

**Supplemental Materials:**

**Appendix 1: Data collection form**

**Name of person/reviewer extracting data:**

**Author of article:**

**Title:**

**Source (e.g. Journal title):**

**Date of study:**

**Study location (geographical):**

**Inclusion/exclusion criteria (list of patient inclusion and exclusion criteria)**

***Inclusion:***

***Exclusion:***

**Sample size:**

*number in each arm of trial*

*a priori power calculation?*

**YES NO NOT STATED**

*trial powered adequately?*

**Patient baseline characteristics:**

*age range:*

*gender:*

*medical condition(s):*

**TRIAL DESIGN DETAILS:**

single centre/multicenter trial?

**Study type**

*randomized controlled trial/matched control/unmatched concurrent control/historic control:*

**Allocation**

*was it random?*                                   **YES NO NOT STATED**

*method of randomization:*

*was it concealed?*                               **YES NO NOT STATED**

**Intervention details**

*care setting:*

*treatment group(s):*

*control(s):*

*co-interventions:*

*who delivered intervention?*

*was the provider performing the procedure blinded?*   **YES NO NOT STATED**

*was the patient blinded?*                       **YES NO NOT STATED**

**Outcome measures**

*what were they?*

*methods of assessing outcome measures:*

*blind assessment?*                               **YES NO NOT STATED**

*when were they measured?*

*validity of assessment:*

*length of follow-up:*

**Analysis:**

*description of analysis employed:*

*statistical methods:*

*comparisons made:*

*intention to treat analysis?*

*subgroups considered?*

*exploration of heterogeneity?*

**Results:**

*Missing data:*

*length of follow up:*

*withdrawals/drop outs - are proportion and characteristics of participants lost to follow up comparable for the study groups at the end of the trial? (Assessment of attrition bias)*

*reasons for withdrawal:*

Number lost to follow up:

(Other outcomes measured) – identify \_\_\_\_\_:

*Intervention arm (1):*

*Intervention (or control) arm (2):*

*Intervention arm (if more than 2 intervention arms are included in the trial):*

*Intervention are (if more than 2 intervention arms are included in the trial):*

*Were all outcomes identified in methods section reported on in the results section? (selective reporting) YES NO*

**Conclusions:**

Implications (e.g. for practice):

Other comments:

*Methodological quality of study:*

*comparability of intervention:*

*baseline comparability:*

**Appendix 2: Characteristics of studies and bias assessments:**

**Characteristics of included studies**

**Berenson 2011**

<b>Methods</b>	Multicenter randomized controlled trial
<b>Participants</b>	Patients requiring bone marrow biopsy for assessment of disease such as lymphoma, leukemia, and multiple myeloma; average age of participants: manual = 66.4±13.4 years; powered = 66.2±14.7
<b>Interventions</b>	OnControl powered bone marrow biopsy system (n=52) versus manual bone marrow biopsy needle (n=50)
<b>Outcomes</b>	<p>Procedure time in seconds</p> <p>Pain at end of procedure as measured via visual analog scale (VAS); scale used 0-10; with higher scores indicating greater pain. Pain also assessed at one day and 7 days post procedure.</p> <p>Device complications and adverse events recorded</p> <p>Size of bone marrow sample: Measured in length (mm) and in volume (mm<sup>3</sup>)</p> <p>Operator satisfaction (0-10 VAS)</p>
<b>Notes</b>	<p>Informed consent obtained</p> <p>Operators skilled in manual method but had limited experience with the powered bone marrow biopsy system (i.e. 3-5 prior uses of powered system).</p> <p>One adverse patient event with powered system: Patient's skin became wrapped around shaft of the rotating needle.</p>








**Berenson 2011 Risk of bias table**

<b>Bias</b>	<b>Authors' judgment</b>	<b>Support for judgment</b>
Random sequence generation (selection bias)	Unclear risk	Sent email to lead author Berenson on 1/24/13 seeking clarification of this. Did not hear back.
Allocation concealment (selection bias)	Unclear risk	Sent email to lead author Berenson on 1/24/13 seeking clarification of this. Did not hear back.
Blinding of participants and personnel (performance bias)	High risk	Clinicians and patients knew which biopsy system was being used by and on them.
Blinding of outcome assessment (detection bias)	High risk	Clinicians who were evaluating VAS and patients who reported on it (via VAS) were not blinded to the type of biopsy method
Incomplete outcome data (attrition bias)	Low risk	All patients enrolled in the study were reported on.
Selective reporting (reporting bias)	Low risk	All outcomes were reported on as listed in the methods section.
Other bias	High risk	All authors of trial received research grant funds from the sponsor of the study, Vidacare Corporation (manufacturer of the powered bone marrow biopsy system), for their participation in the trial.

**Bucher 2013**

<b>Methods</b>	Prospective single center non-blinded randomized trial
<b>Participants</b>	Patients in need of a biopsy to assess for disease state: lymphoblastic leukemia, acute myelogenous leukemia, chronic myelogenous leukemia, myelodysplastic syndrome, non-Hodgkin's lymphoma
<b>Interventions</b>	Powered (n=26) versus manual biopsy (n=24)
<b>Outcomes</b>	<p>Size of biopsy sample (in mm length)</p> <p>Patient pain as measured via VAS scale 0-10; with 10 being maximal pain. Pain measured immediately after the procedure (T1); 15 minutes after the procedure was completed (T2) and 3-5 days post procedure (T3)</p> <p>Procedure time in seconds: measured from time of skin contact of needle until biopsy sample was ejected from the needle.</p>
<b>Notes</b>	<p>Study performed in Germany</p> <p>Informed consent obtained</p> <p>Minimal training on the powered device was performed prior to initiation of the trial (3 procedures)</p> <p>Two patients reported painful hematomas at 3-5 day follow up in the powered group (adverse event)</p>

**Bucher 2013 Risk of bias table**

<b>Bias</b>	<b>Authors' judgment</b>	<b>Support for judgment</b>
Random sequence generation (selection bias)	Low risk 	Differentially colored, labeled, and numbered envelopes containing sheets labeled with "manual" or "powered" were put into envelopes in a random fashion prior to initiation of the study. After informed consent was obtained, the operator picked the next envelope.
Allocation concealment (selection bias)	Low risk 	Directly after opening the envelope, the procedure identified in the envelope was performed
Blinding of participants and personnel (performance bias)	High risk 	Neither patients nor clinicians were blinded to the procedure.
Blinding of outcome assessment (detection bias)	Low risk 	Pathologist unaware of the biopsy method used evaluated the size of the sample.
Incomplete outcome data (attrition bias)	Low risk 	Fifty (50) out of 58 patients screened were randomized
Selective reporting (reporting bias)	High risk 	Adverse events were reported on in results section but were not defined as an endpoint in the methods section.
Other bias	High risk 	Hematologists had significant experience in the manual method (>200 biopsies) and only 3 biopsies with the powered system.




**Miller 2011**

<p><b>Methods</b></p>	<p>Single center randomized controlled trial - bilateral biopsies on each healthy subject were performed with the order in which either powered or manual system used and the side which was biopsied first randomized.</p>
<p><b>Participants</b></p>	<p>Twenty six (26) healthy adult volunteers</p>
<p><b>Interventions</b></p>	<p>Powered bone marrow biopsy (n=24) and manual biopsy (n=24)</p>
<p><b>Outcomes</b></p>	<p>Procedure time in seconds measured</p> <p>Pain intensity measured via visual analog scale (VAS) - 100 point scale (0-100) with higher scores indicating more pain. Pain measured at the following points: needle insertion, biopsy acquisition, needle removal and overall.</p> <p>Size of bone marrow sample: Measured in length (mm) and in volume (mm<sup>3</sup>)</p> <p>Complications and adverse events: Complications included: breakage (failure) of the needle set, inability to remove the stylet, skin winding on the needle set, inability to penetrate the distal cortex, and injury to the operator. Insertion failure, or failure to obtain an adequate quality or quantity of core biopsy sample are not considered complications. Adverse events included: An adverse event (AE) was any unfavorable medical occurrence affecting a clinical investigation subject, which did not necessarily have a casual relationship with the treatment or procedure. An AE was therefore any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease associated with the use of the study devices, whether or not it is considered related to the devices.</p>
<p><b>Notes</b></p>	<p>Informed consent obtained</p> <p>Operators (one in private practice and one academic hematologist/oncologist) were experienced in both methods - powered and manual.</p> <p>One adverse event/complication was reported on in the paper. However, the method of biopsy used was not identified. In 1/25/13 correspondence with the author it was stated: "<i>The patient who experienced the adverse</i></p>



	<p><i>event of intense and extended pain (4 weeks) complained about the right side biopsy site, which was performed using the OnControl system. The patient described the pain as radiating down her leg, from the biopsy site, and complained of difficulty with lying on her back. The patient reported she could "feel everything" during the biopsy procedure on that side suggesting the site may not have been adequately anesthetized."</i></p>
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**Miller 2011 Risk of bias table**

<b>Bias</b>	<b>Authors' judgment</b>	<b>Support for judgment</b>
Random sequence generation (selection bias)	Low risk 	Randomization was performed using sequentially numbered opaque sealed envelopes. Following consenting procedures, and once it has been determined that the subject meets the inclusion/exclusion criteria, the next sequentially numbered envelope was opened to determine which device (Manual or Powered) would be used for the first of the bilateral procedures and on which side the devices would used. Envelopes were used in sequence each time a patient was enrolled in the study.
Allocation concealment (selection bias)	Low risk 	Procedure was performed immediately upon randomization
Blinding of participants and personnel (performance bias)	Low risk 	<p>Patients were blinded to the type of procedure being performed: <i>To minimize the noise caused by the powered device, and to decrease the potential for the noise to compromise the blinding of procedure order, noise cancelling headphones were placed on the subjects during the procedure. Additionally a powered device was activated during the manual procedure as well.</i></p> <p>Clinicians performing the procedure were not blinded to the biopsy</p>

		method used.
Blinding of outcome assessment (detection bias)	Low risk	VAS score as reported on by participant (using VAS scale) was blinded. Pathologists measuring and grading the bone marrow trephine were blinded to the treatment arm.
Incomplete outcome data (attrition bias)	Low risk	Two patients out of the 26 enrolled were excluded due to: one with improper anesthetization and one due to obesity (needle length not long enough to penetrate bone). Thus there were 24 enrolled
Selective reporting (reporting bias)	Low risk	All outcomes were reported on.
Other bias	High risk	Several of the authors were employees of the manufacturer of the powered bone marrow biopsy system. Several of the authors accepted research grant funds from the manufacturer of the powered system.

**Reed 2011**

<b>Methods</b>	Single center randomized controlled trial
<b>Participants</b>	Patients requiring a bone marrow biopsy having various forms of cancer including: lymphoma, acute myeloid leukemia, metastatic carcinoma, and myeloma
<b>Interventions</b>	Use of powered bone marrow biopsy system versus manual biopsy
<b>Outcomes</b>	Size of bone marrow biopsy sample (length in mm)  Procedure time in seconds  Adverse events (not defined in study). Per phone conversation with Dr. Reed on 1/31/13, there was no definition of adverse events on the report forms as well. Adverse events were subjective in nature.  Pain as measured by patient using a visual analog scale (VAS): 0-10 with 10 being worst pain possible.  Procedure ease difficulty (0-10 VAS)
<b>Notes</b>	Informed consent  US trial of hematologists in training  Rather than having patients randomized to either powered or manual bone marrow biopsy procedures, hematologists were randomized to the treatment groups.  No adverse events were observed.  Fellows/operators were put through a training program for the powered system and had 1-2 live cases with it. Most operators had significantly more training/experience with the manual system.








**Reed 2011 Risk of bias table**

Bias	Authors' judgment	Support for judgment
Random sequence generation (selection bias)	Low risk	Sent email to lead author, Reed LJ on 1/24/13 seeking clarification in this. Phone conversation with Dr. Reed on 1/31/13, the randomization scheme from the principal investigator (Reed) was kept confidential with the operators until the treatment started. This randomization scheme entailed using the last digit of the operators/fellows pager number with odd numbers allocated to the powered system and even to manual.
Allocation concealment (selection bias)	Low risk	Sent email to lead author, Reed LJ on 1/24/13 seeking clarification in this. Phone conversation with Dr. Reed on 1/31/13, once the operator was randomized, the procedure was immediately initiated.
Blinding of participants and personnel (performance bias)	High risk	Clinicians and patients were not blinded to treatment arms
Blinding of outcome assessment (detection bias)	Low risk	Pathologists were blinded to the treatment arm in assessing sample size.
Incomplete outcome data (attrition bias)	Low risk	All patients and specimens were reported on in the results section
Selective reporting (reporting bias)	Low risk	All outcomes listed in the methods section were reported on in the results section
Other bias	High risk	Several of the operators had greater prior experience with the manual method than others and greater prior experience with manual method versus powered method. Additionally, per conversation with the lead author on 1/31/13, an unrestricted grant was provided by Vidacare. As well, manufacturer reviewed and provided input into manuscript prior to submission.

**Swords 2011**

<b>Methods</b>	Multicenter randomized controlled trial
<b>Participants</b>	Patients requiring a bone marrow biopsy in order to determine disease state. Forty (40)% of patients were lymphoma.
<b>Interventions</b>	Powered bone marrow biopsy (n=25) versus manual methods (n=25)
<b>Outcomes</b>	Time in seconds to perform the procedure = time from contact of needle to skin to sample retrieval.  Patient pain recorded on a visual analogue scale (VAS) of 0-10; with 10 being the worst possible pain.  Adverse events (not defined in trial)  Operator satisfaction score (0-10 VAS)
<b>Notes</b>	Trial carried out in the US and Europe  Informed consent obtained

**Swords 2011 Risk of bias table**

Bias	Authors' judgment	Support for judgment
Random sequence generation (selection bias)	Low risk 	Per email from Dr. Brenner (coauthor) on 1/24/13: Envelopes containing the randomization were prepared by the sponsor. The IDS pharmacy opened the envelopes to determine the patient assignment, and then provided the device assigned.
Allocation concealment (selection bias)	Low risk 	Per email from Dr. Brenner (coauthor) on 1/24/13: The patient was not aware of which device they were assigned, and the physician immediately was aware prior to procedure.
Blinding of participants and personnel (performance bias)	High risk 	Neither clinicians performing the procedure nor patients entered into the trial were blinded to the treatment arms
Blinding of outcome assessment (detection bias)	High risk 	Pathologic analysis of biopsy samples was blinded. However, pain scores were not
Incomplete outcome data (attrition bias)	Low risk 	All patients were reported on
Selective reporting (reporting bias)	Low risk 	All outcomes as listed in the methods section were reported on in the results section
Other bias	High risk 	<p>Study was supported by funds from Vidacare Corporation, manufacturer of the OnControl, powered bone marrow biopsy system.</p> <p>There was no prior training on the use of OnControl in live patients. Training was performed on anatomically correct mannequins.</p>