Innovative Medical Technology Overview: Number 001/2014

This IMTO review document describes an impartial review of the strengths and weaknesses of the submission by BRAIDLOCK LIMITED regarding the following medical technology.

The Braidlock®

Overview of technology

Braidlock® is a Class I non-invasive disposable medical device which provides securement for peripheral devices using tubing from 3.5Fr to 36Fr.

Braidlock® attaches lines, drains and catheters to a patient, and is suitable for use in a variety of clinical settings including cardiothoracic surgery, obstetrics and gynaecology, plastic surgery, ENT, and neo-natal intensive care. The diameter of the Braidlock® expands when the device is compressed, similar to a ‘Chinese finger trap’. A line can then be inserted through the device and into the body. When decompressed, the Braidlock® squeezes the line tightly and securely.

There are three versions of Braidlock® available, distinguished by means of attachment: by integrated adhesive pad, by hook & loop, and by suture.

Comparator(s) and use in pathway of care

Braidlock® is positioned for use as an alternative to the suture pack for use in the standard ‘roman boot lace’ suture method of peripheral device (e.g. line, drain or catheter) securement. There is anticipated to be no change to the current pathway of care.

Product performance

The main source of evidence relating to product performance was a UK single-centre, non-comparative, post market surveillance study to evaluate the clinical and safety performance of Braidlock® in paediatric patients with one or more chest drains after major chest surgery. A total of 50 subjects were enrolled in the study. The primary objective was to study the device's behaviour and to see whether the device made the securing, manipulation and removal of medical lines (chest drains) simple. Based upon subjective evaluation of the device by healthcare professionals, the study concluded that Braidlock® successfully secured the chest drains in place, is safe and is well received by healthcare professionals.

To offer evidence in support of the use of Braidlock® in adult populations, physician questionnaires were provided which reported the successful use of Braidlock® in a variety of clinical settings; for example ICU and care of the elderly wards.
Safety

Within the aforementioned surveillance study, the incidence and severity of clinically significant device related adverse events - up to the point of removal of the Braidlock® device - were assessed as secondary endpoints. The results of the study showed that, following on the finding that the device successfully secures line, there were no safety issues related to the use of Braidlock®.

The Braidlock® device is non-invasive and non-pharmaceutical.

With regards to the safety of the device, as a Class I device Braidlock® is considered to be low risk. However, there are uncertainties surrounding some safety aspects, for example, the use of the adhesive Braidlock® on patients with fragile skin. It must be noted that the appropriateness of the use of Braidlock®, rather than the standard suture method comparator, will be determined on a case by case basis and therefore such safety concerns can be minimised.

Strengths and limitations of the evidence

The product performance evidence comes from a UK post market surveillance study which shows that the device performs well and is well accepted by users. Also, there were no device related adverse effects identified in the study.

As described previously, Braidlock® offers an alternative to the standard suture method of peripheral device securement. However, there are no comparative studies available to directly compare Braidlock® with the standard suture method.

In terms of limitations associated with the product performance evidence, a surveillance study represents low quality evidence. Furthermore, the study focuses only on one clinical procedure – major chest surgery – and one patient group – paediatric patients. As such, the assumption is made that the results are applicable to line securement across all other procedures. For the adult population, the questionnaires that form the evidence base are also considered to be low quality evidence with particular uncertainties surrounding, for example, the selection of patient suggesting the results are at risk of selection bias.

Despite these limitations, owing to the fact that Braidlock® is a class I medical device - a low risk medical device that does not require any clinical evaluation for regulatory approval – the evidence provided is considered suitable to demonstrate the product performance of Braidlock®.

Economic considerations

With regards to the cost effectiveness of Braidlock®, the manufacturer presented a cost-minimisation analysis of Braidlock® compared with a conventional suture pack for use in the standard ‘roman boot lace’ suture method of peripheral device securement - on the basis that Braidlock® performs the task of line securement at least as successfully as the standard suture method. The analysis compared the respective unit costs per procedure.

Based on the Braidlock® price of £1.50 per unit, and a suture pack and removal kit (i.e. the components required for suture method) cost of £3.27 and £2.25 respectively, the results showed Braidlock® would be associated with unit cost savings of £4.02 per procedure.

The cost comparison with a suture pack and removal kit appears appropriate. However, data on the costs of the suture and removal kits currently used in NHS Scotland were obtained
from National Procurement (removal kit) and from NHS Greater Glasgow and Clyde Finance Department (suture kit). With regards to the suture kit, the data supplied by NHS Greater Glasgow and Clyde Finance Department indicates the cost used by the manufacturer (£3.27) is reasonable. However, National Procurement contract prices show that the cost of a removal kit is approximately £0.16, which results in a total comparator cost of £3.43. As such, the manufacturer has overestimated the unit cost savings associated with Braidlock®, and it is more realistic that these savings are approximately £1.93, rather than £4.02.

Savings in staff time associated with using adhesive Braidlock® were also estimated. The manufacturer submitted estimates, based on clinician feedback, that using the adhesive Braidlock® - rather than taking time to carry out the standard suture method - would save at least two minutes per line fixation. Although the use of the adhesive Braidlock® device may release staff time relating to the fixation and subsequent adjustment of lines, owing to the poor data quality supporting this assumption, it is not reasonable to quantify these time savings.

**Organisational and patient issues**

Owing to the adjustable method through which the Braidlock® device secures lines or drains, the manufacturer states that it is possible to adjust the lines or drains without the re-siting of the securement device. For example, a line may be removed entirely while the Briadlock remains in place, ready for a new line to be inserted. The standard suture method would require the removal of the sutures prior to reattachment.

The use of the adhesive Braidlock® obviates the need for sutures with multiple skin punctures. Following on from this, the manufacturer outlined infection control and comfort advantages as a result of reduced skin punctures around a wound site. However, evidence to support these assumptions was not presented and as such it is not possible to quantify any such benefits.

**Summary**

In summary, Braidlock® appears to be a safe medical device that enables the successful securement of peripheral devices such as line, drains or catheters. Braidlock® may represent a cost saving relative to the conventional suture pack used in the standard ‘roman boot lace’ suture method of peripheral device securement.