

## Reciprocating procedure device for thyroid cyst aspiration and ablative sclerotherapy

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### Abstract

Most thyroid cysts are benign; however, they require aspiration if symptomatic or atypical on ultrasound scanning, and ablation with ethanol injection if recurrent. We have systematically studied the use of new safety technologies for surgical procedures, which protect both the surgeon and the patient. Here, we describe the use of one such technology, the reciprocating procedure device, which enables simpler, safer, more efficient and less painful thyroid cyst aspiration and therapeutic ablation.

**Key words:** Fine Needle; Aspiration; Thyroid; Cyst; Safety

### Introduction

Thyroid cyst aspiration is a crucial diagnostic and therapeutic procedure for cystic lesions of the thyroid.<sup>1–3</sup> In order to prevent recurrence of benign cystic lesions, thyroid cyst ablation with ethanol sclerotherapy is an effective adjunctive therapy.<sup>4–8</sup> Although unusual, serious complications can occur, and have become a focus for lawsuits, medical malpractice legal action and compensation claims.<sup>7–15</sup>

Recently, new surgical safety technologies, such as safety needles and the reciprocating procedure device, have become available to surgeons; use of these technologies has been shown to reduce the incidence of both ‘needlestick’ injuries to surgeons and surgical injuries to patients.<sup>16–21</sup> In the present report, we describe how the reciprocating procedure device can facilitate safer, more efficient thyroid cyst aspiration and ablation.

### Surgical technique

This study was conducted in compliance with the Helsinki Declaration, was approved by the relevant institutional review board and was registered at *ClinicalTrials.gov* a service of the U.S. National Institutes of Health ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)). All products used were commercially available, Food and Drug Administration approved and CE [The CE marking (also known as CE mark) is a mandatory conformity mark on many products placed on the single market in the European Economic Area (EEA). The CE marking (an acronym for the French “Conformite Europeenne”) certifies that a product has met EU health, safety, and environmental requirements, which ensure consumer safety.] marked. A Becton Dickinson, Inc. safety needle with an off-axis rotating safety sheath (305761-25 g 1.5 inch and 305783-22 g 1.5 inch 3.81 cm Eclipse™ needle; BD, Franklin Lakes, New Jersey, USA) was used to reduce needle stick injuries to healthcare workers.

In order to improve quality of care and safety for patients during thyroid cyst aspiration procedures, the reciprocating procedure device was used (models one, three, five, 10 and 20; Avanca Medical Devices, Albuquerque, New Mexico, USA) (Figures 1 and 2). The reciprocating procedure device is formed around the core of a conventional syringe barrel and plunger, but has a parallel accessory plunger and an accessory barrel or track to control the motion of the accessory plunger (Figure 1). The two plungers are mechanically linked by a pulley in an opposing fashion, resulting in a set of reciprocating plungers. Thus, when the accessory plunger is depressed with the thumb, the syringe aspirates, and when the dominant plunger is depressed with the thumb, the syringe injects.<sup>18–21</sup>

### Thyroid cyst aspiration

In order to perform thyroid cyst aspiration, a 21 or 22 gauge needle is mounted on a 5, 10 or 20 ml reciprocating procedure device (Figure 2).

Prior to aspirating the cyst, 1–2 ml of 1 per cent lidocaine is placed into the reciprocating procedure device and injected intradermally, with a 22 gauge needle, into the skin directly over the thyroid cyst. The lidocaine is infiltrated deeper until the entire volume is injected, up to the surface of the cyst, while avoiding the actual lesion itself.

With the reciprocating procedure device emptied of lidocaine and the needle tip at the cyst edge, the thumb moves from the injection plunger to the aspiration plunger, which is depressed to the 1 to 3 ml mark in order to generate a gentle vacuum. The cyst fluid is aspirated completely into the reciprocating procedure device, while the free hand operates the ultrasound transducer or applies manual pressure to the cyst (Figure 2). For large cysts greater than 20 ml in volume, the needle tip is left within the cyst, and reciprocating procedure device syringe exchanges are performed, as necessary, until the cyst is empty. In order to exchange syringes, the reciprocating procedure

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Accepted for publication: 30 June 2008. First published online 17 September 2008.



FIG. 1

The reciprocating procedure safety device, which aspirates when the smaller plunger is depressed and injects when the larger plunger is depressed. A pulley system connects the two plungers so that they reciprocate in a cyclical fashion. Unlike a syringe, the reciprocating procedure device does not lengthen during aspiration or injection, and provides markedly improved safety and needle control.

device is carefully rotated off the needle hub, while the needle hub is held with the fingers. Alternatively, the reciprocating procedure device can be left in position and the needle rotated instead; another empty 10 or 20 ml reciprocating procedure device is then carefully rotated onto the needle (or the needle is rotated onto the new reciprocating procedure device), and the aspiration plunger of the reciprocating procedure device is depressed until the cyst is emptied.

#### Thyroid cyst sclerotherapy

Ethanol sclerotherapy is a well established procedure for the prevention of thyroid cyst recurrence.<sup>4–8</sup> The cyst fluid is first aspirated, using the reciprocating procedure device as



FIG. 2

Clinical photograph showing use of the reciprocating procedure safety device for ultrasound-directed thyroid cyst aspiration. The smaller plunger is depressed with the thumb to generate a vacuum and thus effect aspiration; the small plunger is then released to release the vacuum, prior to withdrawing the needle from the skin. The larger plunger is depressed to expel the fluid sample into a cytological tube or processing solution.

described above. After aspiration, the needle is left in the thyroid cyst and, while holding the external needle hub with the fingers, the reciprocating procedure device is carefully rotated off the needle hub. A 10 or 20 ml reciprocating procedure device filled with 95 per cent ethanol is attached to the intracystic needle, the aspiration plunger is pressed to draw a 'flashback' of cyst fluid into the reciprocating procedure device (in order to confirm the intracystic location of the needle tip) and the cyst is then injected with ethanol (using a volume equivalent to between one-third and one-half of the aspirated fluid volume) by pressing the injection plunger. Ethanol is left in the cyst, resulting in better cyst resolution. In order to prevent ethanol toxicity, the clinician must be careful to monitor the total volume of ethanol and to not exceed a total of 30 ml ethanol, especially in smaller individuals; patients should also be forbidden from driving themselves home immediately after the procedure. Thyroid cyst ablation with ethanol sclerotherapy involves at least two reciprocating procedure devices: one for administering local anaesthesia and for aspirating the cyst, and the other for ethanol instillation.

#### Discussion

Thyroid cyst aspiration is widely considered a relatively safe procedure.<sup>1–3</sup> However, complications, although rare, do occur, in 0.01 to 2 per cent of cases. Such complications include vasovagal reactions, procedure pain, anaesthesia pain, ecchymosis at the puncture site, haematoma, respiratory compromise, infection, abscess, recurrent laryngeal nerve paralysis, local necrosis, fibrosis, thyroid crisis, pneumothorax and tumour seeding along the needle track.<sup>7–16</sup> The operating physician may also suffer a needlestick injury, an occupational hazard for surgeons which can end their career.<sup>16,17</sup> New safety technologies have been demonstrated to reduce the incidence of injuries, for both patients and surgeons, by 40–70 per cent; thus, there is every reason to consider using such technologies when performing thyroid cyst aspiration and ablation.<sup>16–24</sup> The present article demonstrates that established safety technologies plus the reciprocating procedure device safety syringe can be simply used for thyroid cyst aspiration and sclerotherapy.

Safety needles cost 50 to 100 per cent more than conventional needles, but are widely recommended to replace all conventional needles used for nursing, pharmaceutical and medical procedures.<sup>16,17</sup> Currently (i.e. in 2008), the reciprocating procedure device costs approximately US\$1.50 per device. For this reason, the device is at present used primarily for physician-performed syringe and needle procedures and not for nursing or pharmaceutical procedures, which account for 95 per cent of syringes used. In otolaryngology, the reciprocating procedure device is used primarily to enable, more simply and safely, the following procedures: fine needle aspiration of soft tissue tumours; local anaesthesia; nerve blocks; precise administration of botulinum toxin; sclerotherapy of small varicosities; aspiration of head and neck cysts; aspiration of peritonsillar abscess; and, as described above, thyroid cyst aspiration and ethanol sclerotherapy.<sup>18–21</sup>

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Dr W L Sibbitt takes responsibility for the integrity of the content of the paper.  
 Competing interests: None declared

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