerged a consensus that failure rates (in terms of survivorship) of MoM THRs were higher than had been expected and compared unfavourably with other types of THR. Patients with MoM implants were advised to have more frequent and earlier monitoring than would otherwise have been the case, so that any problems would be identified early and at a time when they would not reduce the prospects of success of revision surgery. The mainstream media coverage already mentioned increased the number of MoM patients seeking advice about the necessity or desirability of revision surgery.

[123] In the meantime, members of various disciplines searched for an explanation of what at that time were perceived to be the unacceptable failure rates associated with MoM implants generally, and MoM THRs in particular. In the course of the proof reference was made to a large number of papers, mostly published in the Journal of Bone and Joint Surgery. Some of these papers reported original peer-reviewed research; many consisted of reviews of published material. A large number of other books and articles were cited in the

[7] GS Matharu et al "Risk Factors for Failure of the 36 mm metal on metal Pinnacle total hip arthroplasty", Bone Joint J 2017;99-B;592-600.

reports of the various experts who gave evidence. It is beyond the scope of this opinion to produce a comprehensive analysis of the views expressed in this published material, which spans the disciplines of orthopaedic surgery, bioengineering, histopathology, immunology and toxicology. It is, however, fair to say that no consensus emerges, with many of the articles concluding with a comment along the lines of "further research is necessary". My approach to the published material is guided, as it must be, by the views of the expert witnesses whose evidence has been presented to me. It should not, however, be assumed that because an article is not mentioned in this opinion, it has not been taken into account.

[124] I accept that expression of serious professional concerns, followed by the issuing of an official alert and the withdrawal from the market of an entire range of products constitutes powerful *prima facie* evidence that those products were not performing in accordance with expectation. But that is not necessarily the same as not performing in accordance with *entitled* expectation, and in assessing whether the latter has been established, I am able to proceed with the benefit of hindsight, and to have regard to material that is now available but was not available in 2012 when MoM THRs ceased to be used.

[125] I also accept, as senior counsel for the pursuer submitted, that although it was not necessary for him to show how or why the product in question has not performed in accordance with entitled expectation, it would add coherence to his case if he were able to do so. I turn, therefore, to the evidence relied upon by the pursuer to demonstrate what is said to be the defect in the product. In so doing, I bear in mind the reminder by Lord Hope of Craighead in *Dingley* v *Chief Constable, Strathclyde Police* 2000 SC (HL) 77, at page 89, that the function of the judge in a civil case is to decide whether the case has been made out on a

balance of probabilities, and not to apply the standard of proof that a scientist might adopt in forming a view as to whether a particular thesis has been proved or disproved.

***Is there a causal link between use of MoM implants and ARMD?***

[126] In posing the question in this way, I emphasise the "A" in ARMD, ie adverse, in the sense of harmful or damaging. I have already noted that it is a matter of agreement between the parties (i) that both MoM and MoP implants will inevitably produce debris, and (ii) that not all bodily reactions to debris can be categorised as adverse: some may be beneficial or neutral. In a 2016 article[8], Athanasou observed that

> "…in soft tissue and bone, regardless of whether the material is derived from a MoP or MoM prosthesis, there will be evidence to a greater or lesser extent of cell and tissue injury and a reparative response in which there is an innate and adaptive immune response to the material components of implant wear".

(I pause to record Professor Kimber's view that an adaptive immune response will occur only in some cases.)

[127] A significant difference between polyethylene particles on the one hand and metal particles on the other is that metal particles are very much smaller: they are nano particles invisible even through a microscope. They are also much more numerous. The question is whether there is a causal link between the production of metal debris of this kind and the symptoms experienced by some MoM patients, such as pseudotumours and soft tissue necrosis. Dr Duffus's view, expressed in his rebuttal report, was that abnormal reactions to the release of such nano particles were the probable causes of the phenomena that resulted

[8] N A Athanasou "The pathobiology and pathology of aseptic implant failure", Bone Joint Res 2016; 5:162-168.

in pseudotumours and adverse local tissue reactions ("ALTR"). In support of this view he referred to a 2016 article by Xia et al[9], which contained the conclusion:

> "…The nano-analysis of *in vivo* intracellular wear particles of three different classes of hip implants demonstrated that the particles' physical characteristics and metal composition are highly consistent in each class and correlate with histological differences in quantitative and qualitative aspects of the ALTR, indicating that the immunogenicity and toxicity of the particles is a leading factor in the onset and severity of the reaction".

[128] For his part, Professor Kimber addressed the question whether, and if so to what extent, the development of allergic sensitisation to metal played a role in ARMD and thus in MoM implant failure. He concluded, both in his written report and in his oral evidence, that there was no clear correlation between the two, but accepted that in situations of increased wear rate, the possibility that some susceptible subjects might acquire sensitisation to metal particles could not be excluded. In certain individuals, local inflammation would translate into tissue reaction which caused implant failure. Moreover, if the body's cytotoxic response got out of hand and provoked a strong inflammatory reaction, then that could lead to an adverse reaction to metal debris. He continued to emphasise, however, that he expected this to be a rare occurrence.

[129] I have mentioned that Dr Duffus was unfortunately unable to attend to give oral evidence. In his initial report he noted that the health risks related to the use of MoM THRs had yet to be clearly identified, but that it was reasonable to assume that they were higher than for other bearings because of the demonstrated higher level of metal ion release. In his view, the focus ought to be on cytotoxicity rather than sensitisation. In the joint statement, Dr Duffus and Professor Kimber were able to agree the following:

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[9] Z Xia et al "Nano-analyses of wear particles from metal-on-metal and non-metal-on-metal dual modular neck hip arthroplasty", Nanomedicine: NBM 2017; 13:1205-1217.

- Under some circumstances, wear from implants (metal, polyethylene and ceramic) can cause toxicity resulting in adverse health effects. However, this is critically dependent upon a number of factors, including individual sensitivity, and importantly the level of exposure to wear particles;
- It is likely that metal wear particles have a greater cytotoxic potential than other wear particles;
- If there were to be an adverse immunological reaction to metal wear then the patient would have to have acquired sensitisation. For sensitisation to be induced, and for a hypersensitivity reaction to be thereby elicited, there would be a need for a certain threshold of exposure;
- Any toxicological consequences of nano particles in the blood will be dependent upon a large number of variables, including the nature of the nano particles themselves and the level of exposure.

[130] When I turn to consider the evidence of the histopathologists, Dr Natu and Dr McCarthy, I do not find a great deal to add to that of Dr Duffus and Professor Kimber. It was a matter of agreement between Dr Natu and Dr McCarthy that although histopathologists can diagnose metallosis and ALVAL, which are observable phenomena, the question whether a reaction to metal debris was adverse so as to constitute ARMD was for clinicians to determine under reference to pain and/or loss of function. They further agreed (i) that metallosis as a pathological finding did not necessarily cause any symptoms, and (ii) that a diagnosis of ALVAL was not unique to MoM prostheses.

[131] In her rebuttal report, Dr Natu provided what she termed "a comprehensive overview of the histological appearances of periprosthetic tissues of failed MoM hip arthroplasties" and "a detailed explanation of the immunopathogenesis and sub-

microscopic pathology." The defenders maintained an objection to her evidence as straying beyond her field of expertise as a consultant histopathologist. In cross-examination Dr Natu fairly accepted that she would defer in immunological matters to the opinion of an immunologist, but equally fairly did not accept that it followed that she would defer to Professor Kimber on all immunological matters, regardless of what he said. In assessing her evidence I have treated it as authoritative within the field of histopathology, but have preferred to have regard to the evidence of Professor Kimber (and Dr Duffus) in relation to immunology. That being so, I find little in Dr Natu's histopathological evidence that goes beyond the parties' agreed position in the joint minute, as set out at the beginning of this opinion. Her rebuttal report includes the following observations in relation to the effect of metal debris:

> "In low wear conditions, the metal debris must be within the nano particle size range, not within the resolution of a light microscope, and possess the physical characteristics sufficient to generate a M1/Th1 response also promoting granuloma formation.
>
> With increasing chronicity, M2 response with fibrosis is seen which tries to limit the destruction but also results in formation of tertiary lymphoid organs and further destruction.
>
> At the other end of the ARMD spectrum, in high wear conditions, macrophages laden with metallic debris without a lymphocytic response are also seen to be associated with necrosis.
>
> Necrosis can be explained in part by frustrated phagocytosis, where an ineffective attempt is made to phagocytose non-degradable material causing extracellular release of enzymes and chemical mediators resulting in tissue damage."

It appears to me that this is largely saying the same, from a histological perspective, as Dr Duffus and Professor Kimber agreed, namely that metal debris may cause adverse health effects but only in unusual cases of high exposure.

[132] As regards Dr McCarthy, I have to say that I did not find his evidence particularly helpful. As the holder of dual qualifications in pathology and orthopaedic surgery he is exceptionally well qualified to give evidence on the matters at issue, and his curriculum vitae is extremely impressive. His written report was in most respects uncontroversial (except in his rejection of the term ARMD as "loaded and unhelpful"). However as a witness I found him dogmatic and unduly reluctant to approach questions put to him with an open mind. This may be because he has given evidence on behalf of Depuy in a number of cases in the United States, and in the course of so doing has developed fixed opinions. He did not, for example, wish to use the term ALVAL because it would buy him into what he called "the culture of metal on metal failure". I do not suggest that he departed from his obligation of impartiality, but his attitude lacked the flexibility that one would expect in relation to complex subject-matter. This was most clearly seen in his refusal to accept that it was possible to draw a correlation between a histological finding such as dead tissue and clinically-observed symptoms, such as pain. This appeared to be on the basis that in a different patient the same findings might be asymptomatic. His view was at odds with the other witnesses whose evidence I have summarised, and I prefer to follow the majority.

[133] I return, then, to the question whether I am satisfied that the evidence establishes that there is a causal link between the use of MoM implants and ARMD. The answer must, in my view be "Yes, but only in exceptional cases". I accept that the position is as described in the joint statement of Dr Duffus and Professor Kimber:

- Under certain circumstances metal debris may interact with the innate immune system and also, in some cases, with the adaptive immune system; that wear from implants can in certain circumstances induce sensitisation; that wear from

implants can cause toxicity; and that sensitisation and cytotoxicity can have adverse effects on health.

- But the occurrence of such consequences will be dependent upon a large number of variables, including in particular the level of exposure to metal debris.
- These consequences are not restricted to MoM implants.

[134] These findings appear to accord with the following conclusions reached in a chapter contributed by Matharu et al to a 2013 work[10]:

> "The present study has demonstrated that periprosthetic tissue responses in MoM hips revised for suspected ARMD were diverse with most lacking evidence of a convincing immunologically driven process. Where there is clinical suspicion of ARMD, only a small proportion showed all the true features of ALVAL. Given the diversity of histopathological responses observed, it is suspected different pathogenetic processes are responsible for periprosthetic tissue reactions to metal debris."

In other words, not only (as Dr Duffus and Professor Kimber concluded) is it the case that not all exposure to metal debris will result in ARMD, but also (as the Matharu chapter concluded) it is the case that hips revised for ARMD will not all exhibit damage derived from the same pathogenetic process.

[135] Put very shortly, I find that the pursuer has established, on balance of probabilities, that there *may* be a causal link between the creation of metal debris from a MoM THR and periprosthetic damage, but only in a minority of cases and in limited circumstances including high levels of exposure, and not necessarily for reasons peculiar to MoM THRs. That does not, in my opinion, of itself constitute a failure to meet entitled expectation.

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[10] G Matharu et al "A Clinicopathological Study of Metal on Metal Hips Revised for Suspected Adverse Reactions to Metal Debris", K. Knahr (ed), *Total Hip Arthroplasty.*

***Is there a causal link between MoM THR design and the creation of potentially harmful metal debris?***

[136] The next question to be addressed is whether there is a causal link between MoM THR design and the creation of metal debris that is capable of causing periprosthetic damage. To answer this question it is necessary to consider the biomechanical evidence: that is, primarily, the evidence of Professor Gill and Dr Burke.

[137] I begin once again by identifying certain matters that were not in dispute; these are derived largely from the joint statement by Professor Gill and Dr Burke:

- MoCP bearings operate in the boundary lubrication regime and CoC and MoM bearings also sometimes operate in the boundary regime, but the success of a MoM prosthesis requires it to operate in the mixed (ie boundary and full fluid film) lubrication regime.
- Any orthopaedic metal within the body will undergo some level of corrosion. Corrosion is associated with the release of metal ions from metallic surfaces. The CoCr alloy in a metal femoral head will undergo oxidation in the body and this will give rise to ionic forms of the metals.
- In all types of THR where a CoCr head is implanted on to a metal stem, corrosion generating Co and Cr debris will take place, regardless of the acetabular bearing surface. Wear debris will be generated from the bearing surfaces and from all interfaces. This wear debris will be both particulate and ionic.
- Processes giving rise to material loss at the taper are different from those at the bearing surface, and particles from the taper material processes may have a different morphology from those from the bearing surface. Some literature

suggests that wear debris from the taper junction is more biologically active than debris from the bearing surface, but there is no definitive evidence.

- There are no femoral stems designed exclusively for use with MoM bearings.

[138] The mechanism for production of potentially harmful metal debris by large head MoM THRs such as the Mitch/Accolade product was explained by Professor Gill as follows. Part of the rationale for developing large head MoM THRs was to reduce wear by optimising lubrication between the head and the acetabular cup, because larger heads have greater sliding speeds which would entrain more fluid into the joint. However, when lubrication was not optimal, such devices could generate higher frictional forces due to the longer moment arms arising because of the larger head diameters. Sub-optimal lubrication could occur, for example, after a period of rest when there was often no lubricant between the surfaces, and the friction would be considerably higher. Those higher forces would act on the trunnion, creating stresses and a risk of micro-motion during cyclic loading of the hip, such as occurs during walking. Micro-motion could give rise to fretting, a wear process which degraded the material surfaces in contact, and created spaces between mating parts of stem and head, allowing fluid ingress. With fluid ingress, there was the risk of crevice corrosion, in which accelerated material loss due to electrochemical activity could take place. The rigidity of the trunnion itself also influenced the risk of damage at the trunnion/head interface: the combination of a TMZF stem (with a lower Young's modulus) and a CoCr head (with a higher Young's modulus), as used in the Mitch/Accolade product, resulted in loss of material from the CoCr head. The physical and chemical effects just described would create metal debris at the trunnion/head interface which could in due course enter the periprosthetic tissue. The debris from this interface appeared to be more likely to cause ARMD, for reasons that were not understood.

[139] It followed from Professor Gill's biomechanical analysis that he considered that the Mitch/Accolade product had a higher than normal failure rate (in terms of survival periods) than other THRs because of the use of the large diameter CoCr femoral head with a titanium alloy stem, and in particular the Accolade stem whose TMZF alloy had a lower Young's modulus than standard titanium alloy. For his evidence of higher failure rates he relied upon the statistics quoted in the 2012 MHRA medical device alert. As he put it in his report:

> "The combination of the Mitch TRH with the press-fit Accolade stem made from TMZF, a less rigid alloy of titanium, has shown very high early failure rates, whilst those of the Mitch TRH resurfacing are much lower indicates that the trunnion/head interface plays a key role in these failures; as the bearing surfaces are identical between the resurfacing and total hip replacement variants of the Mitch TRH."

Another factor potentially contributing to trunnion wear would be a weak connection, due to surgical techniques necessitated by the larger-size head, between the head and the stem.

[140] I note in passing that Professor Breusch, approaching the matter from a surgeon's perspective, also attached importance to the combination of metals used in the head and stem of the Mitch/Accolade product. However, he expressed somewhat different concerns: he had been taught not to use a CoCr head with a titanium stem because they could stick together to the extent that in a revision operation it would not be possible to replace the head without also taking out an otherwise well-ingrown and well-functioning femoral stem. He also described gross trunnion failure, where fretting could deform the taper to such an extent that it fractured and the head would fall off.

[141] In the course of cross-examination, Professor Gill was referred to a number of papers, some reporting research and others consisting of reviews of published material, which stated that the evidence as to what caused trunnionosis was inconclusive. Some, but not all, of those papers were concerned with MoM devices; others were based upon reported results in relation to MoP THRs. One of the papers which did relate to a particular MoM THR

product (Whittaker, 2016)[11] included data showing that taper wear rates were measured at less than 10% of bearing wear rates. Professor Gill remained of the view that it was clear from NJR data that head size did have a relationship with hip failure, although it could not necessarily be said that the reason for this was trunnion failure. He did, however, ultimately accept, under reference to a research paper (Matthies, 2013)[12], that there was no consensus in the scientific community that a correlation between taper wear and symptoms of ARMD had been established.

[142] Before turning to the substance of Dr Burke's evidence, it is appropriate to note the basis upon which she was qualified to give expert testimony in this case. Although she has a PhD in biomedical engineering (on bipolar hips), she does not work in the field of academic research. Throughout her career she has worked for manufacturers of orthopaedic medical devices, including Stryker South Pacific, Australia, by whom she was employed, latterly as manager of market development, from 2006 until 2009. She participated in the marketing and launch in Australia and New Zealand of various products including the Mitch/Accolade product with which this action is concerned. Since 2010 she has worked as a self-employed consultant to the orthopaedic industry and profession. She was, unsurprisingly, cross-examined as to whether she could approach the issues in this case with the requisite degree of objectivity. For my part I found Dr Burke's evidence helpful and I am satisfied that she did her best to maintain impartiality and to assist the court. Apart from matters on which she spoke from personal experience, her evidence consisted of material derived from published sources.

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[11] RK Whittaker et al "Variation in taper surface roughness for a single design effects the wear rate in total hip arthroplasty", J Orthop Res 2017; 35(8):1784-1792.

[12] AK Matthies et al "Material loss at the taper junction of retrieved large head metal-on-metal total hip replacements", J Orthop Res 2013; 31(11): 1677-1685.

[143] Dr Burke disagreed with Professor Gill in a number of important respects:

- Professor Gill's statement in his written report that CoCr debris from the female taper on the femoral head was "strongly associated" with the development of adverse reactions was, in Dr Burke's view, unsupported by any evidence.
- The mechanism behind trunnion corrosion was, in Dr Burke's view, complex and probably multi-factorial, and not fully understood. No correlation had been demonstrated between femoral head size and the risk of fretting at the stem/head interface.
- There was no scientific evidence to support Professor Gill's hypothesis that the debris from the head/trunnion interface was more damaging to tissue than debris produced at the bearing surface.
- No definitive association had been established between trunnionosis and the impaction force used in assembly of the head on to the stem.

[144] Dr Burke did, however, accept Professors Breusch and Pandit's observation in their joint statement that the trunnion problem only arose as a result of the use of larger metal heads (ie greater than 36mm), subject to the qualification that larger metal heads were also used at that time in MoP devices. She further accepted that Professor Gill's biomechanical explanation was plausible as a contributing factor to trunnion wear and the consequent production of metal debris at the stem/head interface.

[145] It is not a criticism of Dr Burke to say that much of her evidence was negative in nature, consisting of refutation of assertions made by Professor Gill. I am satisfied that in so far as Dr Burke took issue with assertions by Professor Gill of causal links between trunnion wear and adverse health effects, on the ground that those links had not been scientifically demonstrated, she was well founded in doing so. It was apparent from Professor Gill's

evidence that in concluding that such links existed he was relying not upon biomechanical considerations but rather upon data published in the MDAs and by the NJR in relation to hip failures and survival periods. To that extent, therefore, his thesis that damage was being caused by trunnion wear was dependent upon the reliability of the published data.

[146] My conclusion in relation to the biomechanical evidence is that the pursuer, through the evidence of Professor Gill, has demonstrated a mechanism by which metal debris is capable of being produced in large head MoM THRs in a manner which would not occur either in THRs using smaller head sizes or in MoM resurfacings. That said, I am not satisfied that all of the necessary links in the chain between such a mechanism and adverse health effects have been established on balance of probabilities. In particular, I do not consider that there is any evidence that would entitle me to find that debris from the head/stem interface is, or is even potentially, more damaging than debris from the bearing surface. If anything, the evidence is unsupportive. The proportion of debris produced at the head/stem interface appears, as I have mentioned, to be small in comparison with that produced at the bearing surface. More significantly, it was not in dispute that the combination of a titanium alloy Accolade stem and a CoCr metal femoral head (whether a Mitch component or otherwise) has been used in many other implants including MoP THRs, and no evidence was led of metal debris with especially damaging characteristics having been produced by such combinations. I recognise that the possibility remains that special considerations may apply to large head devices, for the reasons given by Professor Gill, although those reasons did not include any explanation of why the mechanics of large heads might produce not only a greater amount of CoCr debris at the head/stem interface but also CoCr debris with greater propensity to cause tissue damage. In my opinion the latter proposition does not, at present, rise above the level of theoretical possibility. On the basis

of the evidence before me, in order to achieve the status of probability, it relies on drawing inferences from survival data which not only were founded upon by Professor Gill in arriving at his conclusions, but also provided the basis of the MDAs published in relation to MoM THRs including the Mitch/Accolade product.

***Criteria of entitled expectation in relation to the Mitch/Accolade product***

*Introduction*

[147] At paragraph 121 above, I set out the issues which, if any were resolved in favour of the pursuer, could indicate that entitled expectation had not been met in relation to the Mitch/Accolade product. Assessment of the performance of a medical device is discussed by Professor Platt in Part IV of his unchallenged report, prepared in accordance with instructions from the defenders' solicitors, to examine data on the revision rates of the Mitch/Accolade product and to assess its survivorship relative to performance benchmarks. Having noted that hip replacement devices could be evaluated against a variety of criteria, including safety, comfort, durability, range, smoothness of motion, and the activities that they facilitated, Professor Platt identified "time to revision" – to which I have also referred as survivorship – as a commonly reported outcome in joint registry reports and academic studies. This accorded with the evidence of Professor Breusch, who regarded revision rates as a very important measure of implant performance; Professor Pandit, on the other hand, considered that focusing on survivorship alone did not reflect the wide range of factors which, in clinical practice, were relevant to the "success" of a prosthesis. Professor Platt did observe that there were other possible measures including clinician-assessed diagnostics such as the Harris Hip Score, patient-reported outcome measures such as the Oxford Hip Score, and mortality and morbidity rates. Those measures have limitations, in that they can

be subjective, and require measurement of outcomes at multiple points in time. Professor Platt accordingly focused, as do most of the published materials, upon survivorship.

[148] Professor Platt's report does not include any specific discussion of prospects of success (or not) of revision surgery as a criterion. It does, however, appear to me that, given the prominence accorded to this issue at the time of the withdrawal from the market of MoM THRs such as the Mitch/Accolade product, I should have regard to it as a relevant criterion in assessing whether there was a failure to meet entitled expectation.

[149] As I have observed earlier in this opinion, the proof was concerned with the Mitch/ Accolade product and not with MoM THRs in general, or even with large head MoM THRs in general. Any finding that I make must be based upon evidence relating directly or by necessary implication to the Mitch/Accolade product. Because of the short period during which the product was on the market, such evidence is not in abundant supply. Professor Pandit never used it; Professor Breusch has never implanted any MoM device. Dr McCarthy was "not terribly familiar with exactly this combination": since he also said that it had not been used in the United States, I interpret this as no familiarity at all. I was not referred to any article specific to the Mitch/Accolade product and no-one suggested that any such article exists. It is necessary to make what one can of published data in relation to the product, properly interpreted. The evidence of Professor Platt is accordingly of importance.

*(ii) Revision rate/survivorship*

[150] Turning firstly to the issue of survivorship, the excerpt from Mellon, Liddle and Pratt (2013) set out at paragraph 87 above referred to the "high failure rate" of MoM THRs, citing average failure rates at seven years of 13.6% compared with rates of 3.3%-4.9% for hip implants made of other materials. The footnote reference for those figures is the 2012 British

Medical Journal article that I have mentioned, but the ultimate source was the NJR's 2011 Annual Report. The figures may be compared with those contained in Guidance issued in 2000 by the National Institute for Health and Clinical Excellence ("NICE"), which stated:

> "Using the most recent available evidence of clinical effectiveness, the best prostheses (using long term viability as the determinant) demonstrate a revision rate (the rate at which they need to be replaced) of 10% or less at 10 years. This should be regarded as the current 'benchmark' in the selection of prostheses for primary Total Hip Replacement (THR)."

Professor Platt noted that the ODEP criteria for categorising a THR product as "Class A" in relation to the NICE benchmark are revision rates of 3% at 3 years, 5% at 5 years, 7% at 7 years, and 10% at 10 years, and that in 2005, ODEP noted that the survivorship of a medical device would be within the NICE Guidance if the 95% confidence interval of the Kaplan-Meier cumulative revision rates estimate (i.e., 1 minus the Kaplan-Meier survivorship estimate) included the benchmark revision rate.

[151] In the particular case of the Mitch/Accolade product, the MDA issued in April 2012 referred to a revision rate of 10.7% at four years based on 271 patients recorded by the NJR. This figure was used by Professor Gill in his expert report for the present case. Professor Platt provided an analysis based on NJR supplier feedback data of the cumulative revision probability of the Mitch/Accolade product, disclosing a figure of 23.2% (95% confidence interval 18.4%, 28.9%) at 10 years; the figure for four years in the same table is 10.5% (95% CI 7.3%, 14.8%). So far as they go, therefore, the data from 2012 which informed the observations in the MHRA alert and the (latest available) data from 2018 are consistent with one another in showing, *prima facie*, a revision rate for MoM THRs significantly worse than rates for available alternatives.

[152] The thrust of Professor Platt's report, however, was to demonstrate that use of these figures as a measure of survivorship would create a misleading impression. For the

following reasons, in his opinion, registry data ought not to be used to measure current or predict future survivorship of hip implants:

1. Data in the NJR were incomplete. As of 2006, the rate for patients giving consent to their data being reported was only 74%, rising to over 90% by 2008, and the percentage of reported surgical procedures linkable to a particular patient's NHS records was only 69%, rising to 90% by 2012. The omission of a patient from the data could increase or decrease the estimated survivorship; however the direction of any bias was unknown.

2. Data on the Mitch/Accolade product suffered from small sample sizes. There were only 271 in the NJR supplier feedback data, compared with, for example, 11,966 uncemented Depuy Pinnacle devices. Small samples gave rise to wide confidence intervals and low certainty. They also limited the methodology available to detect "outlier" surgeons (discussed below).

3. There were few sources of survivorship estimates specific to the Mitch/Accolade product. The UK NJR, for example, did not include estimates specific to this device.

4. Survivorship estimates were currently only available for 10-12 years of follow-up time. This made it difficult to predict how survivorship estimates would evolve in the longer term. Only a few implants informed the estimates for longer follow-up times: for example, as at 2018, only 98 hips were at risk at 10 years.

5. Survivorship estimates based on observational data could reflect "confounding" (ie selection bias), in that patients' selection of implant devices might be related to characteristics that also influenced expected survivorship. If patients and doctors selected implants based on factors that themselves influenced or otherwise correlated with survivorship, then estimated differences in survivorship across implants or over

time might reflect differences in patient or doctor characteristics rather than differences in implant design. Some potentially confounding factors were observable and measurable, but registry data were incomplete or non-existent. Of particular importance in relation to the Mitch/Accolade product were patients' activity levels. The product was developed for young and/or active patients, so activity levels were potentially an important influence on the choice of implant *and* on survivorship. However, the registry data lacked information on patients' activity levels. In the absence of this information, it was not possible directly to assess the effect of activity levels on implant survivorship, nor to differentiate between the effects of activity levels and implant design when comparing survivorship across devices. High body mass index (BMI) had also been found to reduce implant survivorship, and it might also influence the choice of hip implant device. Again, the recording of BMI in the NJR supplier feedback data available was sparse. In addition to biasing the comparisons of survivorship across devices, variation in patient characteristics might also make it difficult to project future survivorship.

6. A lower threshold for revision would, for reasons unrelated to device design, decrease the observed survivorship of MoM implants. Moreover, to the extent that follow-up guidelines such as the MDAs influenced revision rates, and to the extent that recommendations varied across countries, time, and bearing surfaces, they would further confound comparisons of the survivorship of MoM hip implants with benchmarks.

7. There might be reasons why revision risk was higher among younger patients. Findings of certain studies suggested that the younger population of patients typically implanted with the Mitch/Accolade product faced higher revision risk than

the older population of general THR patients. Any elevation in the Mitch/Accolade revision rate might be attributable, wholly or in part, to the higher risk among the younger patient group. A younger patient might be more demanding, and more willing to undergo revision surgery, than an elderly or frail patient.

8. Patient gender was another potentially important predictor of survivorship. Most studies reported an increased risk of revision for men. The Mitch/Accolade population had a higher proportion of males than the general THR population.

For all of these reasons, in Professor Platt's view, inferences drawn from a simple comparison of Mitch/Accolade and overall THR revision rates would be biased by differences in the underlying patient populations. Unless such a comparison were appropriately adjusted for confounding factors including age, gender, health status, and possibly other factors such as activity level and BMI, they would not provide the basis for meaningful conclusions.

[153] Professor Platt also considered the possible effect on the NJR figures of "outliers", ie surgeons whose revision rates differed significantly from the normal range. In the terminology of the NJR, a "potential outlier" is a surgeon whose revision rate for primary joint replacement lies about three standard deviations from the mean, and a "borderline outlier" is a surgeon whose revision rate lies approximately between two and three standard deviations from the mean. Professor Platt identified as a potential outlier one surgeon who had carried out 18 Mitch/Accolade implants of which 10 were revised, and identified as a borderline outlier one surgeon who had carried out 77 Mitch/Accolade implants of which 25 were revised. He noted that the patients implanted by the latter surgeon tended to have characteristics (older, female) generally associated with lower, not higher, risk of revision. When the revision data of the two surgeons categorised as outliers were excluded, the 10-

year cumulative probability revision estimate for the Mitch/Accolade product fell from 23.2% (95% CI 18.4%, 28.9%) to 14.3% (95% CI 9.8%, 20.7%). Applying the ODEP principle that a device fell within NICE Guidance if the 95% confidence interval of its Kaplan Meier cumulative revision rate included the benchmark revision rate, with the removal of the two outlier surgeons, the Mitch-Accolade product met NICE Guidance.

[154] I find some of Professor Platt's objections to the use of registry data to measure current or predict future survivorship more persuasive than others. It may be that this is a manifestation of the difference between proof to scientific standards and the civil legal standard of proof on balance of probabilities. I would not, for example, dismiss use of NJR data merely on the ground that the register was incomplete, unless there was evidence that the omissions created bias one way or the other. Nor would I regard difficulties in predicting future revision rates as a reason to refrain from reaching a view on survivorship on the basis of evidence currently available. One or two of Professor Platt's reasons could be viewed as double-edged: in relation to higher risk to younger patients receiving the Mitch/Accolade implant, there might be argument about which is the cause and which the effect.

[155] I am, however, convinced by Professor Platt's other reasons that the available evidence in relation to revision rates of the Mitch/Accolade product is not sufficient to establish that it has a materially lower survivorship than other available products or national standards. In the first place, I am satisfied that without adjustment of the 2012 NJR revision rate for the device, referred to in the MDAs and relied upon by Professor Gill, to take account of the two identified outlier surgeons, it cannot provide the foundation for a conclusion that the rate is higher than indicated as acceptable by NICE – or, to put it in terms closer to the statutory test, a conclusion that the revision rate of the Mitch/Accolade

product was worse than that of alternative devices then available. When appropriate adjustment is made, the revision rate ceases to fall outside the acceptable range. In the second place, even if it were not appropriate to adjust the figures to take account of outlier surgeons, I am satisfied that the confounding factors identified by Professor Platt render it unsafe to draw a conclusion from the bare NJR data that the revision rate of the device was below the entitled expectation of those who received it. In particular, I find that the Mitch/Accolade product was to a significant degree implanted in the younger and/or more active patients for whom large head MoM THRs were designed, and that they were predominantly male. On balance of probabilities, those factors are likely to have lowered the average survivorship of Mitch/Accolade implants, for reasons unconnected with the product itself.

[156] I also accept that revision rates for the Mitch/Accolade product are likely to have been affected by the publicity accorded to MoM THRs generally by the MDAs and wider media coverage. Professor Breusch noted in his report that the threshold for offering revision surgery based on recurrent onset of pain in the presence of metal-on-metal total hip arthroplasties had become much lower. He reiterated this point in his evidence, acknowledging that there was a lowering of the threshold for revision surgery because of clinicians' fears that they would otherwise have a complication that had developed into something they could not satisfactorily deal with, and that this may have had an effect on revision rates. Professor Pandit considered that the only explanation for the dramatic rise in revision rates between 2009 and 2016 was a lowering of the threshold for revision surgery. This was the result of a combination of concerns that all MoM implants were likely to have a poor outcome, and reports in the wider media (not to date established as well-founded) that metal debris from MoM implants could have broader systemic consequences. The MDAs

recommended a monitoring regime which included annual follow-up for the life of the implant, and the possibility of revision surgery in asymptomatic patients. I accept that it is likely, on balance of probabilities, that these factors will have had the effect of increasing the revision rate in relation to the Mitch/Accolade product for reasons other than the performance of the product itself. They constitute a further reason not to treat the NJR data as a reliable indicator of the "success" of the product.

*(iii) Prospects of success of revision surgery*

[157] The other criterion in relation to entitled expectation that I have identified is the prospect of success of revision surgery for those patients whose initial implant fails and requires replacement. Studies in the late 2000s indicated that because of soft tissue damage caused by metal debris generated by MoM implants (whether THR or resurfacing), the prospects of a successful revision operation were significantly reduced. An example is the Grammatopoulos paper referred to at paragraph 82 above. This risk was much less likely to arise with MoCP devices. Professor Breusch described the challenges of revision surgery where significant soft tissue damage had occurred as follows:

> "If you now go into a hip which has failed by this rare but potentially catastrophic failure, then the connection between the muscles on the top, the gluteal muscles and the muscles in the thigh no longer exists. And if there is a large portion of tendon and muscle missing you have no chance of providing this patient with reasonable function afterwards. So this patient will be limping for life, depending on crutches for life, and some end up in a wheelchair simply because we are unable as surgeons yet to regrow muscles and tendons."

[158] If the possibility of occurrence of ARMD caused by metal debris produced by the MoM THR device with which this case is concerned gave rise to a likelihood that some patients would suffer the consequences of soft tissue damage thus described by Professor Breusch, I would, applying the rationale of the *Boston Scientific* decision, regard this as a

defect for the purposes of the 1987 Act. I am not, however, persuaded that it has been proved on balance of probabilities that this is the case. In the first place, it is necessary to emphasise once again that this action concerns a particular device as opposed to MoM THRs in general. No evidence was presented in relation to revision surgery where a Mitch/Accolade device had been used initially, other than the evidence of Mr Siegmeth regarding the pursuer himself. That evidence did not include anything about soft tissue damage having rendered the revision surgery more challenging or the eventual outcome less satisfactory than would otherwise have been the case.

[159] More generally, Professor Pandit gave evidence casting doubt on the concerns expressed in the 2000s. Research reported in recent papers by the Nuffield team at Oxford (in which he has participated as a co-author) has not supported the 2009 hypothesis that revision for ARMD was likely to have a worse outcome than revision for reasons unrelated to metal debris. Matharu et al (2017) carried out a retrospective study[13] of all primary MoM THRs and resurfacings recorded in the NJR between June 2008 and August 2014 as being for ARMD. The contributing authors concluded that the short-term risk of re-revision following MoM hip arthroplasty (THR or resurfacing) revision surgery performed for ARMD was comparable with that reported in the NJR following all-cause non-MoM hip arthroplasty revision surgery. The paper noted also that in MoM arthroplasties undergoing revision for ARMD, the future re-revision risk was not influenced by whether the primary implant had been a THR or a resurfacing. A possible reason for improved prospects of successful revision performed for ARMD was simply that surgeons had become more skilful at dealing with problems posed by ARMD, but this could not be proved or quantified.

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[13] Matharu et al "Which factors influence the rate of failure following metal-on-metal hip arthroplasty revision surgery performed for ARMD?", Bone Joint J 2017; 99-B:1020-1027.

[160] In a separate paper (Matharu, 2017)[14], a retrospective study was carried out of the same patients as had been reported on by Grammatopoulos in 2009. They found that 10-year survival free from re-revision was no different for patients revised for pseudotumours than for patients revised for fractures.

[161] Finally, reference was made to the abstract of an as yet unpublished article by Matharu et al (including Professor Pandit) comparing the rates of adverse outcomes following MoM hip replacement revision surgery in matched ARMD and non-ARMD patients. The results of the study were that, contrary to previous observations, patients revised for ARMD had approximately half the risk of re-revision and death compared to non-ARMD revisions. The authors commented:

> "We suspect worldwide regulatory authorities have positively influenced outcomes following ARMD revision by widely recommending that surgeons exercise a lower threshold for performing such procedures. Our findings suggest the threshold for performing ARMD revision surgery need not be lowered further."

In his expert report in the present case Professor Pandit's opinion was expressed in rather less guarded terms. He considered that the findings in these studies were clinically significant and novel for surgeons, patients and policy makers as they were completely opposite to what had previously been widely believed. They suggested that revisions for ARMD were successful, and that the risk of re-revision was significantly less than in cases where revision was performed due to other reasons for failure of the primary implant. He considered that the recommended follow-up regime recommended by various regulatory authorities (including the NJR) had not been justified.

[162] It is not possible to be certain at this time whether the results in the Matharu studies will be replicated by others, or whether they will themselves prove to be "outliers". It does,

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[14] GS Matharu et al "Poor Survivorship and Frequent Complications at a Median of 10 Years After Metal-on-Metal Hip Resurfacing Revision", Clin Orthop Relat Res 2017 Feb; 475(2):304-314.

however, appear to be the case that concerns about the potential difficulties of revision surgery for ARMD have not, or not yet, materialised. I place considerable weight on the opinion of Professor Pandit in this regard. His views have been at the heart of the development of the thinking of orthopaedic professionals in relation to MoM implants. Having participated in some of the research which first raised concerns about large-head MoM THRs, he has continued to contribute to the leading edge of such thinking, and now recognises that some of those concerns, expressed on the basis of a small number of years' experience of MoM implants, are not supported by evidence based upon a longer period of experience. I accept his view that the recent research indicates that risks of re-revision are not greater following a revision for ARMD than following a revision for another reason. It follows that I do not accept that the pursuer has established, on balance of probabilities, that metal debris produced by MoM THRs such as the Mitch/Accolade product created a risk that revision surgery following failure of the primary implant would be less likely to lead to a satisfactory outcome than revision surgery following failure of a primary implant made of other materials such as MoCP or COC.

***Conclusion on entitled expectation***

[163] At paragraphs 147-149 above I identified the practical criteria that I proposed to adopt in assessing whether it had been proved that entitled expectation in relation to the Mitch/Accolade product had not been met, namely time to revision, ie survivorship, and the existence or otherwise of higher risk of unsuccessful revision, as practical criteria against which to test whether entitled expectation was met in relation to the Mitch/Accolade product. In my opinion, for the reasons set out in the preceding paragraphs, the pursuer has

not proved, on balance of probabilities, at the time when his prostheses were supplied, either

(a) that survivorship was worse for the Mitch/Accolade product than for existing alternative products that could have been implanted instead; or

(b) that use of the Mitch/Accolade product gave rise to an increased risk that revision surgery, in the event of its failure, would be unlikely to achieve as satisfactory an outcome as if the primary implant had been one of the existing alternatives,

I therefore find that the pursuer has not proved, on balance of probabilities, that the entitled expectation in relation to the Mitch/Accolade product at the time of its supply to the pursuer was not met. It follows that he has not proved, on balance of probabilities, that there was a defect in the product so as to give rise to liability on the part of the defenders under the 1987 Act. The question for determination at the proof, set out at paragraph 89, is answered in the negative.

[164] That is sufficient to dispose of the matters with which the restricted proof was concerned. As I have sought to emphasise, it did not fall within the scope of the preliminary proof to make a finding as to the safety of MoM THRs generally or even of large-head MoM THRs generally. In holding that the pursuer in the present action has failed to prove that the Mitch/Accolade product supplied to him was defective, I do not exclude the possibility that another pursuer might be able to present evidence in relation to a different product sufficient to establish, on balance of probabilities, that entitled expectation in relation to that product had not been met. I have noted the view of Professors Breusch and Pandit, expressed in their joint statement, that "it is a consensus opinion now among orthopaedic surgeons that all large head MoM implants are associated with an increased risk of early [sic] failure than comparator non-MoM implants but most currently remain satisfactory

under long term surveillance". They further observed that there was a huge variation in the reported revision rates amongst different brands of MoM hips. Professor Breusch stated in the course of his oral evidence that he would regard any MoM THR with a large metal head on a very small taper as a risky combination and product.

[165] I am aware also of the following statements that appeared in the 2018 NJR Annual Report, containing surgical data to 31 December 2017, at paragraph 3.3.12 (very similar statements appear in the 2019 NJR Annual Report, published since the proof, at paragraph 3.3.12):

> "Metal-on-metal stemmed and resurfacing implants continue to fail at higher than expected rates and their use is now extremely rare. The best performing brand of resurfacing has a failure rate of 7.95% (95% CI 7.56-8.37) at ten years. The use of metal-on-metal bearings has undoubtedly led to a large excess of revisions which would not have occurred if alternate [sic] bearings had been used. This has been modelled and published in the Journal of Bone and Joint Surgery. For every 100 MoM hip-resurfacing procedures, we estimate that there would be 7.8 excess revisions by ten years, and similarly for every 100 stemmed MoM THR procedures that there would be 15.9, which equates to 8,021 excess first revisions.
>
> It is striking to note the high rates of revision for adverse soft tissue reaction to particulate debris in patients who have received metal-on-metal bearings. Analysis of stemmed metal-on-metal bearings by head size shows that 28 mm heads have the best survivorship, but this is still poor compared to alternatives.
>
> Revision rates by year of surgery for the entire cohort increased dramatically from 2003 to 2008 and then declined until 2013. This matches the use of resurfacing arthroplasty and stemmed metal-on-metal with the peak usage of these devices in 2008 corresponding with the highest failure rates by year of primary surgery. This demonstrates the profoundly negative effect metal-on-metal has had on hip replacement outcomes."

The source referenced for the figures in the first of these paragraphs was not one of those referred to in the course of the preliminary proof, and as neither that source nor the passage I have just quoted was put to any of the witnesses, I have attached no weight to either of them in reaching my conclusions. It may be, for example, that the assertions made in the passage quoted are subject to criticisms similar to those that I have accepted in relation to

figures used to demonstrate an unacceptably high failure rate of the device with which this case is concerned. Be that as it may, I wish simply to make the point that my opinion should not be read as a finding that it has been positively proved that the safety of large-head MoM THRs as a class was such as persons generally were entitled to expect at the time when they were supplied.

**Disposal**

[166] The defenders seek absolvitor from the conclusions of the summons. That appears to me to be the appropriate course of action, but I shall put the case out by order to be addressed on this and on any other matters arising from my opinion. In the meantime I express my gratitude to all counsel and solicitors for their assistance with this complex matter, and for the co-operative and constructive manner in which the proof was conducted.