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A New Single Use Needle for Simultaneous Bone Marrow Aspiration and Trephine (Core) Biopsy Utilizing the Same Needle and Same Entry Site While Maintaining the Specimen Quality

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ABSTRACT

A needle is described for use in simultaneously taking a bone marrow aspirate and a core biopsy sample without sacrificing the quality of either specimen from the posterior iliac crest. The needle comprises a hollow tube with a front-end portion formed to a reduced diameter. The front end is tapered utilizing circumferentially spaced facets, forming a cutting edge. A tapering transition portion, between the main wider portion of the hollow tube and its reduced-diameter front end portion, is formed with a series of serrations/flutes that help in cutting the dense cortical bone, facilitating penetration. The distal, narrower portion of the needle has two side holes that communicate with the internally hollowed-out trocar and provide means of bone marrow aspiration.

Keywords: Bone Marrow Aspiration; Bone Marrow Trephine Biopsy; Bone Marrow Needle; Simultaneous Bone Marrow Aspiration and Bone Marrow Biopsy Using Same Needle

Introduction

Bone marrow examination plays a critical role in the investigation, diagnosis, and management of patients with various hematological, as well as non-hematological, disorders [1-6]. Optimal examination of the bone marrow requires combined cytomorphological evaluation of aspirated cells along with the histopathological examination of an undisturbed trephine (core) biopsy specimen, where the architectural relationships with trabecular bone, marrow, and fat cells are well preserved. A bone marrow aspiration is typically obtained from the sternum or from the posterior iliac crests, using a sternal puncture, or similar but longer needle, specially designed to obtain bone marrow aspirate samples from the posterior iliac crests [7,8]. Since it was introduced by Mikhail Arinkin in 1929 [9], the sternal puncture has been the most common procedure to access the hematopoietic marrow. In recent years, however, the choice of aspiration site has moved away from the sternum and shifted to the posterior iliac crests because it is safer there and delivers a larger volume of marrow aspirates when needed, and because of the advent of technologically improved bone marrow aspiration needles [7,8]. The latter anatomical site is also the largest and most readily accessible area of marrow-rich bone in the body and is also devoid of any important structures such as the great blood vessels that lie underneath and close to the sternum.

An adequate bone marrow aspiration and trephine biopsy specimens can be obtained from the posterior iliac crest simultaneously and without the danger of damaging critical structures such as the great blood vessels that lie underneath the sternum. The

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space between anterior and posterior plates of the sternum is shallow and quite limited, resulting in a definite fear and apprehension of penetration of the posterior wall of the sternum during the sternal puncture procedure, particularly if the distal penetrating end of the needle is too long, as in the conventional sternal puncture needles [10]. This problem may be exacerbated if the operator is inexperienced or if the bone is too soft, as in cases of osteoporotic marrow. In some instances, including the aforementioned situations, sternal puncture has resulted in death [11]. Because of the inherent disadvantages of the sternal puncture procedure currently, both bone marrow aspiration and core biopsies are performed at the posterior iliac crests using either the one- or two-needle technique [12]. Since the aspirate and trephine biopsy provide complementary information, both types of specimens are desirable and are co-obtained at the same site in a vast majority of cases. In the two-needle technique, a bone marrow aspiration is first obtained using a smaller diameter aspiration needle. Then using the same entry point but pointing the needle in a slightly different angle (direction), a trephine (core) biopsy is performed using a larger diameter trephine (core) biopsy needle.

However, because of the required extra time and inconvenience as well as the additional cost of using two needles, some investigators use the same bone marrow trephine (core) biopsy needle consecutively for both purposes. This is known as the one-needle technique [12]. The one-needle technique of aspiration and trephine biopsy using the same bone marrow biopsy needle at the same site has distinct disadvantages. In a recent comparison of the two techniques [12],

a) Aspiration before trephine biopsy using the same bone marrow biopsy needle (one-needle technique), and

b) Aspiration before trephine biopsy using an aspirate needle first for aspiration and then using a separate bone marrow biopsy needle for obtaining a trephine (core) biopsy (two-needle technique), the two-needle technique was found to be superior. The two-needle technique was noted to be neater and less bloody, providing ideal samples without compromising the technical quality and morphologic integrity of the biopsy specimens. However, the two-needle method requires two separate needles, which is time-consuming as it requires two separate procedures. It is also not cost effective as it requires two separate needles.

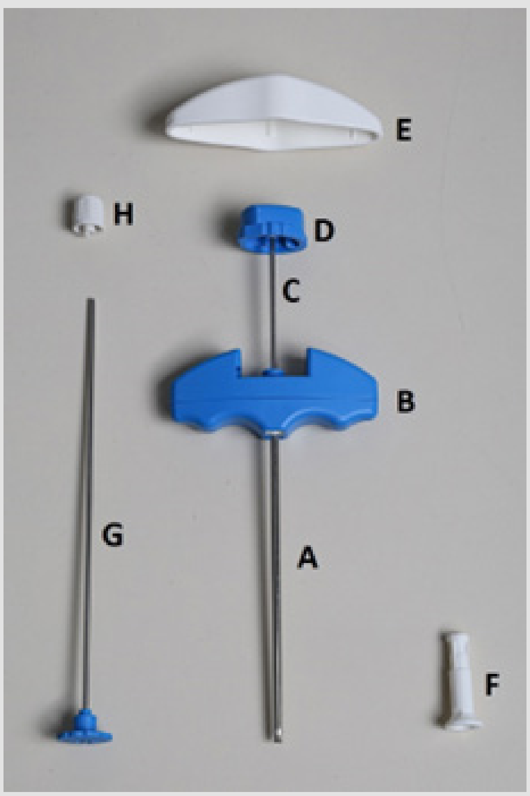

Figure 1:

A. The needle
B. Transverse (T-bar) handle
C. Trocar/stilette
D. Trocar head
E. Large plastic cap'
F. Insertion aid
G. Pusher rod
H. Small plastic Luer-lock cap

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To overcome the limitations of both the one-needle and two-needle techniques we have designed a new single-use needle to perform both aspiration and a trephine (core) biopsy simultaneously without sacrificing the quality of either the bone marrow aspirate or the bone marrow trephine (core) biopsy specimen. This new needle employs the same individual needle assembly and sole puncture site for withdrawal of liquid bone marrow (bone marrow aspiration) and trephine (solid core) biopsy specimen from the patient's body. In this new system, the trocar itself is used as a vehicle for bone marrow aspiration. The two side apertures/holes (one on each side near the distal narrower portion of the needle that communicate with the hollowed-out trocar) permit suction and flow of marrow from the surrounding lateral side (Figure 7 #3 arrows). This permits the distal marrow region (from where a core biopsy is obtained immediately following the bone marrow aspiration) undisturbed. This latter intact marrow—with its boney trabeculae and marrow architecture undisturbed—is then captured in the identical way a core sample is retrieved [13] by this new core retention bone marrow biopsy needle.

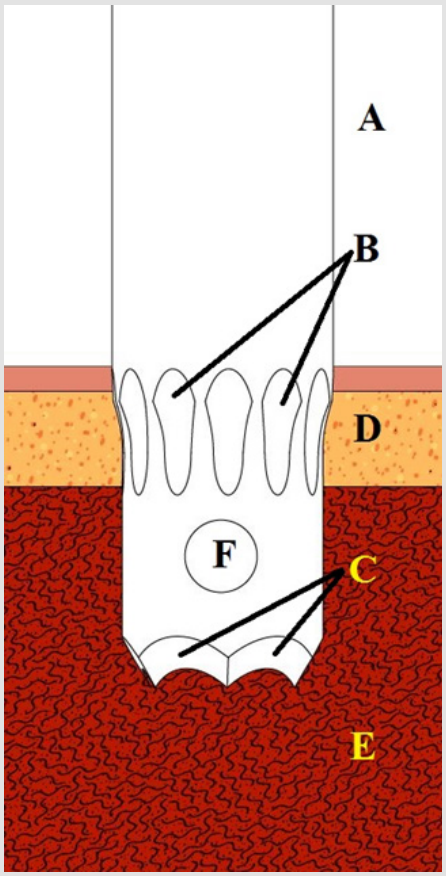

Figure 2: A schematic representation of the distal cutting end of the needle

A. The needle
B. External flutes/serrations
C. Sharp cutting facets
D. Dense cortical bone
E. Spongy bone/marrow cavity
F. Side hole/aperture

Materials and Methods

The Instrument (Figure 1) Consists of Six Parts:

The needle (Figure 1A) has an overall length of 70 -125 mm, a uniform external diameter of 3.30 mm, and a constant internal diameter of 2.9 mm except for the 3.5-millimeter distal portion where it is narrowed and has multiple outside serrations (flutes) (Figure 2B) and has six sharp cutting facets (Figure 2C). The internal diameter of this distal portion (2.1 mm) is less than the overall internal diameter of the longer proximal portion and begins with a short, slanted step of 0.2 mm (Figure 3G). The needle's specially designed distal cutting end (Figures 3G & 3E) cuts all the trabecular connections at the base of the biopsy specimen that might keep the biopsy firmly anchored to its base, and also retains the biopsy specimen so that it does not slip out of the needle during the process of its extraction. The distal shorter and narrower portion of the needle has two side holes/apertures (Figure 4C), one on each side, which communicate with the centrally hollowed out trocar that permits suction and flow of bone marrow from the surrounding lateral side (Figure 7 #3). The wider internal diameter of the proximal and longer portion of needle provides a

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free space within the interior of the instrument (Figure 3C). This free space allows the biopsy specimen to expand and become larger in diameter, which in turn prevents the biopsy specimen from slipping out of the needle through the narrower and shorter distal portion. This free space also avoids crushing and compression of the tissue as well as plugging the lumen of the needle.

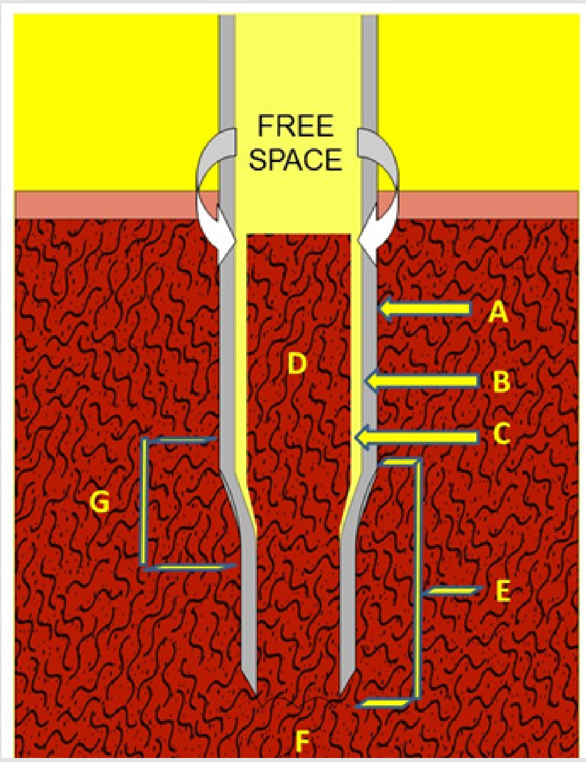

Figure 3: A schematic representation of the biopsy technique:

A. Outer wall of the needle

B. Inner wall of the needle,

C. Free space between the inner wall of the needle and the marrow core

D. Marrow core

E. The specially tooled distal cutting end of the needle

F. The base of the marrow core

G. The internal step that holds the core sample and prevents its dislodgement during the extraction of the needle from the patient.

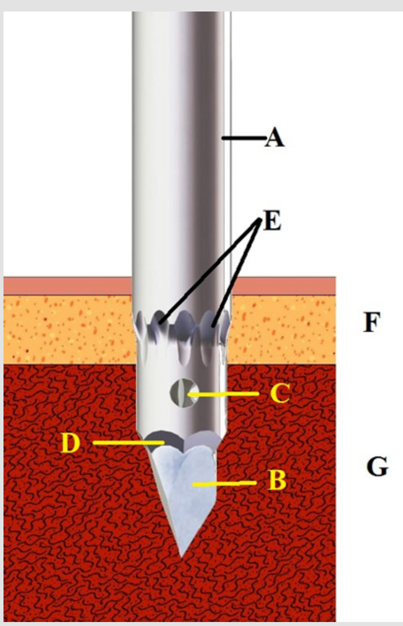

Figure 4: Schematic representation of the fully assembled needle at its distal end:

A. The needle

B. Sharp trocar pointed stilette

C. Side hole/aperture

D. Sharp cutting facets

E. Outside serrations/flutes

F. Cortical bone

G. Marrow and spongy bone

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Furthermore, it allows easy delivery of the biopsy sample (core) through the proximal end of the needle. The introduction of the needle through the hard cortical bone may be hampered by the wider proximal portion of the needle. To prevent this obstruction and ensure a smooth entry of the needle into the marrow cavity, multiple external serrations/flutes are provided at the junction of the distal narrower portion with its adjoining proximal wider segment (Figure 2B). These outside serrations provide a means of cutting (like a saw) as the needle is being rotated by clockwise and counterclockwise rotary motions, helping advance the needle through the hard cortical bone. The transverse (T-bar) handle (Figure 1B) is ergonomically designed to provide a firm grip, avoid pain and discomfort and improve maneuverability during the biopsy procedure. A large plastic cap (Figure 1E) fits and covers the top of the plastic T-bar handle, fitting snugly in the palm of the operator's hand and providing comfort during the biopsy procedure.

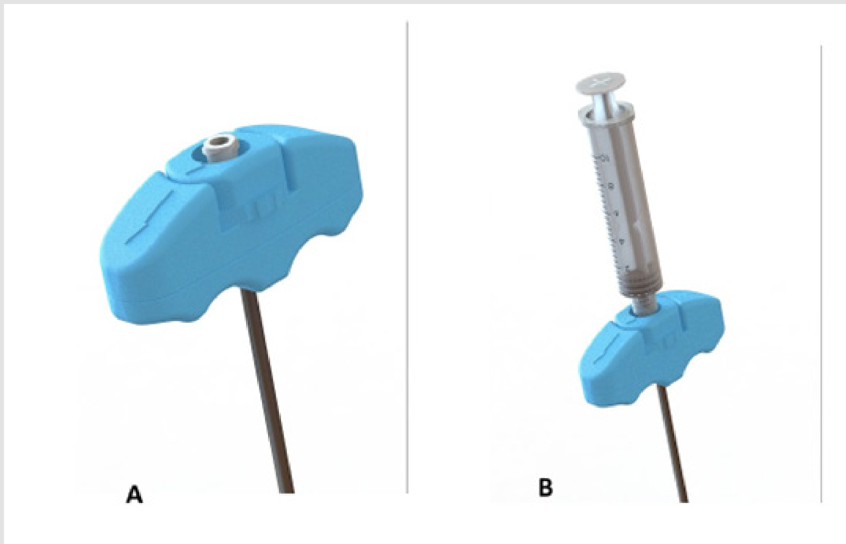

Figure 5: Illustration of the top of the trocar head

A. Which houses the female Luer-lock with external thread

B. Which acts as a connector for the attachment of a syringe for BM aspiration as well as attachment of the small plastic Luer-lock cap (Figure 2 H) to avoid spilling of marrow following the bone marrow aspiration.

The stilette/trocar (Figure 1C) is a centrally hollowed out shaft of 2.0 mm in outside diameter. It ends with a 3.0 mm, sharply pointed trocar tip that projects beyond the cutting edge of the needle (Figure 4B). The stilette also provides a means of easy penetration of the skin, soft tissue, and dense cortical bone. The proximal end of the stilette/trocar is fitted with a round plastic knob (head of the trocar) (Figure 1D). The top of this knob (trocar head) is also fitted with a housing (connector) with an external thread (Figure 5A) to receive the nozzle of both Luer-lock and non-Luer-lock syringes for bone marrow aspiration (Figure 5B) and also to attach the small Luer-lock cap (Figure 1H) to avoid any spilling of marrow following the bone marrow aspiration (Figure 9A). An insertion aid (Figure 1F) is used to facilitate the easy removal of the biopsy specimen through the proximal end of the needle. It is 30 mm in height, and round in most parts. The central area of the front portion of this insertion aid is hollowed out and shaped to receive and tightly fit the distal cutting end of the needle. The central rear portion of the insertion aid is hollowed out and shaped like a funnel that helps enter and attain proper alignment of the pusher rod with the mouth of the needle. It helps in guiding the pusher rod directly into the mouth of the needle and assists in easy dislodgment and extrusion of the biopsy sample through the proximal end of the needle (Figures 6A & 6B). A pusher rod (Figure 1G) is used to remove the biopsy specimen through the proximal end of the needle with the help of the insertion aid (Figures 6A & 6B).

The distal end of the pusher rod is chamfer shaped, facilitating its entry into the mouth of the needle, particularly when it is covered by redundant and extra bony soft tissue.A small Luer-lock cap (Figure 1H) is used to close the distal opening at the stilette/trocar head following bone marrow aspiration to avoid any spilling of marrow and blood (Figure 9A).

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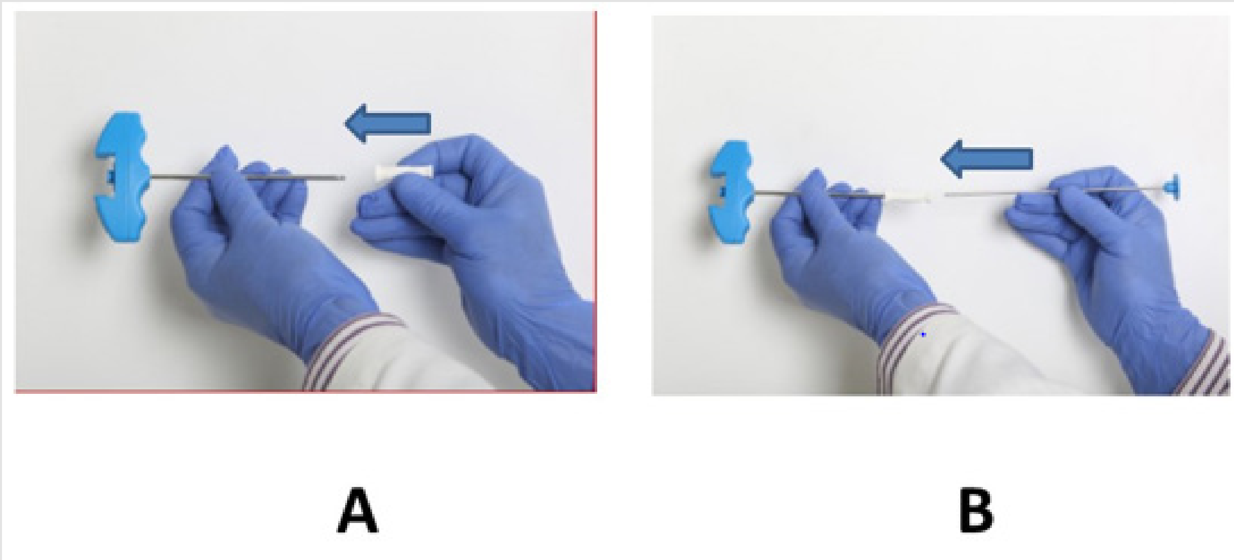

Figure 6: Photographs showing attachment of one end of the insertion aid to the distal cutting end of the needle and introduction of the pusher rod through the opposite open end of the insertion aid.

A. Attachment of the insertion aid to the distal cutting end of the needle

B. Removal of the biopsy specimen from within the lumen of the needle by gently pushing it forward

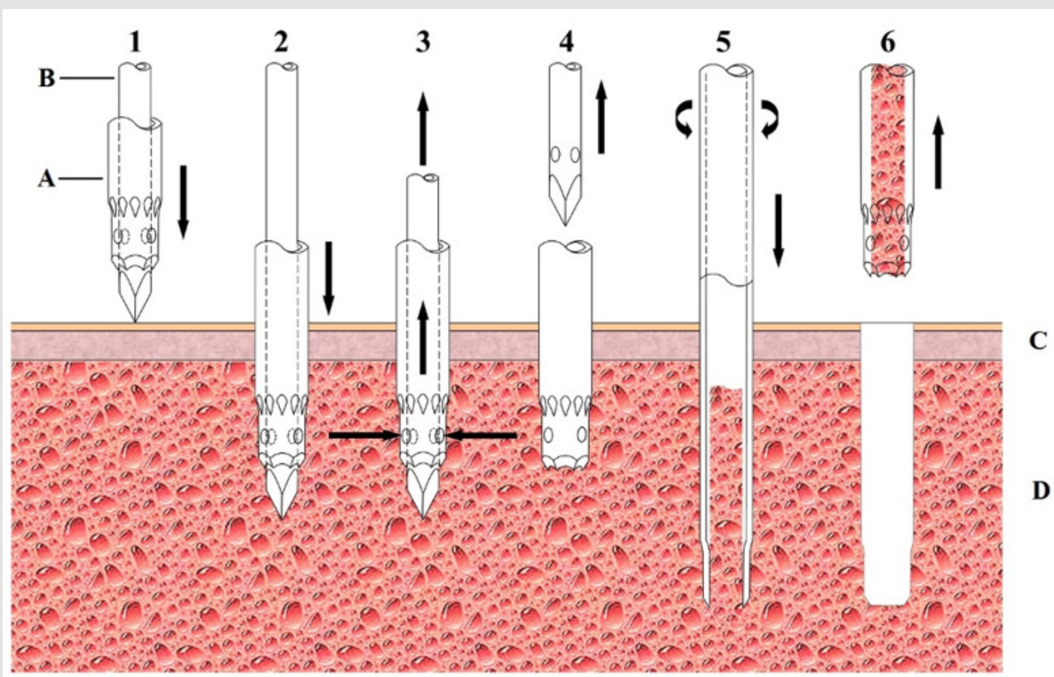

Figure 7: Schematic representation of the bone marrow aspiration and trephine (core) biopsy procedure. See text for details.

A. The needle

B. The stilette

C. Cortical bone

D. Spongy bone containing marrow.

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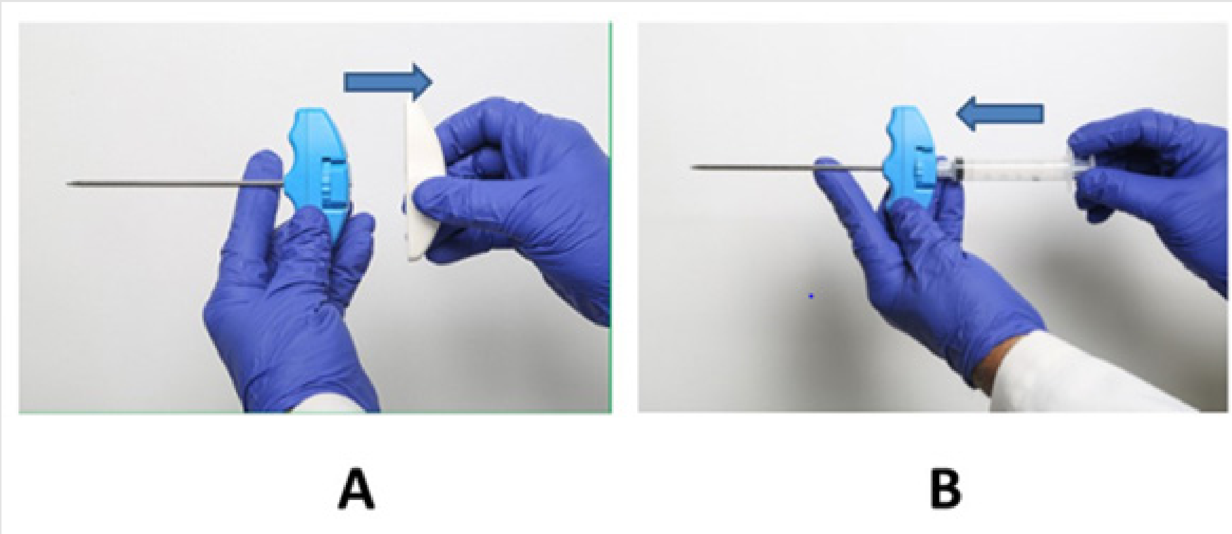

Figure 8: Photographs showing the removal of the large plastic cap (A) and attachment of a syringe to the trocar head (B).

Aspiration and Biopsy Procedure (Figure 7)

The new instrument has been designed to obtain bone marrow aspiration and trephine (core) biopsy specimens from the right or left posterior iliac crests. Its operative technique is similar to what has already been utilized in the past [13-17] except that, importantly, in this system the trocar itself is used as an aspiration needle. As a result, it has the advantage of performing both bone marrow aspiration and trephine (core) biopsy at the same time using the same needle assembly and using the same puncture (entry) site, thus providing not only an excellent bone marrow aspirate specimen but also an excellent trephine (core) biopsy specimen without disrupting or altering the marrow architecture of the trephine (core) biopsy specimen. The patient is placed in a right or left lateral decubitus position with the top knee bent forward and drawn up and the back comfortably flexed or in the prone position with a pillow beneath the hips. The site of the posterior iliac crest is identified by palpation or by ultrasound and marked with indelible ink [16]. The area over the posterior iliac crest is then prepared with Betadine, alcohol, and is draped. Then the skin, subcutaneous tissue, and the periosteum are infiltrated with a local anesthetic. A 3 mm skin incision is made with a sharp-pointed scalpel blade. The aspiration-biopsy needle with the stilette/trocar with its plastic knob (trocar head) in place is advanced slowly through the incision, pointing towards the anterior superior iliac spine.

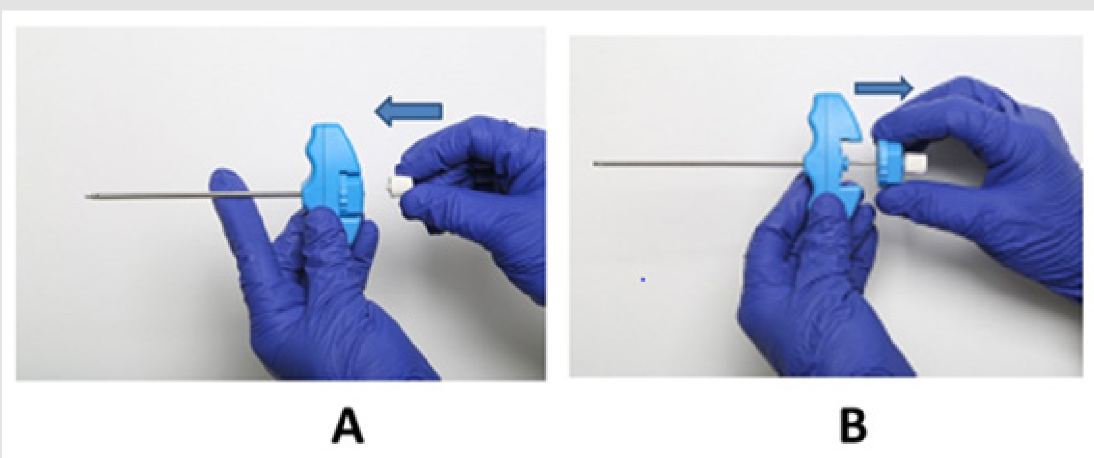

Figure 9: Photographs showing the attachment of the small plastic Luer-lock cap to the trocar head (A) and its withdrawal (B).

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When the posterior iliac crest is reached (Figure 7 #1), it is then penetrated by gentle rotary motions of the needle. Once the cortex is penetrated and the trocar and distal end of the needle are in the marrow cavity (Figure 7 #2), the large plastic cap is removed, a syringe is attached to the trocar head (Figures 8A & 8B) and a bone marrow aspiration is performed (Figure 7 #3). Following the bone marrow aspiration, the small plastic Luer-lock cap is attached to the trocar head to avoid any spilling of blood and marrow (Figure 9A). The trocar is then withdrawn by pulling it rearwards (toward the operator) (Figure 9B) (Figure 7 #4). Following the withdrawal of the trocar, the large white plastic cap is replaced (Figure 10A) and the biopsy needle is then advanced (Figure 10B) into the marrow cavity with slow, steady, and controlled clockwise-counterclockwise rotary motions until an adequate depth (15-20mm) is reached (Figure 7 #5). The biopsy needle is then rotated completely several times to sever all trabecular connections at the base of the marrow core and break lose the biopsy sample from the surrounding trabecular bone. The needle is then slowly withdrawn with a straight pull, gently alternating rotary motions of the needle (Figure 7 #6). No rocking, sculling, gyratory movements, change in direction of the tip of the needle, or an extractor such as sleeve or marrow acquisition cradle is necessary. Once the needle is withdrawn, the large white plastic cap is removed from the T-bar handle. The insertion aid is then attached to the distal cutting end of the needle (Figure 6A) and the biopsy specimen contained within the lumen of the needle is then removed by introducing the pusher rod through the opposite end of the insertion aid (Figure 6B).

Once the aspiration and biopsy procedure is complete, the edges of the wound are pressed together with adhesive tape. A gauze dressing is applied, and the patient is instructed to lie on his/her back for 10-15 minutes or longer if the patient has a low platelet count or other bleeding disorder or has been on aspirin or other anticoagulants.

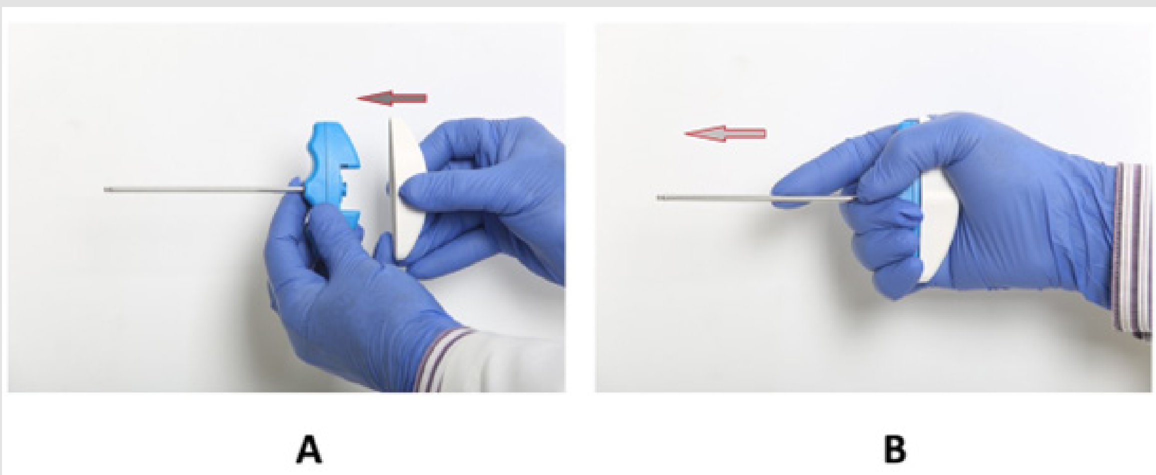

Figure 10: Photographs showing the replacement of the large plastic cap (A) and advancement of the needle into the marrow cavity to secure a trephine (core) sample (B).

Results

The needle has been extensively tested on adult human cadavers. Tissue collection was done on vertebral bodies at autopsy. More than 20 samples of bone marrow aspirate and core biopsy from multiple cadavers were obtained. Adequate bone marrow aspirate and core biopsy samples (Figure 11) were obtained in each case. The bone marrow aspirates were stained with Wright-Giemsa's stain and examined under a light microscope, revealing good morphological details of hematopoietic tissue. The bone marrow core biopsies were fixed in 10% formalin, decalcified, and processed in paraffin. Histological sections were prepared, stained with hematoxylin and eosin, and examined under a light microscope. The sections revealed clean-cut boney trabeculae with little or no crush artifact. Although the length of the specimens obtained at each attempt varied from 12 to over 20 mm, there never was any loss of a specimen.

Although the needle assembly (the needle and the trocar) was used to obtain the bone marrow aspiration before the trephine biopsy, this manipulation did not affect the quality of the solid core biopsy specimen that was subsequently obtained. The architectural relationships of the bone, marrow, and fat in the trephine biopsies were well preserved. This ideal preservation was maintained because the bone marrow was aspirated via the lateral hole/apertures (Figure 4C, & Figure 7#3) near the distal penetrating end of the needle, while the solid core intact marrow biopsies were obtained from the distal region that was not affected by the earlier aspiration.

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Figure 11: Shows a BM biopsy specimen obtained with this needle. Note the long and uniform core of marrow tissue that is obtained.

Discussion

Bone marrow aspiration (9) and trephine (core) biopsy [18], since their introduction in the early 20th century, have achieved significant importance in the field of medicine, particularly in hematology and oncology and are now routinely used in the investigations, diagnosis, and management of patients with various hematological as well as non-hematological conditions. Conventionally, a bone marrow aspiration is performed on the sternum with Salah or Klima needles, or similar kinds of bone marrow aspiration needles [19]. However, because of serious complications such as injuring the great blood vessels that lie underneath the sternum and other disadvantages (such as the fear and apprehension by the patient as the needle is being introduced into the chest) associated with the sternal puncture procedure, most bone marrow aspirations are currently performed at the posterior iliac crest. Before 1929, bone marrow biopsies were obtained from the tibia (in children) or anterior iliac crests [18,19], while currently the posterior iliac crest is favored [13-17]. The bone marrow aspiration and trephine biopsies employing hand-held instruments at the anterior iliac crest are difficult to perform because the bone is thicker and harder at this site, which also contains less marrow as compared to the posterior ilium. The invention of newer needles such as Jamshidi, Islam, and other single use implements has universalized the practice of bone marrow aspiration and biopsy at the posterior iliac crests.

The Jamshidi needle, which initially popularized the technique of bone marrow core biopsy in the early 1970s, has one major problem: it is unable to consistently retain the biopsy specimens within the lumen of the needle as the needle is being withdrawn from the patient. It is known that core loss rates vary between individual users of the same make of needles, due in part to variations in the level of experience and intrinsic skill of different operators. However, the loss of the core biopsy specimen continued to be a persistent problem. The Jamshidi and other brands of needles had this issue because they did not have a core retention mechanism. Because of this, the operator had to resort to certain extraneous maneuvers with the needle, such as rocking, sculling, or gyratory movements or a change in the direction of the tip of the needle to secure a core sample. Such extraneous maneuvers require extra time, and cause pain to the patient as well as damage to the needle and biopsied tissue. The "core losing" problem of the Jamshidi needle has been recognized since 1980s and was addressed by the subsequent development of a new and improved bone marrow biopsy needle with a core retention device [13,15,20].

The problem of core loss by the most popular bone marrow biopsy needle-the Jamshidi needle-and other makes of similar needles is now universally recognized. To overcome this problem, several different single-use needles have been recently introduced to prevent the loss of the core biopsy specimens [21,22]. Each of these needles features different methods of capturing a core sample during the withdrawal of the needle from the patient. Unfortunately, in the process of doing so, all these needles significantly complicate the biopsy procedure by introducing multiple steps and a nearly unmanageable assortment of extra parts and components. Indeed, in some cases, these needles contain up to six additional parts. Furthermore, these core-capturing devices, when they grasp the biopsy specimen by tweezer-like or drain-spade-shovel-like components, may also cause breakage of the core sample and considerable crush artifacts, reducing the amount of marrow tissue available for histological examination [23]. Accordingly, the advantage of the newly devised needle under discussion lies not only in its simplicity and technical efficiency but also in conferring the advantage of performing both bone marrow aspiration and core biopsy simultaneously using the same needle and the same single

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puncture (entry) site, without sacrificing the quality of the specimens. In this new system, the same trocar is used both for bone penetration and for bone marrow aspiration, thus avoiding the need for a separate aspiration needle. This reduces the cost of the procedure.

In addition, the distal cutting end of the needle, which bears the internal core retention feature, has also been fitted with multiple outside serrations/flutes on the tapering transitional portion, between the main wider portion of the hollow needle and its reduced-diameter front end segment. These surface serrations/flutes enhance the force of boring through the hard cortical bone and facilitate the entry of the main wider portion of the biopsy needle into the marrow cavity. The internal diameter of the distal narrower portion is less than the overall internal diameter of the wider proximal portion of the needle. This specially designed distal (3.5 mm) portion of the needle with sharp cutting facets cuts all the trabecular connections at the base that might keep the biopsy specimen anchored to its base, while firmly holding the core sample (Figures 3E & 3G) so that it does not slip out of the needle during its extraction. Once the biopsy specimen has passed through the distal narrower portion and enters the wider proximal segment of the needle, the biopsy sample expands to some extent. Here, the internal step acts as a shoulder (bottleneck) that prevents the slightly expanded biopsy sample from slipping out of the needle during its withdrawal from the patient with a straight pull. Notably, the larger internal diameter of the needle provides free space within the interior lumen of the needle, thereby preventing crushing and compression of the tissue and/or plugging the lumen of the needle. This also allows easy smooth delivery of the biopsy specimen through the proximal end of the needle. The distal cutting end of the needle—where it joins the main body of the needle-is wider. As a result, the introduction of the needle through the hard cortical bone may be hampered by the wider proximal portion. Multiple outside serration's/flutes are provided at this junction to avoid this potential obstruction and promote an easy and smooth entry of the needle through the hard cortical bone.

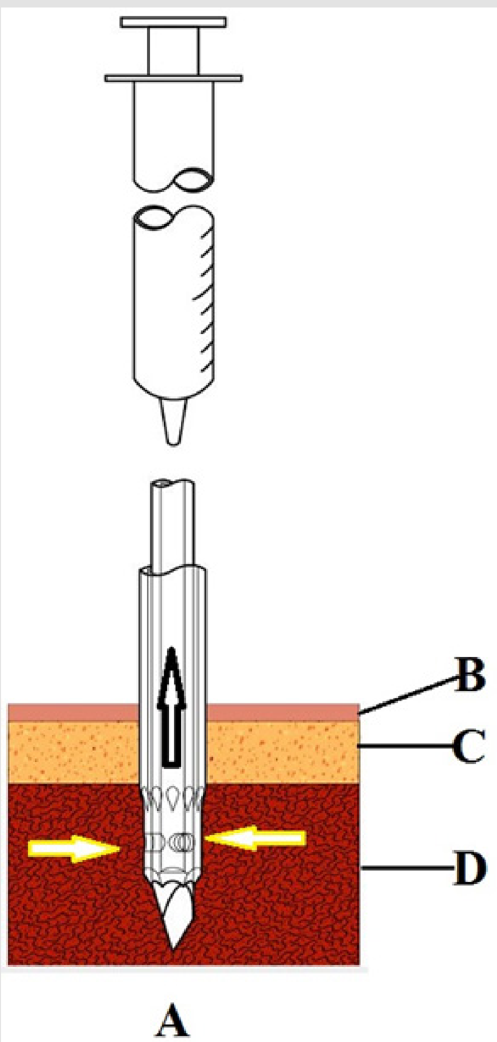

Figure 12: Shows a schematic representation of the bone marrow aspiration through the lateral holes/apertures near the distal narrower and cutting end of the needle, illustrating that when the marrow is drawn during the bone marrow aspiration procedure (upward arrow), it draws marrow mostly from the lateral sides (side arrows). As a result, this leaves undisturbed the distal central area of the marrow

(A) From where the trephine (core) biopsy is obtained. This provides an intact, artifact-free, and undistorted trephine (core) biopsy specimen.

(B) Skin, soft tissue, and fat;

(C) Cortical bone;

(D) Marrow and spongy bone.

Although the advantageous features of Islam bone marrow biopsy needles are well recognized [24], until now one could not perform a bone marrow aspiration with the same individual needle without sacrificing the quality of the yielded biopsy specimens [12]. With the new needle, this limitation has now been overcome; both bone marrow aspiration and trephine biopsy can be obtained with the same needle assembly utilizing the same entry point but without sacrificing the quality of the biopsied specimens. In this new system, unlike any other currently available needle on the market, the trocar is used for soft tissue and cortical bone penetration as well as bone marrow aspiration. As a safeguard to prevent disruption of the marrow and trabecular architecture in the area from where the actual trephine biopsy is obtained (Figure 12 area A), the distal narrower portion of the needle is fitted with horizontally placed side holes/apertures (Figure 4 C). As a result, when the bone marrow is aspirated, it draws marrow only from the lateral side (Figure 7 #3 side arrows, Figure 12 side arrows) and not from the distal area (Figure 12 area A). Conventionally, when a bone marrow aspiration is performed using a bone marrow biopsy needle before the trephine biopsy is obtained using the same biopsy needle, the process is bloodier and technically cumbersome because of the rapid overflowing of blood through the proximal end of the needle once the syringe used for aspiration is removed. Furthermore, after the typical aspiration process has been completed, the biopsy needle usually still contains a considerable amount of blood and marrow that is often clotted. As a result, there is always an elongated ribbon of clotted blood that precedes the biopsy specimen when it is pushed out of the needle. This thread of clotted blood may also obscure the identification of the clot versus the core sample when ejected from the needle.

The insertion aid is an innovative addition to this technical process, used to facilitate the extrusion of the biopsy specimen from within the lumen of the needle. One end of this device is designed to receive the distal narrower portion of the biopsy needle and the other end is designed to receive the chamfer-shaped distal end of the pusher. This guiding system assists the proper alignment of the pusher with the mouth of the needle and facilitates easy dislodgement and removal of the biopsy sample through the proximal end of the needle. In many cases it has been observed that the adherent and redundant extra bony and soft tissues would obscure the mouth of the needle after its withdrawal from the patient. Consequently, because of the presence of this redundant tissue at the mouth of the needle, conventional blunt pushers might often slip and could not readily enter the lumen. By contrast, in such circumstances, the chamfer-shaped pusher, with the help of the insertion aid, can easily find its way into the mouth of the needle. In addition, the insertion aid reduces the risk of sharp injury to the operator whilst maneuvering the distal sharp cutting end of the needle. Furthermore, the biopsy technique is simple and does not require any manipulation such as rocking, or gyratory movement of the biopsy needle within the patient to secure the biopsy sample. This clearly makes a potentially uncomfortable procedure more tolerable for the patient.

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