National Institute for Health and Clinical Excellence

358 – Intramedullary distraction for lower limb lengthening

Comments table

IPAC date: 15 September 2006

Consultee name and organisation	Section no.	Comment no.	Comments	Response Please respond to all comments
Individual respondent – manufacturer	**1 – Provisional recommendations**	1	The ISKD device was evaluated very carefully to obtain CE marking and FDA approval, and is currently the only device to have both of these approvals. It is premature to place restrictions on its usage. The complications of the device are no more than with lengthening by external fixation or over a nail, although they may well be different. This has happened before as the technology evolved. We do not think that the complications of this procedure should be looked at in isolation, but with reference to those of existing techniques. Lengthening has always produced a proportion of complications, which are recognised in the literature, and divided into those that are fully remediable with a further procedure and those that will leave	Thank you for your comment. It is not within the remit of the interventional procedures programme to fully evaluate the relative effectiveness of devices.

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			sequelae of some sort. The prime objective of surgery in all cases treated with the ISKD device was achieved. The technique of intramedullary lengthening requires careful patient selection and preoperative planning, as is made clear in the manuals. All surgeons who are cleared to use the ISKD device have been trained to do this by experienced peers, including patient selection, implant selection, operative technique and postoperative management.	
Individual respondent – manufacturer	**2.1 – Indications**	2	The known complications of external fixation should be considered. Prof. R. Aldegheri pioneered the use of monolateral external fixation for lengthening, and in 1999 reported the complication rates of tibial lengthening in 230 tibiae in 150 patients (JBJS-A 1999, 81:624-34). Ten (14%) of the seventy procedures performed because of a limb-length discrepancy and forty-six (29%) of the 160 performed because of a short stature were associated with a complication. In 2001 he reported the results of 140 patients lengthened for short stature (J.Ped.Orthop-B 2001;10:238-247). In the 130 patients with disproportionate short stature, the average gain in	Thank you for your comment. The guidance is concerned with the safety and efficacy of the procedure in question: it is not within the remit of the Programme to compile a clinical guideline on the condition.

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			length was 18.23.93 cm: 43.8% had complications and 3.8% sequelae; the average treatment time was 31 months. Noonan reported 61% complications in 261 lengthenings in 1998. Dahl reported 13% for monolateral and 33% for circular fixation in 1994. The community of reconstruction surgeons who lengthen bone meet frequently to discuss these complications and how to reduce them. Intramedullary lengthening is included in this and a UK ISKD users group met in November 2005 as part of this peer group evaluation.	

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Individual respondent – manufacturer	**2.2 – Outline of the procedure**	3	3 devices are being considered: the Albizzia Lengthening Device was introduced in 1993, and is a mechanical device which lengthens by turning a threaded rod against a ratchet. The patients had to twist the leg 23 degrees to achieve one click of the ratchet. This is painful and required an anaesthetic to a variable extent. The device was withdrawn at the end of 2005 and is no longer available. The Fitbone device produces distraction by the activation of an internal motor via an external transducer. It does not have regulatory approval in Europe or the USA. The ISKD has a threaded rod as the Albizzia device, but distraction is achieved differently: the drive mechanism does not carry axial load, as in the Albizzia, and works by physiological movements of the leg (3-9 degrees) by the activation of two opposed clutches. Once implanted and fixed the device can exert a distraction force which causes gradual separation of the osteotomy at a rate of around 1.0 mm a day, and this stimulates the formation of new bone at the osteotomy site. NONE of the available devices produce distraction by releasing a pre-loaded spring as described.	Thank you for your comment. It is not within the remit of the IP programme to fully evaluate the relative effectiveness of devices. The overview sets out which safety outcomes relate to which device.

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Individual respondent – manufacturer	**2.3 – Efficacy**	4	There are no randomised controlled trials (RCTs) comparing different methods of lengthening. This is not a procedure that lends itself to an RCT. It would be extremely hard to do and possibly not ethical. We think that this should be recognised in the review. 3 out of 6 of the Case Series reviewed concern the use of the Albizzia lengthener. This is not surprising as it was the first device to become available. At the end of 2005 the manufacturer, DePuy Johnson and Johnson, Villeurbanne, France, ceased production and is no longer selling this device, presumably recognition that the technology has moved forward. We do not consider that it is appropriate that the first three papers out of six to be considered in relation to this technology should refer exclusively to the now obsolete Albizzia device. The problems with this device are no longer relevant. We also wish to point out that the Fitbone device is not CE marked or FDA approved. Its usage in Europe is severely limited and the product should still be considered to be under development. We suggest that the paper which refers to this device should also not be included in any	Thank you, your comment has been noted. Studies were selected for inclusion in the overview based on sample size and follow-up length, regardless of the device used. In line with the IP Programme Manual on the use of evidence for devices without a CE mark, the evidence relating to the Fitbone device has been removed from the overview.

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			evaluation.	
Individual respondent – manufacturer	**2.4 – Safety**	5	If the papers regarding the Albizzia and Fitbone devices are discounted regarding the use of this technique today, all of the complications described in these two sections would be removed. The last sentence would remain, describing a series of 18 patients proceeding with treatment without major problems. We have details of all of the complaints referred to the Quality Department of the ISKD manufacturer of record, who is Orthofix Inc. in the USA. It is a statutory requirement that this information is recorded and acted upon, and that where indicated the complaint is referred to the FDA. During the period of data collection 928 ISKD devices were implanted globally; there were 202 complaints, of which 14 were reported to the FDA. We are not suggesting that this is the total number of complications which occurred during this period, but it is the total number of complications considered serious enough by the surgeon to report to the manufacturing company. I wished to supply this document, but there is no mechanism to do it.	Thank you for your comment. Studies were selected for inclusion in the overview based on sample size and follow-up length, regardless of the device used.