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Patient name:			
Date of birth:	11/01/1963	Laboratory:	Admin
Gender:	F	Report date:	11/01/2023
NHS number:		Implant for consideration:	Resurfacing implant
Genetic testing date:	11/01/2023	Referring surgeon:	
Hospital name:			

Orthotype risk estimation:

This report provides estimates for the risk of a patient developing ALVAL/delayed type hypersensitivity (DTH) following joint replacement involving a component/components manufactured from standard medical grade cobalt chrome (CoCr) metal alloy.

The development of ALVAL/DTH depends on the interaction between patient factors and the amount of metal released from the implant through wear and/or corrosion. It is impossible to accurately predict the wear of a device preoperatively. Therefore, this report presents two general scenarios:

Implant performs well; blood metal ion levels remain close to background levels following surgery (cobalt < 2 micrograms per litre).

Implant performs sub optimally; blood metal ion levels remain significantly elevated following surgery (cobalt 2 – 4 micrograms per litre).

The risk percentages provided in this report are intended to be used as a guide to the absolute risk of a metal reaction developing post implantation. We advise that the key metric to aid in your clinical decision making process, however, is the relative risk compared to the comparator background population. This will help to place the predictions into context with your own clinical experience. Note that while the differences in risk of ALVAL/DTH may seem small at lower levels of metal exposure, in general these differences become more pronounced if the implants shed greater than expected amounts of metal. This may occur due to wear, component loosening or corrosive processes.

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Orthotype predictions for this individual

- With a well-functioning implant (blood cobalt concentrations < 2 micrograms per litre), this patient has an estimated **risk of developing ALVAL/DTH of 6%** within ten years of surgery

- The equivalent **background risk**, for patients matched for age and gender (who do not possess this patient's HLA genotype) **is 4%** over the same follow up period

- If the implant does not function as well as expected (resulting in sub optimal cobalt concentrations in the range of 2 – 4 micrograms per litre), this patient has an estimated **risk of developing ALVAL/DTH of 31%** within ten years of surgery

- The equivalent **background risk**, for patients matched for age and gender (who do not possess this patient's HLA genotype) **is 21%** over the same follow up period

⚠ *Patients with existing CoCr implants: If the patient already has an implant in situ made of at least one CoCr component, the predictions are based on the assumption that the existing implant is generating low/expected levels of metal debris (a stable Co concentration below 2 micrograms per litre).*

⚠ *Predictions are given on the assumption that the patient has a normal renal function*

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The Orthotype™ Test ⚠

Orthotype™ has been developed for use in the consideration of implantation of a device containing CoCr. It is intended to be used in conjunction with a well-performing device which is resilient to the variation in component alignment encountered in normal surgical practise. It is not intended to identify patients who will be resistant to developing metal hypersensitivity when exposed to massive CoCr concentrations. However, survival predictions are provided for mild elevations in wear which may occur due to patient specific factors such as joint laxity, increased mobility or atypical activities.

The Orthotype™ algorithm was developed through the study of patients with metal-on-metal hip arthroplasties. The accuracy of the survival predictions for devices other than hip arthroplasties containing the same cobalt chrome alloys (such as the most commonly used total knee arthroplasties) has not been validated. However, there is no strong evidence to suggest that HLA genes show greater activity in different joints in the body.

Metal ion concentrations in context: ⚠

The development of metal hypersensitivity depends upon an interaction between patient factors, and the amount of metal exposure over time. Blood or serum metal ion concentrations provide a reliable assessment of the wear and corrosion occurring at the implant surfaces. For context, well-functioning metal-on-metal hip bearings wear at less than 1mm^3 per year, and this generally equates to blood or serum cobalt concentrations less than 2 micrograms per litre. The volumetric wear generated from other types of arthroplasties has not been established with certainty, and blood metal ion studies involving patients with TKAs are few in comparison to those on patients with MoM hips. The published studies report median cobalt concentrations ranging from between 0.28 micrograms per litre (in patients with TKRs with titanium tibial trays), to 4.28 micrograms per litre in patients with bilateral knees with CoCr trays and up to 8.80 micrograms per litre in patients with unstable CoCr components.

Genetic diversity in different populations: ⚠

The Orthotype™ validation study involved patients who were mostly of European descent, resident in the North East of England (the United Kingdom), New York (United States) and Perth (Australia). Different human populations can display different genetic associations to the same disease processes.

Terminology:

Delayed type metal hypersensitivity in this report refers to the development of perivascular T cell lymphocytic aggregates in the periprosthetic tissue. The term is used interchangeably/is synonymous with aseptic lymphocyte dominated vasculitis association lesion (ALVAL). The threshold for “ALVAL/delayed type hypersensitivity” in this report is defined as a mild, moderate or severe ALVAL response as described by Natu et al.