Cases of blunt needle in Nexplanon® insertion device

I have used both the Implanon® (discontinued October 2010) and the new Nexplanon® in practice since 2006. Only recently did I notice that during fitting one particular batch of Nexplanon (195129/312993) was slightly harder to both puncture the skin and then advance the needle. I do not routinely use a scalpel blade to facilitate fitting and neither do I anaesthetise along the track. I was able to achieve a subdermal placement but felt that these implants were slightly deeper than my usual fittings. This could be subjective as I was still able to palpate the implant post-insertion. This was reported to the Nexplanon team at MSD in January 2013. Upon further contact with MSD on 22 May 2013 we were informed that these implants were found to have a blunt needle, a Class III recall has been undertaken and the batch in question has been recalled from the wholesalers level but not surgery level. We were also told that the matter was reported to the Medicines and Healthcare Regulatory products Agency and we are yet to hear of any further action.

In total 12 implants of this batch number were fitted from 28 January until 14 May 2013. No intra-insertion (bruising, itching or pain) or short-term (poor wound healing or infection) complications were recorded. Ten patients did not request any follow up. Two patients were reviewed for non-insertion-related adverse effects (one for irregular bleeding and one for abdominal bloating, worsening anxiety and headache).

I found one study comparing the relative safety of sharp versus blunt needles. The study concluded that blunt needles are less likely than sharp ones to damage vital structures and/or produce haemorrhage. This may not be significant with respect to Nexplanon as subdermal insertion is unlikely to encounter anatomically vital structures. Bruising following fitting is fairly common and is not reported to practitioners. Intentional use of a blunt needle, therefore, is unlikely to be of significant benefit.

Some studies show that compared to intradermal lidocaine, ethyl chloride is less potent in producing skin anaesthesia. It would be of interest to know if ethyl chloride-induced anaesthesia (used by some clinicians for fitting) would have been sufficient in these cases.

The only significant long-term complication might be difficulty in removal as the implant could have been placed in a slightly deeper plane. The patient may require a more aggressive procedure, which might adversely influence subsequent implant uptake. However, bearing the aforementioned study in mind, the blunt needle is less traumatic and might lead to less bleeding and capsule formation. This could actually facilitate removal.

Only prospective follow-up of these patients will reveal the significance, if any, of this incident. I am wondering if any Journal readers have come across similar cases.

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REFERENCES