

**National Institute for Health and Care Excellence**  
**IP1544 / Aortic valve reconstruction with processed bovine pericardium**

IPAC date: 14 December 2017

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
1	Consultee 1 NHS Professional	NA	<p>This comment below has been created by Dr. [REDACTED] ([REDACTED]) and by [REDACTED], the [REDACTED] used for the procedure described in this consultation/revision.</p> <p>"Comments for Dr. [REDACTED]</p> <p>The NICE document is reviewing the use of bovine pericardium for aortic valve reconstruction.</p> <p>It is not assessing the Ozaki procedure although the technique is in "theory" described. It is also not assessing the safety of [REDACTED] as no reference is made to the product itself.</p> <p>The literature used doesn't suggest assessment of aortic valve repair in children.</p> <p>• For Ozaki procedure the long-term outcome data and literature is known in adults.</p> <p>• In some countries that can't use glutaraldehyde treated pericardium various supplements as [REDACTED] or [REDACTED] patch are used .</p> <p>• There are no big clinical review studies describing the Ozaki procedure outcomes in children ( [REDACTED] : this will be the same also in adults)</p> <p>For aortic valve repair in children the situation is very different to adults.</p> <p>There are limitations to the use of prosthetic valve replacement.</p> <p>The options are therefore various repair techniques, homograft or Ross procedure. And recently the Ozaki procedure.</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The consultee supports the use of autologous pericardium using the Ozaki technique instead of aortic valve reconstruction using processed bovine pericardium.</p> <p>The UK regulation on the use of glutaraldehyde for intraoperative tissue processing may limit the use of the Ozaki technique with autologous pericardium.</p> <p>The Committee has recognized the potential value of aortic valve reconstruction and has decided to review the evidence on the technique using processed bovine pericardium, which is approved and extensively used in cardiothoracic surgery in the UK.</p> <p>The IP programme issues guidance on procedures rather than individual devices.</p>

			The Ross procedure offers an excellent immediate result but with a life long risk for autograft failure and homograft replacement. Two valves are therefore placed at risk.	
2	Consultee 2 Company		<p>"Comments from ██████</p> <p>As ██████ has stated above, the review from NICE has stated that this procedure is to use Bovine pericardium which is clearly different from the Ozaki procedure which is supposed to use Autologous Pericardium, as noted in the review from NICE.</p> <p>Therefore, as noted in the literature above, we have stated the data for the Ozaki procedure which has been implemented for 10 years with great outcomes.</p> <p>We believe that NICE should support the Ozaki procedure which has more back-up data and more concrete outcomes other than the usage of bovine pericardium.</p> <p>The below paper is not an article directly related to the Ozaki technique, but related to the long-term outcome of autologous pericardium with the similar procedure. This will be able to shed light on those</p> <p><a href="https://www.ncbi.nlm.nih.gov/pubmed/16039963">https://www.ncbi.nlm.nih.gov/pubmed/16039963</a></p>	<p>Thank you for your comment.</p> <p>The consultee supports the use of autologous pericardium using the Ozaki technique instead of aortic valve reconstruction using processed bovine pericardium.</p> <p>The UK regulation on the use of glutaraldehyde for intraoperative tissue processing may limit the use of the Ozaki technique with autologous pericardium</p> <p>The Committee has recognized the potential value of aortic valve reconstruction and has decided to review the evidence on the technique using processed bovine pericardium, which is approved and extensively used in cardiothoracic surgery in the UK.</p> <p>The IP programme issues guidance on procedures rather than individual devices.</p> <p>This study is included in the main extraction table.</p>
3	Consultee 2 Company		<p>"For aortic valve repair / reconstruction the following literature should be used:</p> <p><a href="https://doi.org/10.1016/j.jtcvs.2012.11.033">https://doi.org/10.1016/j.jtcvs.2012.11.033</a></p> <p><a href="https://doi.org/10.1093/ejcts/ezw259">https://doi.org/10.1093/ejcts/ezw259</a></p> <p><a href="http://dx.doi.org/10.1136/hrt.2009.190520">http://dx.doi.org/10.1136/hrt.2009.190520</a></p>	<p>Thank you for your comment</p> <p>Study reports the use of glutaraldehyde treated autologous pericardium in paediatric aortic valve repair.</p> <p>Study reports outcomes of several aortic valve repair surgeries rather than a complete reconstruction of the aortic valve.</p>

		<p><a href="https://doi.org/10.1016/j.athoracsur.2015.05.002">https://doi.org/10.1016/j.athoracsur.2015.05.002</a></p> <p><a href="https://doi.org/10.1093/ejcts/ezx172">https://doi.org/10.1093/ejcts/ezx172</a></p> <p>For [REDACTED] the following literature should be used:  <a href="https://doi.org/10.1586/17434440.2015.985651">https://doi.org/10.1586/17434440.2015.985651</a></p> <p><a href="https://doi.org/10.1016/j.jtcvs.2014.08.002">https://doi.org/10.1016/j.jtcvs.2014.08.002</a></p> <p>For the Ozaki procedure following literature should be used:  <a href="https://www.ncbi.nlm.nih.gov/pubmed/23228404">https://www.ncbi.nlm.nih.gov/pubmed/23228404</a>  <a href="https://www.ncbi.nlm.nih.gov/pubmed/24585287">https://www.ncbi.nlm.nih.gov/pubmed/24585287</a>  <a href="https://www.ncbi.nlm.nih.gov/pubmed/24954174">https://www.ncbi.nlm.nih.gov/pubmed/24954174</a>  <a href="https://www.ncbi.nlm.nih.gov/pubmed/23427312">https://www.ncbi.nlm.nih.gov/pubmed/23427312</a>  <a href="https://www.ncbi.nlm.nih.gov/pubmed/22572232">https://www.ncbi.nlm.nih.gov/pubmed/22572232</a>  <a href="https://www.ncbi.nlm.nih.gov/pubmed/25818901">https://www.ncbi.nlm.nih.gov/pubmed/25818901</a>  <a href="https://www.ncbi.nlm.nih.gov/pubmed/27060046">https://www.ncbi.nlm.nih.gov/pubmed/27060046</a>  <a href="https://www.ncbi.nlm.nih.gov/pubmed/16039963">https://www.ncbi.nlm.nih.gov/pubmed/16039963</a></p>	<p>Clinical review, does not report on the outcomes of interest for aortic valve reconstruction using processed bovine pericardium.</p> <p>Paper reports the echocardiographic findings for different aortic valve repair techniques. Does not report on the outcomes of interest for aortic valve reconstruction using processed bovine pericardium.</p> <p>Study reports the use of glutaraldehyde treated autologous pericardium in paediatric aortic valve repair.</p> <p>Does not report on the outcomes of interest for aortic valve reconstruction using processed bovine pericardium.</p> <p>Report on the use of processed bovine pericardium in animal recipient.</p> <p>The suggested publications report results of the Ozaki technique using autologous pericardium.</p>
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*nd to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."*