MANAGEMENT IN CONFIDENCE

# CLINICAL PRIORITIES ADVISORY GROUP
# 05 12 2018

| | |
|---|---|
| **Agenda Item No** | 02.3 |
| **National Programme** | Trauma |
| **Clinical Reference Group** | Complex disability and rehabilitation |
| **URN** | 1628 |

| **Title** |
|---|
| Osseointegration for Transfemoral Amputation (adults) |

| | |
|---|---|
| **Actions Requested** | 1. Support the adoption of the policy proposition. |
| | 2. Recommend its approval as an IYSD. |

**Proposition.**
The proposal is that Osseointegration for Transfemoral Amputation is not for routine commissioning.
After reviewing the evidence available, it was concluded that there is insufficient sound evidence on which to base a policy for the routine commissioning of this intervention.

| **Clinical panel recommendation** |
|---|
| The Clinical Panel recommended that the policy progress as a not for routine commissioning position. |

| **The committee is asked to receive the following assurance:** | |
|---|---|
| 1. | The Head of Clinical Effectiveness confirms the proposal has completed the appropriate sequence of governance steps and includes an: Evidence Review; Clinical Panel Report. |
| 2. | The Head of Acute Programmes / Head of Mental Health Programme confirms the proposal is supported by an: Impact Assessment; Stakeholder Engagement Report; Consultation Report; Equality Impact and Assessment Report; Clinical Policy Proposition. The relevant National Programme of Care Board has approved these reports. |
| 3. | The Director of Finance (Specialised Commissioning) confirms that the impact assessment has reasonably estimated a) the incremental cost and b) the budget impact of the proposal. |
| 4. | The Operational Delivery Director (Specialised Commissioning) confirms that the service and operational impacts have been completed. |

| **The following documents are included (others available on request):** | |
|---|---|
| 1. | Clinical Policy Proposition |
| 2. | Engagement Report |
| 3. | Evidence Summary and Evidence Report |
| 4. | Clinical Panel Report |
| 5. | Equality Impact and Assessment Report |

| **The Benefits of the Proposition** | | |
|---|---|---|
| *No* | *Outcome measures* | *Summary from evidence review* |
| 1. | Survival | Not measured |
| 2. | Progression free survival | Not measured |
| 3. | Mobility | Four case series assessed mobility. Mobility can be assessed using:<br>- Mean prosthetic use score ((0 = no use, 100 = more than 15 hours per day for 7 days)<br>- Mean prosthetic mobility score<br>- Measures of how frequently the prosthetic is used<br><br>A prospective case series in a single centre in Sweden (Brånemark R, Berlin Ö, Hagberg K, et al. 2014) found that the mean prosthetic use score increased from 47 to 70 (this difference was statistically significant i.e. unlikely to have occurred due to chance), the mean prosthetic mobility score increased from 52 to 70 (this difference was statistically significant) and that 40/45 patients had daily use of the prosthesis compared to 29/5 before the procedure.<br><br>A prospective case series in Australia of 16 transfemoral amputees (Khemka A, Frossard L, Lord S, et al. 2015) with a two year follow up found that the mean prosthetic use score increased from 63 to 91, and that the mean prosthetic mobility score increased from 64 to 82.<br><br>A prospective case series in the Netherlands of 22 transfermoral amputees (Van De Meent H, Hopman MT, Frölke JP2013) found that prosthetic use increased from 56 hours to 101 hours per week, and that the six minute walk test (i.e. how far people were able to walk in a six minute time period) increased from 321 metres to 431 metres.<br><br>A case series with control groups of 12 people with an |

| | | |
|---|---|---|
| | | osseointegrated implant (Frossard L, Hagberg K, Häggström E, et al. 2010) found that the cadence (i.e. number of strides per minute) was an average of 46 strides per minute, which was 2% faster than patients with a socket and 11% slower than patients who were able bodied. Thus, patients with an osseointegrated implant could walk faster than amputees with a more conventional prosthesis but walked slower than a control group who did not have a prosthesis. The difference between the three groups was small and thus the practical difference this would have made to patients would have been small.<br><br>In summary, patients who are fitted with an osseointegrated prosthesis tend to use it for longer than they did when using their previous conventional prostheses. |
| 4. | Self-care | Not measured |
| 5. | Usual activities | Not measured |
| 6. | Pain | One case series, published as two references, reported on pain as an outcome ie Brånemark R, Berlin Ö, Hagberg K, et al. 2014 and Hagberg K, Brånemark R. 2009.<br><br>Almost constant pain was reported by one out of the 51 people who had the Osseointegrated Prostheses for the Rehabilitation of Amputees (OPRA prosthesis), up to 2 years after the implantation. Intermittent pain during the rehabilitation phase occurred in 5 out of the 51 people. In the larger case series two people out of 100 had severe phantom limb pain and 1 had contralateral limb pain.<br><br>Thus, very few patients report continuing pain with this type of prosthesis. |
| 7. | Anxiety / Depression | Not measured |
| 8. | Replacement of more toxic treatment | Not measured |
| 9. | Dependency on care giver / supporting independence | Not measured |
| 10. | Safety | Deep infections affected between 1% and 8% of cases but not all required implant removal, (Juhnke DL, Beck JP, Jeyapalina S, et al. 2015, Juhnke DL, Aschoff HH.2015). Newer techniques and changes in the titanium rod appeared to reduce the number of infections, though it is likely that superficial infections will continue to be a common occurrence. In these |

| | | |
|---|---|---|
| | | case series they occurred in between 32% and 96% of cases but were usually adequately treated with oral or intravenous antibiotics, though a large number of early cases required revision surgery. The overall removal rate was 8% to 20%, but re-implantation was successful in half of these cases. There was no available data on deaths associated with osseointegration.<br><br>Implant structure appears to be robust with only 1 reported structure failure. Bending or fracture of the abutment was more likely but this still occurred at a low frequency of just 9 cases. Bone fracture rate around the implant also appears to be very low at between 0% and 7% over up to 9 years. Implant stability was good up to 5 years but there were some bone structural changes such as cortical thinning, although no bone resorption. |
| 11. | Delivery of intervention | Not measured |

| **Other health outcome measures determined by the evidence review** | | |
|---|---|---|
| No | Outcome measure | Summary from evidence review |
| 1. | Quality of life | Quality of life (Hagberg K, Brånemark R, Gunterberg B, et al. 2008, Van De Meent H, Hopman MT, Frölke JP. 2013) assessed using standard questionnaires after 1 or 2 years showed improvement for each technique (with varying levels of detail) though it stayed the same for a small proportion and worsened for a few cases. Mobility increased with a substantial number of people using the osseointegrated prosthesis on a daily basis. Due to the short length of follow up, changes in technique, improved design and small numbers of cases, it is not clear how long osseointegrated prostheses are likely to last. |

| **Considerations from review by Rare Disease Advisory Group** |
|---|
| Not applicable. |

| **Pharmaceutical considerations** |
|---|
| Not applicable. |

| **Considerations from review by National Programme of Care** |
|---|
| 1) The proposal received the full support of theTrauma PoC Board on the 30th October 2018 |