Aesculap® Metal Allergy

Allergy Diagnosis – Procedure – Implant Materials

Aesculap Orthopaedics

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Aesculap® Metal Allergy

Metal Allergy

It has been discovered that a possible contact allergy to implant materials or the components contained in bone cement may lead to implant intolerance. Endoprostheses are known to release metal ions into the human body. This can lead to immune reactions in patients who are at risk of allergy. Symptoms that have been described include eczema, impaired wound healing, bruising, pain, restricted movement and loosening of the implant.
The most common allergenic metals are nickel, cobalt and chromium. People have also been known to exhibit sensitivities to certain components of cement, such as acrylate and gentamicin.
With between 10 % and 15 % of the population allergic to metals, it would appear that such sensitivities are relatively high;[1] however, the number of metal allergy sufferers to develop an intolerance to implant materials following endoprosthetic implantation has not yet been conclusively proven.

Incidence of skin reactions to metals[2]

- General population 10 %
- Patients with a well functioning prosthesis 25 %
- Patients with a loose prosthesis or pain 60 %

Contact allergy after endoprosthesis[3]
239 patients experiencing implant complications, 181 of whom with knee or hip endoprostheses, underwent contact allergy investigation.[3]

- Nickel allergy 21.3 %
- Cobalt allergy 10.9 %
- Chromium allergy 5.0 %
- Allergic reaction to components contained in bone cement 24.8 %

Among patients with endoprosthetic complications, the incidence of contact allergies to metals and potentially to components in bone cement is higher than among the general population.

Allergological Diagnosis

The criteria for diagnosing a metal implant allergy have not yet been defined conclusively, such that differential diagnoses (infection) have to be excluded and several test methods have to be considered at the same time.

The standard allergological diagnosis should include an **epicutaneous test,** if possible with **histological evaluation** of the tissue surrounding the implant. Additional information can be provided by the **lymphocyte transformation test (LTT)**.

The Implant Allergy Working Group of the DGOOC (German Association of Orthopaedics and Orthopaedic Surgery) came up with an allergological procedure for clarifying a suspected metal allergy, as described below.

Allergies associated with implants are generally of type IV hypersensitivity (Gell and Coombs classification[4]):
A T-cell-mediated, delayed type hypersensitivity (DTH).

Epicutaneous testing

Test metals are administered to the skin and the results read after 2, 3 and in some cases 7 days. Suspect metals (nickel, chromium and cobalt) are tested in a standard series of tests. Components of bone cement should also be tested if cement was used to attach the implant.
The test compounds are standardized to detect a contact allergy; to nickel, for instance. However, the results may be affected by altered immune reactions or immunotolerance. Although the test is conducted on the skin and therefore only has limited applicability to subcutaneous tissue, the results are at least able to identify allergy sufferers. More detailed exploration would then be required for clinical relevance.

Patch testing using metal discs is no longer recommended for the following reasons[5]:

- Because it is not standardized, false-negative or false-positive reactions may arise and it is unclear which metal the individual is reacting to.
- The test discs can rub and press down on the skin, causing skin irritation that leads to false-positive results.

In view of the above, B. Braun Aesculap no longer offers patch test discs.

Histological evaluation

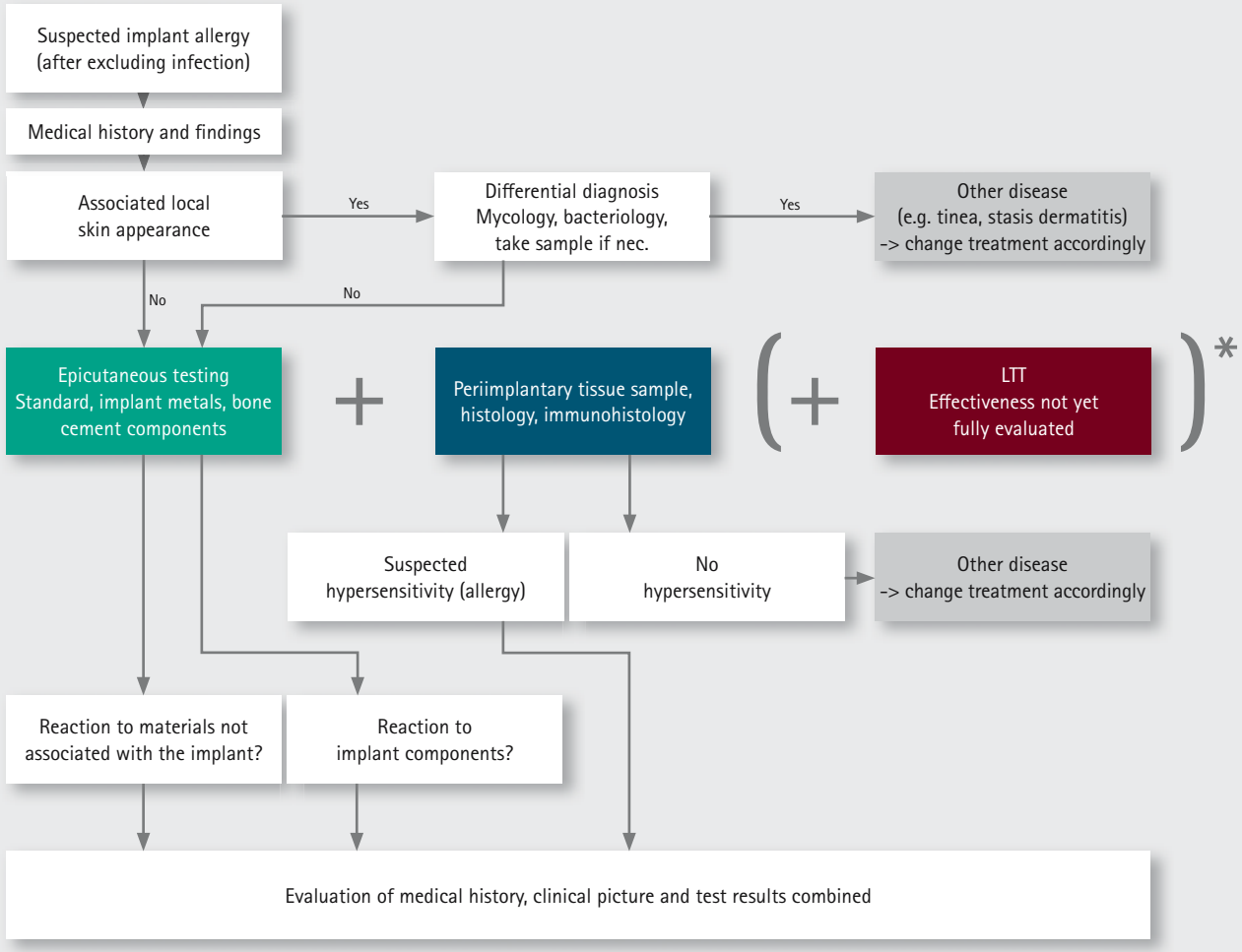
Periimplantary tissue collected arthroscopically from total knee replacement patients should be fixed in formalin and subjected to further immunohistological investigation for inflammatory cell infiltration, foreign body reaction or infection-associated changes.[6] In the specific case of loosening of the endoprosthesis, the following consensus classification is described for (immune) histological testing of tissue.[6]

- Type I (wear particle induced) refers to an infiltration consisting predominantly of macrophages and multinucleated giant cells.
- Type II (infectious) may indicate a pronounced or minimal infection with chronic granulomatous inflammation.
- Type III (combined) is a combination of both wear particle induced and infections.
- Type IV (indeterminate) refers to a clinical picture with fewer cells, but high collagen fibre.

Lymphocyte transformation test (LTT)

The LTT shows, by means of inducible T-cell proliferation following the in-vitro addition of antigens, that the donor's blood lymphocytes 'recognise' the antigen added to the cell culture (sensitization). This figure is shown in comparison to the negative control of unstimulated cultures in a ratio, which is referred to as the stimulation index (SI). An SI>2 indicates sensitivity.
The test can show whether a patient is sensitive to metals[7]; however, a sensitivity does not necessarily mean an allergy.

Metal Allergy Investigation Procedure



* LTT as a further scientific approach (effectiveness still under evaluation)

Chart: Metal allergy investigation procedure as defined by the Implant Allergy Working Group[5]

Aesculap Implant Materials

Materials	ISODUR$_F$	ISODUR$_C$	ISOTAN$_F$	Plasmapore coating/ ISOTAN$_P$
ISO standard	ISO 5832-12	ISO 5832-4	ISO 5832-3	ISO 5832-2
Alloy base	Cobalt	Cobalt	Titanium	Titanium
Alloy type	CoCrMo	CoCrMo	Ti6Al4V	Ti
Carbon	≤ 0.35	≤ 0.35	≤ 0.08	≤ 0.10
Silicium	≤ 1.0	≤ 1.0	–	–
Manganese	≤ 1.0	≤ 1.0	–	–
Cobalt	Residual	Residual	–	–
Chromium	26.0 - 30.0	26.5 - 30.0	–	–
Molybdenum	5.0 - 7.0	4.5 - 7.0	–	–
Nickel	≤ 1.0	≤ 1.0	–	–
Vandium	–	–	3.5 - 4.5	–
Aluminum	–	–	5.5 - 6.7	–
Iron	≤ 0.75	≤ 1.0	≤ 0.3	≤ 0.3
Titanium	–	–	Residual	Residual
Nitrogen	≤ 0.25	–	≤ 0.05	≤ 0.05
Oxygen	–	–	≤ 0.2	≤ 0.45
Hydrogen	–	–	≤ 0.015	≤ 0.0125

Table: Constituent substances of alloys used in implant components

AS Coating
- Multilayer ceramic coating made from zirconium and various intermediate layers (ZrN-CrN-CrCN-Cr)
- Knee implants: AS Columbus, AS e.motion, AS e.motion PS Revision, AS Vega
- Special patient-specific knee implants: univation, Columbus Revision, EnduRo, cementless implants

ISODUR$_F$
- Knee implants: Extension stems, obturator, augmentation, tibia univation
- Hip implants: Metal heads, Metha modular necks, cemented stems

ISODUR$_C$
- Knee implants: Columbus, e.motion, Vega, femur univation, EnduRo, Search

ISOTAN$_F$
- Hip implants: Cementless stems, Plasmacup, Screw socket SC

Plasmapore coating
- Hip implants: Bicontact, Excia, Plasmacup
- Cementless knee implants: Columbus, e.motion

Plasmapore µ-CaP coating
- Hip implants: Metha, Excia, Prevision
- Knee implants: e.motion

For more information about Aesculap knee systems:

www.asimplants.com

Literature

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Aesculap AG | Am Aesculap-Platz | 78532 Tuttlingen | Germany
Phone +49 7461 95-0 | Fax +49 7461 95-26 00 | www.aesculap.com

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