Minutes

Explant Alliance

Thursday, 18 February 2016

11.00 am– 4.30 pm

British Orthopaedic Association Boardroom at the Moynihan Room

Royal College of Surgeons of England

Attendees:-

Mr Peter Kay (Chairman, Steering Committee, Beyond Compliance)

Professor Tom Joyce, Mr David Langton (Northern Retrieval Registry)

Dr Harry Hothi, (London Implant Retrieval Centre)

Dr Richard Cook (Southampton Retrieval Centre)

Dr Sophie Williams (Leeds University)

Mr Magnus Flett representing industry (Corin)

Dr Simon Collins representing industry (Matt Ortho Ltd)

Mr Keith Tucker (Beyond Compliance Advisory Group Chairman and Chairman of ODEP)

Apologies for absence:-

Mr Tony Nargol

Mr Jeremy Latham

James Holland

Conflicts of Interest:-

The Chairman made the point that those people around the table will have some sort of potential conflict of interest. The emphasis is to be with interest. Conflicts of interest will need to be logged with Beyond Compliance in due course. Mr Kay declared in the past he has been involved in the development of a hip replacement but has not received any remuneration. Mr Tucker made the same point and also added that he has shares in Accentus Medical. Mr David Langton stated that he is a paid witness in matters related to explants. Dr Williams stated that she is a consultant to DePuy Synthes for speaking at surgeon education events; her institution receives support from DePuy Synthes relating to implants. Others at the meeting declared no conflict of interest.

The minutes of the meeting in Milan:-

It was agreed that these were an acceptable record of the event.

Membership of the Alliance:-

It was generally agreed that Alliance was a satisfactory description of this grouping of the implant retrieval centres that are available in the UK. The word can also be used with the relationship between the implant retrieval centres, Beyond Compliance and industry.

1. **Representatives from Retrieval Centres:-**
   There are 4 retrieval centres in the UK. They all focus on hip replacement. The London Implant Retrieval Centre is able to receive requests for forensic analysis of both hips and knees without concerns. The Northern Retrieval Registry is presently more focused on hips than knees but is undertaking knee work and has previously published in this area as well as retrieval analysis of fingers and toes. Southampton has less experience in knees and this is also the case with Leeds. Leeds offer retrieval analysis of ankles.

2. **Representatives from Industry:-**
   Both Magnus Flett and Simon Collins felt that in the future there should be more representatives from industry. We were expecting Imran Khan from Zimmer Biomet. When this meeting was set up we had hoped to have a representative from one of the big companies, one of the medium companies and one of the innovative companies.
   The group recommended that the following should also be approached: -
   - Claude Reiker from Zimmer Biomet: claude.rieker@zimmer.com
   - Amir Kamali from Smith & Nephew: amir.kamali@smith-nephew.com
   - Tom Dalton from DePuy Synthes (via Graham Isaacs)
   - Ann Roques from Aurora

3. **Representatives from Patient Groups**
   It was generally thought that having representatives from patient groups at scrutiny meetings would be inappropriate but some representation from the layman in more general meetings would be welcome.

4. **Representatives from Beyond Compliance.**
   Mr Tucker indicated that he would try and enlist the support from other members of the Beyond Compliance Advisory Group to take part in this initiative.

Toxicologist

It was generally felt that it is very difficult to find appropriate toxicologists. A toxicologist who deals with metal may not be able to discuss toxicology related to a plastic or other material. Everybody around the room found that when they had tried to arrange toxicological analysis it has been difficult and usually failed.

The Chairman will see if there is any central body that could be approached to provide a list of individuals who would be prepared to give advice.

Chairman, Secretary (Executive Group)

Mr Tucker indicated that he would be happy to chair the meeting provided everybody else was in agreement. It was pointed out that he was independent of the Implant Retrieval Centres and would

be in a position to take a strategic and more general view. He pointed out that taking minutes and chairing is difficult and felt that some load sharing should take place with further meetings and encouraged the Alliance to think about developing an inner caucus group to whom the chair can refer when setting up meetings etc.

Aims and objectives:-

It is clear that everybody agrees that obtaining high quality data on Explants is ideal and the standard that we should aspire is excellence. Magnus Flett questioned whether it was necessary in every Explant. Mr Langton indicated that it was important for the retrieval centres to become au fait with a particular device by seeing several Explants, so as to be in a better position to identify what is normal and abnormal after a period of years of use. Mr Tucker emphasised that he felt that a report which showed absolutely no wear damage etc. was not of negative value.

Standards:-

It was agreed that representatives from the four implant retrieval centres should get together to draw up an agreed list of standards. They would include:-

1. **Legal aspects.** A note about the legal aspects including how to make sure the patient's rights are carefully protected.
2. **Ownership of the implant** was discussed. Up to now it has been presumed that the patient has ownership of their implant. Mr Tucker made the point that patients in the Beyond Compliance process would have signed a consent form which have three headings. These include consent for the BC Advisory Group to look at their data (anonymised), that Northgate can email the patient and that the patient agrees should they ever need revision the implant will be taken to a retrieval centre for forensic analysis.
3. **Patient's attached tissue.** Mr Langton made the point that if the implant has tissues on it then it is definitely the property of the patient.
4. **NHS,** Mr Nargol had contacted us to suggest that a case could be made that the implant was the property of the Health Service if they were a Health Service patient.
5. **It was generally** agreed that at present we should accept that the patient owns the implant. Certainly when it comes to legal issues that must be the best way forward. Hopefully patients will always give their consent for forensic analysis when they sign their Beyond Compliance consent form.

Transport:-

Mr Tucker, as a surgeon, made the point that surgeons would much prefer a simple slick method of transferring the implant from the wound to the Implants Retrieval Centre without any difficulties. It was suggested that dropping it in a bag or box from the surgeon's hand with no argument or doubt etc. was the best way. Thus, receptacles should be available for the implants. These receptacles should be designed in an agreed way that is acceptable to the transport companies and to the receiving implant receiving centres. This requires further work and it would be helpful if the retrieval centres communicated with each other as to exactly what they are offering at present.

ACTION: - Retrieval centres to liaise with each other to decide on the standards for transport.

The use of formalin:-

At present all the implant retrieval centres suggest that the implants are put into formalin i.e. the receptacle that accepts the implant should have formalin in it so that the implant is submerged. Leeds reported some problems with formalin leaking and clearly this is an area that needs to be carefully controlled. Having the receptacle with the formalin and implant in it inside one or two more bags should ensure safety.

Concerns about formalin:-

Were as it was thought the formalin was perfectly alright for metal and ceramic materials this might not be the case with polythene or for some the new materials coming into the market. Concerns were raised about the possible oxidation of polys if left in air. Vacuum wrapping at -20 degrees centigrade was discussed. Mr Tucker wondered whether polythene could be submerged in either hibitane or povidone rather than formalin as it might be less poisonous to the implant. Osmotic gradient between the fluid and the polythene needs to be checked out.

ACTION: - Keith Tucker to write to Stephen Kurtz asking his opinion on the effect of formalin or other chemicals on poly.

Question by KT:

"Does Formalin affect HDP, either physically or chemically? For that matter does formalin affect any other orthopaedic materials?"

Answer by SK

“We normally get our implants washed off in a sink (no cleaning) and dropped in a bag and shipped to us dirty because it is really simple, our greatest fear is that the hospital will try to sterilize the implant. There is no problem with formalin and implants or tissue. We collect dirty implants as bio-hazard and clean them ourselves so we can be sure that the process is standardized. You don’t want to try to train multiple hospitals how to clean. I have heard that formalin may dissolve some small particles of bone cement. May want to check up on that further. We will send you our retrieval collection and shipping SOPs obviously they will be need to be updated for British shipping regs. ;-) We normally do not ship implants in formalin because as a “hazardous substance” there are limits to how much volume can be shipped without ridiculous cost in the US. We only ship tissue samples collected at revision this way. We have instituted specialized protocols for tissue collection or when we want to specifically study bone ingrowth but those may not be practical on a “national scale.”

Procedure to be adopted on reception of implant at the Retrieval Centre:-

It was generally agreed that the product code, lot number, etc. is recorded from the implant. (This is sometimes difficult to find as parts become welded together). This is links with the records. The device is photographed from all angles. The implant is not labelled as such.

Cleansing:-

It was generally agreed that the implants should be washed and rinsed whilst leaving debris in place, blood etc. to be removed and visual inspection was sufficient to record that this had been effectively achieved.

For further decontamination it was generally agreed that implants should then go into formalin for another 24 hours to make absolutely sure that they were safe for use.

Assessment:-

Visual assessment is obviously very important. Using sophisticated devices the material geometry of hips is assessed, taper angles etc. and an assessment of wear is undertaken. This would lead to total volumetric wear and at the same time the distribution of wear would be mapped. It is essential that these wear measurement methods have previously been validated via peer-reviewed publications.

Ingrowth:-Where appropriate ingrowth assessment would be undertaken.

Taper:-. Volumetric wear measurements and measurements of maximum wear depth to be undertaken. Similar to trunnion - be assessed as far as possible in terms of unworn geometry (specific reference to the cone angle), surface finish with the use of CMM/Redlux/contacting/non contacting profilometry. Only where volumetric or linear wear assessment proves impossible should the Goldberg score be used

Stem: - From the point of view of the stem, the visual assessment and recording of the evidence using the Bryant score 1-5 would be noted

Trunnion: should be assessed as far as possible in terms of unworn geometry (specific reference to the cone angle), surface finish with the use of CMM/Redlux/contacting/non contacting profilometry

Elemental analysis as necessary.

Dimensions of original design:- Reference of be made of original dimensions etc of the implant (This may require an NDA in place with the manufacturer).

Clinical input:-

Everyone agreed that assessment of an implant is less useful without clinical and other investigations.

Clinical details would include age, BMI, ASA, indications for primary surgery, reason for revision, findings at revision, x-rays, scans etc.

Histology of local tissues as appropriate.

Bacteriology as appropriate.

ACTION:- Keith Tucker to discuss with the Advisory Group the responsibility of surgeons to evaluate x-rays and clinical data about a failed implant. This might well be the rapporteur associated with that product but if they felt that they had not sufficient experience at looking at x-rays for that particular device then further help might be required.

Funding:-

The Chairman stated that the ideal situation would be that the retrieval analysis would be paid for independently from the manufacturers. Magnus Flett made the point that when it was obvious why the revision occurred that the manufacturer is not going to be keen on paying for forensic analysis. Simon Collins noted that a complete set of patient/surgical operation pathology/history/data is required to perform a failure analysis and that previously basic fundamentals such as X rays have been missing. Mr Tucker made the point that forensic analysis would never be wasted because if it shows that everything is perfect that is not a negative point, but appreciated that forensic analysis if expensive.

At a previous meeting a subscription fee to the Implant Retrieval Centres was a theoretical opinion. A fee per item service would be a somewhat unreliable way of maintaining funding of these important centres.

It is realised that individual centres will have their own charges and it would be inappropriate for the Alliance to necessarily discuss charges.

Alternative funding:-

Professor Sion Glynn-Jones from Oxford leads on the NIHR funding scheme and has approached Keith Tucker to see if ODEP and Beyond Compliance projects can be introduced into this scheme. Those present today were concerned that forensic examination was essentially an on-going evaluation and, therefore, it is unlikely that grants would be available for day to day analysis as they are only usually available for scientific research.

Mr Tucker has also approach PARENT to see if they would be interested in a European initiative to produce information.

The chair reminded the group that the Commons Select Committee (Professor Tom Joyce was a witness) did recommend that all Explants should now be analysed forensically. It was suggested that the Member of Parliament and Minister for Life Sciences, Mr George Freeman, should be approached for his support.

Action point:-

Chair to speak to Professor Glyn-Jones and get back to PARENT.

Earlier in the discussion it was thought that possible MD study could be “effect of formalin etc on implants coming for forensic testing”.

AOB:-

No other business to discuss

Date of next meeting:-

A date has not yet been decided.

When these minutes are agreed they will be placed on the BC website