Implant Fitters Workshop 2022

Unity Update Day

10/05/2022

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What we will cover today

- New insertion site – Jan 2020
  – Why it matters
- CEU FSRH guidance – Feb 2021
  – Different approach to counselling about bleeding, broken implants, extended use
- Demonstration of insertion and removal procedure
- Case discussions and Q&As

Insertion site

- Why does it matter?
  - Incidences of deep insertion
  - Referral to deep implant removal clinics (DIC)
- Consequences of deep insertion:
  - Intravascular insertion and Migration
  - Nerve injury
- MHRA alert about migration June 2016
- Strong advice from manufacturers and FSRH 2016 to avoid placement in groove

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Insertion issues -1

- Likelihood of deep insertion?
  – The incidence of deep implants in the study was 8.8 per 1000 insertions (Nexplanon Organisational Risk Assessment study)
  – Non-interventional, safety study
  – 7,364 women in US between 2011-2017
  – Published March 2018
  – Called the NORA study

Insertion issues-2

- How common is migration?
- Observational study- followed up 100 Implanon® insertions: if inserted correctly, migration of implant from insertion site is typically < 2cm
- BUT
  - – case reports of greater local migration(6-12 cm)
  - – distant migration has also been reported…
- MSD data: one case of intravascular migration for every 1 million implants sold

» French data suggest rate of 1 in 100,000 BUT note no requirement for formal training

Patient counselling

"individuals considering the implant should be made aware that intravascular insertion and distant migration are rare complications"

"individuals considering the implant should be made aware that deep insertion is a complication"

"individuals considering the implant should be made aware that nerve injury is a complication"

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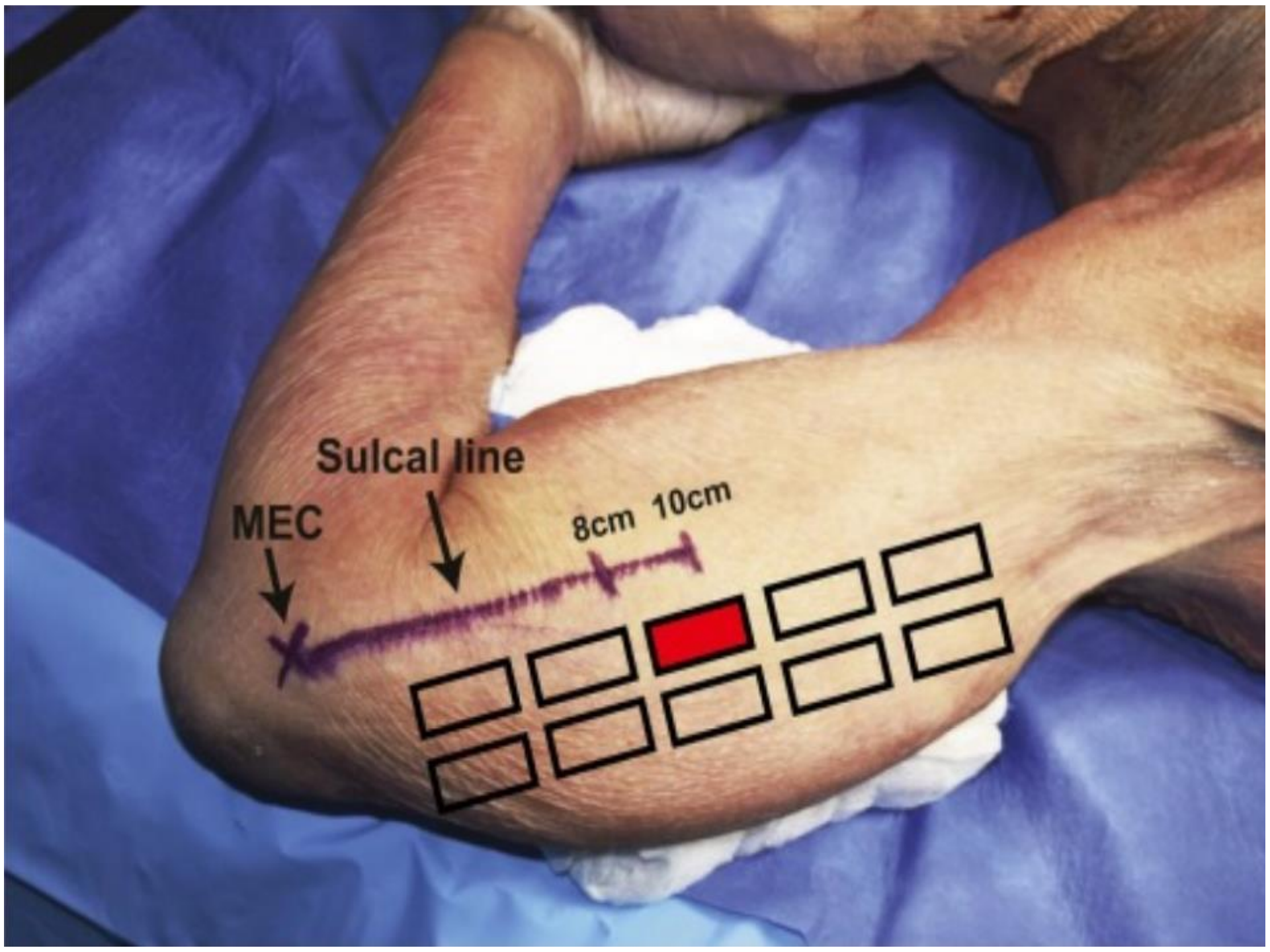
Study -Contraception Mar 2019

- 40 female cadaveric arms dissected
- Two rows of 10 dissection windows were created in the inner arm overlying the triceps approximately 2–3 and 4–5 cm posterior to the bicipital sulcus
- primary window: 8–10 cm proximal to the medial epicondyle and approx 2–3 cm posterior to the sulcus
- The entire medial upper arm was dissected to visualize underlying structures

- https://www.contraceptionjournal.org/article/S0010-7824(19)30041-1/fulltext


Sulcal line
MEC
8cm
10cm

Results of the Study

- No major neurovascular structures were located 3–5 cm posterior to the sulcus.
- Elbow flexion with the hand underneath the head displaced the ulnar nerve anteriorly towards the sulcus.
- The ulnar nerve pierces the fascia and becomes superficial 6–8 cm proximal to the medial epicondyle.

Insertion

- No major structures located 3-5cm posterior to sulcus
  - Nerve injury can result in numbness, paraethesia, decreased pressure and pain sensation, burning sensation, impaired grip

Insertion

- New advice
- - Arm flexed at elbow and hand under head (moves ulnar nerve out of way); 8-10cm from the med epicondyle and 3-5cm posterior to sulcus
  - Use non-dominant arm
  - Measure with a ruler
  - Insert parallel to groove
  - Keep as superficial as possible

1. Updated position of arm

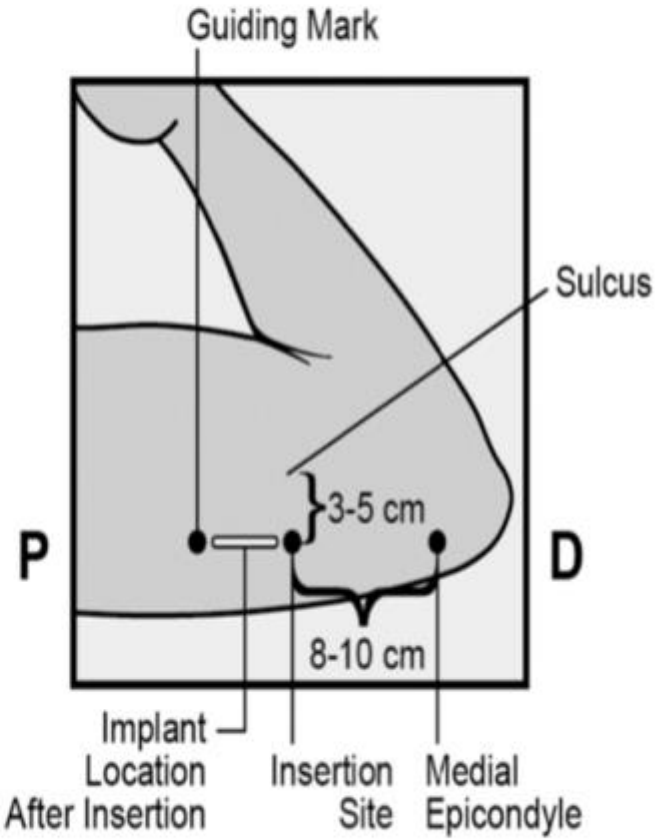
- arm should be flexed at the elbow
- hand underneath head
- during insertion and removal of the implant.
- flexing the elbow moved the ulnar nerve anteriorly, towards the sulcus and away from the implant insertion site

2. Updated insertion site

- overlying the triceps muscle:
  - 8-10 cm (3-4 inches) from the med epicondyle

  AND

  - 3-5 cm (1.25-2 inches) posterior to the sulcus (groove)



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Insertion and removal instructions

Insertion

1. Lidocaine with or without adrenaline; ethyl chloride spray – max 3ml
2. No-touch technique
3. Angle of insertion
4. Avoid scalloping
5. Palpate implant after insertion
6. Pressure for 24-48 hrs

Removal

1. Removal: max 1ml LA
2. Sterile gloves for removal
3. Use a 2mm Longitudinal incision for removal
4. Steri-strips; pressure for 48 hours

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Possible variations – where there is no evidence or lack of consensus to guide a recommendation

1. Use of written consent
2. Non-sterile or sterile gloves for insertion
3. cleaning skin - steret/ wipes or solution
4. Whether to anaesthetise entire track or just insertion point
5. Type of scalpel eg 11 vs 16

Main changes in advice

1. No recommendation to switch arms after 2 consecutive implants
2. No need to “consider earlier replacement in heavier patients”
3. An association between implant and reduction in BMD cannot be confirmed or excluded – (note this is a more cautious interpretation in guidance than in existing FSRH guidance)
4. Bleeding patterns

Bleeding patterns

- Emphasis on unpredictability of bleeding
- Move away from presenting stats of likely bleeding patterns as this implies an element of predictability

Advise:

1. change in bleeding pattern likely at start
2. Bleeding pattern is unpredictable, often irregular
3. bleeding may change during use at any time
4. how to access support for management of problematic bleeding

Rx:

- 3/12 trial of use of COC
- or a five day course of mefenamic acid

Take home messages

- Inadvertent deep implant insertion : risk approx 1%
- Avoid groove and use non-dominant arm
- Emphasis on unpredictability of bleeding when counselling prior to insertion
- No need to replace earlier if >150kg
- Always measure and document length of implant on removal
- Consider possibility of retained fragment if implant was reported to be broken
- No need to defer IUC fit if patient presents in year 4

Thank you

We move to demonstration and case discussions