# National Institute for Health and Care Excellence

# IP1557 Vertebral body tethering for idiopathic scoliosis in children and young people

**IPAC date: 14 April 2022**

| Com. no. | Consultee name and organisation | Sec. no. | Comments | Response<br>Please respond to all comments |
|---|---|---|---|---|
| 1 | Consultee 1 | **1.2** | I am not a medical person, I do know VBT has been carried out in the private sector. There is data out there. Is NICE working with the private sector to collect evidence? NICE had already previously done a VBT trail I believe. How long is the recommended research period and how much evidence is required? | Thank you for your comment.<br><br>The overview details the types and sources of evidence reviewed. The guidance states that further research should include randomised controlled trials or analysis of registry data. The committee wanted both short and long term data. Long-term data would usually be collected through post-market surveillance. NICE welcomes any submissions of new data on this procedure which can inform future reviews of this guidance. |
| 2 | Consultee 1 | **3** | Considerations - what about considerations from the patient or the patient's parents? No parents want to see their child suffer from pain or be deformed. All Spin surgery is scary.<br>VBT is an alternative to spinal fusion with rods. It is being practiced by many surgeons globally.<br>As a parent presented with VBT versus fusion with rods, opting for fusion should be the last resort. Once it is fused together, it is forever, limited flexibility to bend and stretch. VBT seems a logical choice to buy a child a few more years of spinal flexibility while reducing the curvature unit the person reaches adulthood.<br>I would like to see medical comparison / evidence between VBT and Fusion with patient feedback reporting back on the patient's on going livelihood. | Thank you for your comment.<br><br>The overview includes studies that compared VBT with posterior spinal fusion, and summaries health-related quality of life data when reported.<br>NICE sent a questionnaire to relevant patient organisations but none was returned. NICE also encouraged these organisations to comment on the consultation documents, and therefore received feedback from Scoliosis Association UK (comments 13 to 16). |

| Com. no. | Consultee name and organisation | Sec. no. | Comments | Response<br>Please respond to all comments |
|---|---|---|---|---|
| 3 | Consultee 1 | **3.1** | VBT had been around for a while, there are medical professionals (mostly in the private sector) practicing and doing VBT surgery. Has enough evidence been compiled from a wide, global selection of medical professional? | Thank you for your comment.<br><br>NICE seeks the opinion of at least 2 professional experts in the UK on a procedure before it is considered by the committee. These professional experts are nominated or ratified by their professional organisations. For this procedure, 2 professional experts completed and returned the questionnaires. |
| 4 | Consultee 1 | **3.4** | Surely patient feedback/patient's parent feedback is important.<br>Did you provide a survey to make it easy for patients to provide feedback?<br>Not just medically, I want to know what is the impact to the patient carrying out every day activities e.g. what they can and cannot do before and after the surgery?; how do they feel on a daily basis before and after the surgery? | Thank you for your comment.<br><br>NICE sent a questionnaire to relevant patient organisations but none was returned. NICE also encouraged these organisations to comment on the consultation documents, and therefore received feedback from Scoliosis Association UK (comments 13 to 16). |
| 5 | Consultee 1 | **3.1** | The link does not work. We can't find this page<br>It's probably been moved, updated or deleted. | Thanks for your comment.<br>The link has been fixed. |
| 6 | Consultee 2<br>Zimmer Biomet | **2.3 & 3.3** | Please note this comment also is appropriate for section 3.3. From the expert questionnaires, the subject of complications appears to be gauged in the context of bracing as the standard treatment. VBT is only indicated after conservative management and as such is no longer an option in the group of patients concerned (i.e. bracing has failed or patient is intolerant to bracing). While the range of bracing recommendations varies (e.g. Kaelin 2020 notes bracing is indicated for curves 25° to 40°-45°) it is generally accepted that efficacy decreases as curve magnitude increases, further distinguishing the VBT and bracing populations. The nature of complications should be considered in the context of surgical alternatives to VBT, such as posterior spinal fusion (PSF) or lengthening rods, rather than bracing. | Thank you for your comment.<br><br>Section 2.3 has been changed to: "*Treatment of idiopathic scoliosis depends on a number of factors, including age, severity and location of the spinal curve, and the pattern and progression of the curve. In many cases, idiopathic scoliosis is mild and does not need treatment other than close monitoring and physical therapy. For moderate scoliosis and severe scoliosis,* |

| Com. no. | Consultee name and organisation | Sec. no. | Comments | Response<br>Please respond to all comments |
|---|---|---|---|---|
| | | | | *treatment **may progress through** casting, bracing and **spinal** surgery*".<br><br>The key safety outcomes are based on professional expert questionnaires and the evidence presented in the overview, which includes studies that compared VBT with other surgical alternatives. |
| 7 | Consultee 2<br>Zimmer Biomet | **1.2** | Zimmer Biomet is supportive of ongoing data collection for VBT procedures. A non-randomized, parallel assignment clinical study comparing the outcomes of VBT-treated and PSF-treated AIS patients is currently recruiting. The primary outcome measure of this study is revision within 2 years of the index procedure, and secondary outcome measures include major Cobb angle progression, curve progression, and curve flexibility, as well as spinal disc health in patients treated with VBT.<br>RCTs for this population, however, are generally infeasible. Tethering is not only a paediatric procedure which has existing RCT challenges due to parents being reluctant to consent their children, but also because of the major differentiation vs. fusion. | Thank you for your comment.<br><br>NCT03506334 was included in the ongoing trials section.<br>Section 1.2 states: *"further research should include randomised controlled trials or analysis of registry data",* but it doesn't describe that research should exclusively be RCTs. |
| 8 | Consultee 2<br>Zimmer Biomet | **1.3** | Zimmer Biomet welcomes the recommendation that VBT should be carried out by surgeons who have undergone a structured training programme. The first expert questionnaire mentioned the learning curve as a procedural concern and potential hindrance to wider NHS adoption, the study by Baroncini et al. (2021) cited in the draft IPG literature review reported contrary to this, with associated clinical benefits, they found "VBT [to have] a rapid learning curve: the estimated blood loss per screw is expected to decrease by 60%, intubation time and surgical duration by over 50%, and hospitalization length by 32% for each treated patient." | Thank you for your comment.<br><br>The committee considered both the professional expert questionnaires and the evidence included in the overview when making the recommendations. |
| 9 | Consultee 2<br>Zimmer Biomet | **3** | From the expert questionnaires, the subject of complications appears to be gauged in the context of bracing as the standard treatment. VBT is only indicated after conservative management and is no longer an option in the group of patients concerned (i.e. bracing has failed or patient is intolerant to bracing). While the range of bracing recommendations varies (e.g. Kaelin 2020 notes bracing is indicated for curves 25° to 40°-45°) it is generally accepted that efficacy decreases as curve magnitude increases, further distinguishing the VBT and bracing populations. The nature of complications should be considered in | Thank you for your comment.<br><br>Please see response in comment 6.<br><br>Pehlivanoglu (2021) was included in the key evidence of the overview. |

| Com. no. | Consultee name and organisation | Sec. no. | Comments | Response<br>Please respond to all comments |
|---|---|---|---|---|
| | | | the context of surgical alternatives to VBT, such as posterior spinal fusion, rather than bracing.<br><br>Additionally, there would be concerns around how to compare the outcomes given the different benefit/risk profiles of the treatments. As prospective comparative studies are published, it will remain important to view outcomes through the lens of differing patient goals when it comes to seeking treating with VBT versus PSF as both patient motivation for seeking treatment and their goals for the surgery often differ between the procedures. While the literature generally shows fusion to currently provide a greater percentage of curve correction, this improvement may be irrelevant to patient perception and long-term quality of life as long as tethering is able to stabilize the curve at a clinically acceptable angle. In a retrospective matched comparison of VBT and PSF patients, Pehlivanogli et al. (2021) found VBT to have statistically significant improvements over PSF in lumbar ROM, anterior–lateral lumbar bending flexibility, flexor and extensor endurances of trunk, and average motor strength of trunk muscles as well as “statistically superior SRS-22 and SF-36 scores.” VBT may currently have a higher re-intervention rate but, similar to what has been observed with growing constructs, this risk may be acceptable for families/surgeons given the unique benefits of VBT. | The Committee makes recommendations based on its assessment of the evidence on the efficacy and safety of this interventional procedure and it does not evaluate comparative effectiveness of different procedures for the same indication. |
| 10 | Consultee 2<br>Zimmer Biomet | **3.1** | In addition to the literature considered, there has been a substantial amount of evidence identified that has not been referenced in the summary document on any of pages p70-71 or in papers considered but excluded on p 74-88 of the overview. These references are supplied below:<br>• Cuddihy LA, Antonacci MD, Hussain AK, et al. Progressive Neuromuscular Scoliosis Secondary to Spinal Cord Injury in a Young Patient Treated With Nonfusion Anterior Scoliosis Correction. Top Spinal Cord Inj Rehabil 2019;25(2):150-156.<br>• DiBiasio EL, Barnett DE, Braun JT, Grottkau BE, Nimkin K. Anterior vertebral tethering: imaging of tether rupture [published online ahead of print, 2022 Jan 4]. Pediatr Radiol 2022;10.1007/s00247-021-05259-6.<br>• Hoernschemeyer DG, Boeyer ME, Tweedy NM, Worley JR, Crim JR. A preliminary assessment of intervertebral disc health and pathoanatomy changes observed two years following anterior vertebral body tethering. Eur Spine J 2021;30(12):3442-3449.<br>• Krakow AR, Magee LC, Cahill PJ, et al. Could have tethered: predicting the proportion of scoliosis patients most appropriate for thoracic anterior spinal tethering. Spine Deform 2021;9:1005–1012. | Thanks for your comment.<br><br>The recent studies by DiBiasio (2022), Hoernschemeyer (2021), Lee (2021), McDonald (2022), Meyers (2021), and Mishreky (2022) have been added to the overview.<br>Cuddihy (2019), Krakow (2021), Liu (2015), Polly (2021), Qiu (2021) and Yaszay (2017) did not meet the inclusion criteria.<br>Pehlivanoglu (2021), Rushton (2021) and Samdani (2015) were included in the overview. |

| Com. no. | Consultee name and organisation | Sec. no. | Comments | Response<br>Please respond to all comments |
|---|---|---|---|---|
| | | | • Lee NS & Kydes A. Regional Anesthetic Approaches for Postoperative Analgesia Following Vertebral Body Tethering: A Case Series. A&A Pract 2021;15(8):e01510.<br>• Liu J, Li Z, Shen J, et al. Spinal growth modulation with posterior unilateral elastic tether in immature swine model. Spine J 2015;15(1):138-145.<br>• McDonald TC, Shah SA, Hargiss JB, et al. When successful, anterior vertebral body tethering (VBT) induces differential segmental growth of vertebrae: an in vivo study of 51 patients and 764 vertebrae [published online ahead of print, 2022 Jan 22]. Spine Deform 2022;10.1007/s43390-022-00471-2.<br>• Meyers J, Eaker L, von Treuheim TDP, Dolgovpolov S, Lonner B. Early operative morbidity in 184 cases of anterior vertebral body tethering. Sci Rep 2021;11(1):23049.<br>• Mishreky A, Parent S, Miyanji F, et al. Body mass index affects outcomes after vertebral body tethering surgery [published online ahead of print, 2022 Jan 11]. Spine Deform 2022;10.1007/s43390-021-00455-8.<br>• Pehlivanoglu T, Oltulu I, Erdag Y, et al. Comparison of clinical and functional outcomes of vertebral body tethering to posterior spinal fusion in patients with adolescent idiopathic scoliosis and evaluation of quality of life: preliminary results. Spine Deform 2021;9(4):1175-1182.<br>• Polly DW, Larson AN, Samdani A, et al. Cost-utility analysis of anterior vertebral body tethering versus spinal fusion in idiopathic scoliosis from the perspective of the US integrated healthcare delivery system. ClinicoEconomics Outcomes Res 2021:13 175–190.<br>• Qiu C, Talwar D, Gordon J, Capraro A, Lott C, Cahill PJ. Patient-Reported Outcomes Are Equivalent in Patients Who Receive Vertebral Body Tethering Versus Posterior Spinal Fusion in Adolescent Idiopathic Scoliosis. Orthopedics 2021;44(1):24-28.<br>• Rushton PRP, Nasto L, Parent S, et al. Anterior Vertebral Body Tethering (AVBT) for Treatment Of Idiopathic Scoliosis in the Skeletally Immature: Results of 112 Cases. Spine 2021;46(21):1461-1467.<br>• Samdani AF, Ames RJ, Kimball JS, et al. Anterior vertebral body tethering for immature adolescent idiopathic scoliosis: one-year results on the first 32 patients. Eur Spine J 2015;24(7):1533-1539.<br>• Yaszay B, Doan JD, Parvaresh KC, et al. Risk of implant loosening after cyclic loading of fusionless growth modulation techniques: nitinol staples vs flexible tether. Spine 2017;42(7):443–449. | |
| 11 | Consultee 2 | **3.4** | Further efforts should be made to approach any / all of the numerous patient groups who offer support to the individuals and their families who resort to | Thank you for your comment. |

| Com. no. | Consultee name and organisation | Sec. no. | Comments | Response<br>Please respond to all comments |
|---|---|---|---|---|
| | Zimmer Biomet | | travelling abroad and paying privately, often via crowd-funding for the procedure. The patient voice in this assessment is critical, particularly as VBT offers an alternative to fusion with a different benefit/risk profile. The decision to perform VBT almost always is the result of a shared decision-making process between the surgeon and family with a critical review of what each treatment offers vs. what is important to them.<br><br>Please also refer to comments related to "The Evidence" which examines how patients may view the risks / benefits of VBT. | NICE appreciates the importance of patient opinion on individual procedures. NICE sent a questionnaire to relevant patient organisations, but no patient commentary was received. NICE also encouraged these organisations to comment on the consultation documents, and therefore received feedback from Scoliosis Association UK (comments 13 to 16).<br>The committee has considered the recent studies (please see response in comment 10) and decided not to change the guidance. |
| 12 | Consultee 3<br>BOA | **1** | We understand the British Scoliosis Society (BSS) has responded directly to this consultation, and we have had sight of their response and would support their comments and the need for well constructed, high-quality research trials. | Thank you for your comment. |
| 13 | Consultee 4<br>Scoliosis Association UK | **1.1** | Agreed, but Scoliosis Association UK (SAUK) members who have contacted us through our Helpline and those who I have talked to were unanimous in their desire to have this procedure for their children on the grounds that the recovery from surgery is much quicker than for spinal fusion (hence interfering less with schooling) and that flexibility of the spine is preserved. These are the overriding considerations for parents and their children. I spoke in depth to 5 parents. All five of their children were just prepubertal with a curve size around 45 degrees at the tie of VBT. Only one child had had the procedure in the NHS system and that was as part of an RCT at RNOH Stanmore. In only one did VBT have a satisfactory outcome. The tether broke in the other four cases. SAUK has been pressured by some members to lobby for VBT to be available on the NHS, but we have consistently said that the evidence that it is a reliable and effective method is not available and that we cannot recommend it.<br>The scoliosis surgeons I have talked to, all members of the British Scoliosis Society, all say that spinal fusion works and works for all children and that it is their treatment of choice for AIS in the appropriate age group. | Thank you for your comment.<br><br>The committee welcomes and has considered the feedback from patients and scoliosis surgeons. |

| Com. no. | Consultee name and organisation | Sec. no. | Comments | Response<br>Please respond to all comments |
|---|---|---|---|---|
| 14 | Consultee 4<br>Scoliosis Association UK | **1.2** | Agreed. Reliable research is absolutely needed and it is encouraging that a large RCT is underway in the UK. | Thank you for your comment. |
| 15 | Consultee 4<br>Scoliosis Association UK | **1.3** | Absolutely agree with this. I would add that the message needs to reach GPs. Too often we hear that GPs refer scoliosis patients the local orthopaedic department, which introduces a delay to treatment while the child is referred on to a scoliosis centre. | Thank you for your comment.<br><br>Section 1.3 provides an overview of who should do the procedure but not a description of the referral process. |
| 16 | Consultee 4<br>Scoliosis Association UK | **1.2** | Clearly VBT has a higher complication rate than spinal fusion. Parents and their children with scoliosis are very keen to have VBT because of the perceived advantages of a short recovery and preservation of spinal flexibility. But the long term consequences are not known, so these can be regarded as only short term benefits. The success of spinal fusion is not in doubt but patients and their families find it a daunting prospect, which is understandable. It is essential that RCTs are done to establish the true success rate of VBT before it can become a recommended treatment. Educating the public about the pros and cons of VBT seems to be desirable. | Thank you for your comment.<br><br>Section 1.2 recommends the types of research needed but not a detailed description of the requirements for conducting research. Long-term data would usually be collected through post-market surveillance. |
| 17 | Consultee 5<br>British Scoliosis Society (BSS) | 1.1 & 1.2 | 1. BSS supports the draft recommendation that VBT should only be used in the context of research.<br>2. BSS feels that the quality of any research should be of a higher standard focussing on key outcomes supporting the hypothetical superiority of VBT over posterior spinal fusion (motion, growth) and studies should report on long term outcomes (including outcomes after skeletal maturity). | Thank you for your comment.<br><br>Section 1.2 provides an overview of the types of research needed but not a detailed description of the requirements for conducting research. Long-term data would usually be collected through post-market surveillance. |
| 18 | Consultee 5<br>British Scoliosis Society (BSS) | 1.3 | BSS supports the service specification provided by CRG via NHSE. This procedure should only be completed in centres satisfying the full service specification for paediatric spine surgery with specific training and infrastructure supporting anterior scoliosis surgery | Thank you for your comment.<br><br>Section 1.3 provides an overview of who should perform the procedure but not a description of the requirements for the specialist centres. |
| 19 | Consultee 5 | 2.3 | 1. Scoliosis in this context is a 3 dimensional deformity of the spine<br>2. Treatment thresholds vary and are dependent on progression and skeletal maturity as well as other factors. Both the BRAIST trial (Weinstein SL et al. | Thank you for your comment. |

| Com. no. | Consultee name and organisation | Sec. no. | Comments | Response<br>Please respond to all comments |
|---|---|---|---|---|
| | British Scoliosis Society (BSS) | | Effects of bracing in adolescents with idiopathic scoliosis. N Engl J Med. 2013;369(16):1512-1521) and the current NIHR BASIS UK trial set a range of 20-40 degrees for bracing. | Section 2.1 has been changed to: "*Scoliosis **is a 3 dimensional spinal deformity. It** causes the bones of the spine to twist or rotate so that the spine curves sideways. Scoliosis curves most commonly happen in the upper and middle back (thoracic spine). It can also develop in the lower back and, occasionally, happens in both the upper and lower parts of the spine."*<br><br>Section 2.3 has been changed, please see the updated wording in comment 6. |
| 20 | Consultee 5<br>British Scoliosis Society (BSS) | 2 | 1. International clinical experience is finding that although VBT is indicated in skeletally immature children, there is a higher rate of overcorrection in children who are very immature (Sanders< 3). VBT is usually indicated in flexible scoliosis curves and in curves that are not hyperkyphotic. There is no evidence of benefit in skeletally mature patients (page 5 – what the procedure involves).<br>2. There is no evidence of improvement in vertebral body rotation with VBT (which is responsible for the visible deformity and rib prominence) | Thank you for your comment.<br><br>Sections 2.4 to 2.6 provide an overview of the procedure but not a detailed description. |
| 21 | Consultee 5<br>British Scoliosis Society (BSS) | 3.1 | 1. It is a pity that despite the evidence identified in the literature review, the complication rate is not more obviously outlined in the document.<br><br>2. Most evidence is retrospective and non-comparative. | Thank you for your comment.<br><br>The overview details the complication rate when reported. Section 1.1 recommends evidence on the safety is limited but raises concerns of serious complications… this procedure should only be used in the context of research. |
| 22 | Consultee 5<br>British Scoliosis Society (BSS) | 3.5 | 1. International clinical experience is finding that although VBT is indicated in skeletally immature children, there is a higher rate of overcorrection in children who are very immature (Sanders< 3). VBT is usually indicated in flexible scoliosis curves and in curves that are not hyperkyphotic. There is no evidence of benefit in skeletally mature patients.<br>2. Although a PSF is not precluded; complications related to revisional surgery are not well documented and need to be considered / researched.<br>3. The complication rates (including mechanical failure such as tether breakage) | Thank you for your comment.<br><br>For point 1, please see response in comment 20.<br>Points 2 to 4 – please see response in comment 21. |

| Com. no. | Consultee name and organisation | Sec. no. | Comments | Response<br>Please respond to all comments |
|---|---|---|---|---|
| | | | are higher than PSF.<br>4. There is a perception that complications are under reported in the literature. | |
| 23 | Consultee 5<br>British Scoliosis Society (BSS) | | 1. Baroncini A et al retrospectively reported on a non-comparative cohort of 31 VBT operated patients that they administered a validated sport activity questionnaire. Thirty-one patients aged 14.5 years completed the SAQ. Within 3 months from VBT, 97% returned to school, 61% resumed physical education, 97% carried a backpack, 68% run, and 82% rode a bike; 70% bent within a month from VBT. Ninety-four percent of patients returned to their preoperative athletic level. Within 3 months, 63% of responders resumed noncontact, 61% contact and 53% collision sports. No relevant associations were observed between the SAQ and demographic, radiographic and surgical data. In particular, number of instrumented vertebrae, level of the lowest instrumented vertebra and postoperative Cobb angle did not influence patients' return to preoperative activities. They concluded that VBT allows patients to quickly return to their preoperative activity level, irrespectively of the postoperative Cobb angle or type of instrumentation.<br>(Baroncini, A et al. Return to sport and daily life activities after vertebral body tethering for AIS: analysis of the sport activity questionnaire. European Spine Journal (2021) 30:1998–2006). | Thank you for your comment.<br><br>Baroncini et al. (2021) was included in the appendix.<br>The committee considered all the evidence included in the overview when making the decision. |
| 24 | Consultee 5<br>British Scoliosis Society (BSS) | General | The following were collated comments from the British Scoliosis Society (BSS) executive:<br>1. BSS supports the draft recommendation that VBT should only be used in the context of research.<br>2. BSS feels that the quality of any research should be of a higher standard focussing on key outcomes supporting the hypothetical superiority of VBT over posterior spinal fusion (motion, growth) and studies should report on long term outcomes (including outcomes after skeletal maturity).<br>3. Most evidence is retrospective and non-comparative.<br>4. The complication rates (including mechanical failure such as tether breakage) are higher than PSF.<br>5. There is a perception that complications are under reported in the literature.<br>6. The revision procedure may have significant complications as it is a revisional anterior procedure.<br>7. There does seem to be a subgroup (yet to be determined) that would benefit from VBT<br>8. There seems to be no advantage on using this technique in skeletally mature | Thanks for your comment.<br><br>Point 1 & 2: please see response in comment 17.<br>Point 3: please see response in comment 21.<br>Points 4 to 6: please see response in comment 22.<br>Points 7 & 8: Section 3.5 states: *"The committee was informed that: this procedure is indicated for patients with progressive scoliosis who still have significant growth potential..."* and section 1.1 recommends that … this procedure should only be used in the context of research. |

| Com. no. | Consultee name and organisation | Sec. no. | Comments | Response<br>Please respond to all comments |
|---|---|---|---|---|
| | | | patients (USA, Germany and Turkish centres using on skeletally immature and mature patients). | |
| 25 | Consultee 6<br>Spinal Services Clinical Reference Group (CRG) NHSE | 1 | 1. The Spinal Services CRG supports the British Scoliosis Society view and the NICE draft recommendation that VBT should only be used in the context of research.<br>2. The Spinal Services CRG supports the BSS view that the quality of any research should be of a higher standard focussing on key outcomes supporting the hypothetical superiority of VBT over posterior spinal fusion (motion, growth) and studies should report on long term outcomes (including long term outcomes after skeletal maturity). | Thank you for your comment.<br><br>Please see response in comment 17. |
| 26 | Consultee 6<br>Spinal Services Clinical Reference Group (CRG) NHSE | 1.3 | The spine surgery service specification from the Spinal Services CRG (NHSE) is already published outlining the requirements for paediatric spine surgery centres. This procedure should only be performed in centres where the full service specifications are met and the skills and infrastructure for paediatric anterior spinal surgery are established. | Thank you for your comment.<br><br>Please see response in comment 18. |
| 27 | Consultee 6<br>Spinal Services Clinical Reference Group (CRG) NHSE | 2 | Spinal Services CRG supports the British Scoliosis Society view that:<br>1. Scoliosis in this context is a 3 dimensional deformity of the spine.<br>2. Treatment thresholds vary and are dependent on progression and skeletal maturity as well as other factors. Both the BRAIST trial (Weinstein SL et al. Effects of bracing in adolescents with idiopathic scoliosis. N Engl J Med. 2013;369(16):1512-1521 )and the current NIHR BASIS UK trial set a range of 20-40 degrees for bracing.<br>3. International clinical experience is finding that although VBT is indicated in skeletally immature children, there is a higher rate of overcorrection in children who are very immature (Sanders< 3). VBT is usually indicated in flexible scoliosis curves and in curves that are not hyperkyphotic. There is no evidence of benefit in skeletally mature patients.<br>4. There is no evidence of improvement in vertebral body rotation with VBT which is the abnormality that leads to visible deformity and rib prominence. | Thank you for your comment.<br><br>Points 1 and 2, please see response in comment 19.<br>Points 3 and 4, please see response in comment 20. |
| 28 | Consultee 6<br>Spinal Services Clinical Reference Group (CRG) NHSE | 3 | The Spinal Services CRG supports the British Scoliosis Society view that:<br>1. Most evidence is retrospective and non-comparative.<br>2. The complication rates (including mechanical failure such as tether breakage) are higher than PSF.<br>3. There is a perception that complications are under reported in the literature.<br>4. The revision procedure may have significant complications as it is a revisional anterior procedure. Even though PSF is not precluded, the complications from revisional surgery of any type are not reported and needs to be researched. | Thank you for your comment.<br><br>Please see response to comment 24. |

| Com. no. | Consultee name and organisation | Sec. no. | Comments | Response<br>Please respond to all comments |
|---|---|---|---|---|
| | | | 5. There does seem to be a subgroup (yet to be determined) that would benefit from VBT<br>6. There seems to be no advantage on using this technique in skeletally mature patients (USA, Germany and Turkish centres using on skeletally immature and mature patients). | |
| 29 | Consultee 6<br>Spinal Services Clinical Reference Group (CRG) NHSE | 3 | 1. It is a pity that despite the good evidence review, the complication rates are not clearly outlined in the document.<br>2. Most evidence is retrospective and non comparative. | Thank you for your comment.<br><br>Please see response in comment 21. |
| 30 | Consultee 6<br>Spinal Services Clinical Reference Group (CRG) NHSE | 3 | The complication rates should be stated clearly in this document | Thank you for your comment. |
| 31 | Consultee 6<br>Spinal Services Clinical Reference Group (CRG) NHSE | General | The British Scoliosis society have shared the following comments with CRG. The Spinal Services CRG supports these comments as the BSS is the main spine society dealing with this disorder and scoliosis treatment in the UK:<br>1. BSS supports the draft recommendation that VBT should only be used in the context of research.<br>2. BSS feels that the quality of any research should be of a higher standard focussing on key outcomes supporting the hypothetical superiority of VBT over posterior spinal fusion (motion, growth) and studies should report on long term outcomes (including outcomes after skeletal maturity).<br>3. Most evidence is retrospective and non-comparative.<br>4. The complication rates (including mechanical failure such as tether breakage) are higher than PSF.<br>5. There is a perception that complications are under reported in the literature.<br>6. The revision procedure may have significant complications as it is a revisional anterior procedure.<br>7. There does seem to be a subgroup (yet to be determined) that would benefit from VBT<br>8. There seems to be no advantage on using this technique in skeletally mature patients (USA, Germany and Turkish centres using on skeletally immature and mature patients). | Thank you for your comment.<br><br>Please see response in comment 24. |

*endorsed by NICE, its officers or advisory committees."*