Minimally Invasive Cancellous Bone Biopsy Instruments: A Patent Review

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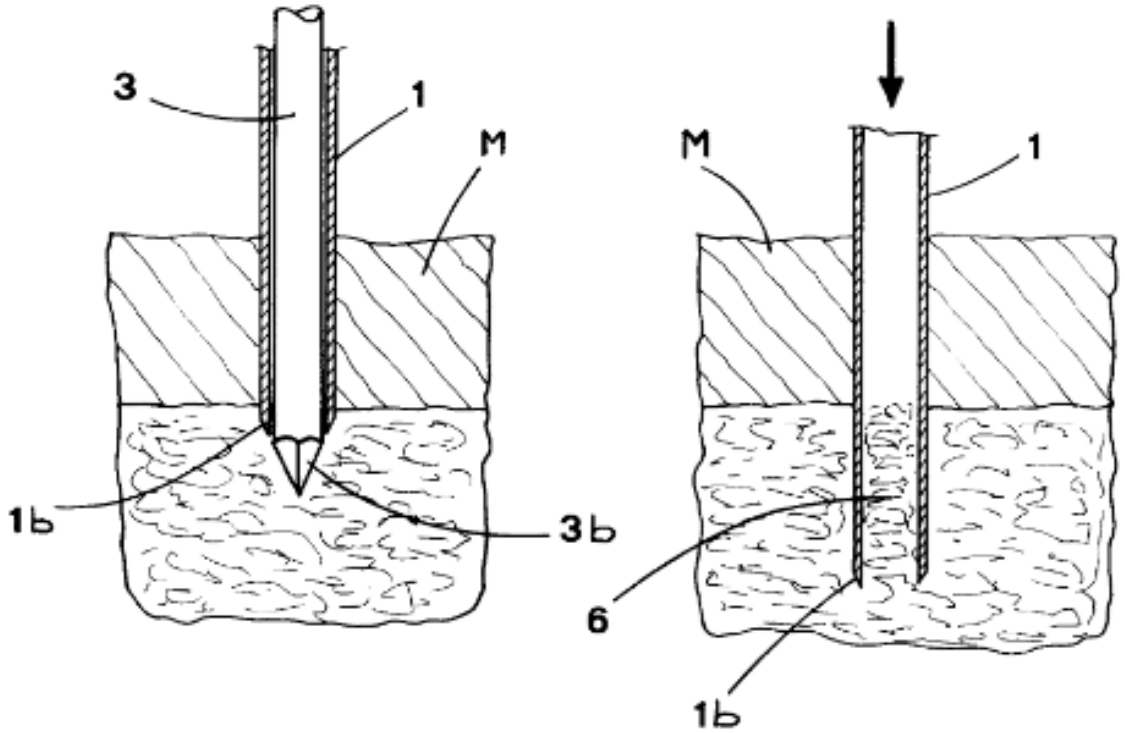

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Abstract

Cancellous bone biopsy instruments are used to obtain a sample of cancellous bone. To ensure minimal discomfort for the patient when only a small sample is needed, minimally invasive methods are used. The instruments commonly used in this method suffer from a range of disadvantages. This study explores the different strategies available to combat these disadvantages by providing a comprehensive overview of the patent literature on minimally invasive cancellous bone biopsy instruments. To this end, the Espacenet database was queried with a combination of search terms and the CPC classification. 52 patents were analyzed and categorized. The instruments were first divided in their overall strategies. One of the two strategies contained the overwhelming majority of patents. This strategy involves forcing a hollow needle, or cannula, into cancellous bone to extract a sample. This procedure consists of two phases: 1) entering the bone and 2) extracting the sample. These two phases have both been categorized separately. 1) The golden standard uses a rigid needle, or trocar, inside a cannula to breach the hard cortical bone, after which the cannula is advanced into the cancellous bone. Four strategies have been found to perform this function. 2) The golden standard uses a sideways movement to shear the end of the sample off from the rest of the cancellous bone. The golden standard included, six different strategies have been found and categorized to extract the sample. Although a quarter of the patents use both these strategies used by the golden standard, three quarters of the patents propose some non-standard strategy. The insights into the design of minimally invasive cancellous bone biopsy instruments may serve as source of inspiration for the generation of new designs and developments.

CONTENTS

I. INTRODUCTION

A. Background

Bone biopsy instruments are used to carry out the bone biopsy procedure. This procedure is employed to extract a bone sample from a patient to check it for abnormalities. Bone consists of several types of tissue. Three are of import to this study. The outermost layer is called cortical bone. This bone tissue is the hardest and least active part of the bone. It is the main part in terms of adding strength. Beneath, clearly distinguishable from the cortical bone, is the cancellous bone. This tissue is more porous and active than the cortical bone [1]. Despite its porous nature, it is still very capable of its load-bearing function while it also makes it able to adapt to changing conditions, by adding strong bone tissue when undergoing increased loads and removing excess bone when it is not necessary. Underneath, as well as within the cancellous bone one can find bone marrow. This tissue is located within the crevices of the cancellous bone and other open spaces within bone. Bone marrow is a semi-solid tissue which has the bone's most active functions. It contains the blood vessels and sustains the transport of necessary substances across the bone, as well as several other functions.

Obtaining a sample from these three types of tissue calls for very different operations. While obtaining a sample from cortical or cancellous bone involves cutting away a solid piece of tissue, obtaining a sample of bone marrow typically involves using a syringe to extract marrow like a fluid. Because these procedures are fundamentally different and encounter distinct difficulties, this study will focus on a single procedure: Obtaining a sample from cancellous bone or, in other words, *Cancellous bone biopsy*.

To obtain a sample of cancellous bone, two broad strategies are employed. The first, most obvious, strategy is called an open biopsy [2]. The surgeon opens the surrounding tissue and cuts away the targeted tissue, therefore this procedure is often used to obtain large samples of tissue.

The second strategy uses a specially designed instrument in order to use a minimally invasive technique to extract a sample of cancellous bone. This instrument comprises a hollow needle, also called cannula, as its main part, therefore it is often called a needle biopsy. Figure 2 shows such a needle, shown in yellow, with its cutting edge shown in green for increased clarity. This hollow needle, or cannula, acts as a trephine. It cuts a circular shaped incision in the bone, while advancing further, which thus forms a cylinder-shaped sample inside the cannula.

Open biopsy and minimally invasive cancellous bone biopsy are two very different procedures, each carried out with a different goal. While a minimally invasive surgery is less intensive for the patient, the size of the sample is often smaller and its shape less flexible. This review is focused on one specific procedure, where the instruments can be compared on a clear desired outcome. Therefore this review will only include instruments designed for minimally invasive cancellous bone biopsy.

Cancellous bone biopsies are often carried out with similar procedures, of which a simplified version is illustrated in Figure 1. In this figure, two important layers of bone are cleary distinguishable. The outer layer, shown in pink on the top, is called cortical bone. This type of bone is very hard. To penetrate it, a very sturdy needle is needed. Often, the cannula (shown in yellow) is too weak to properly cut through it. Also, this bone structure is often not the tissue of interest, but rather the layer underneath it. Therefore, a trocar is often used, shown in red. This is a solid, sharpened needle which fits inside the lumen of the cannula and is designed to penetrate the cortical bone.

The underlying tissue is called cancellous bone. Once the trocar-cannula combination reaches this tissue, the trocar is taken out. Without the trocar, the cannula can be advanced into the cancellous bone, allowing a small sample of the tissue to enter the cannula's lumen, as shown in part three of Figure 1.

Once an adequate sample has entered the cannula, the

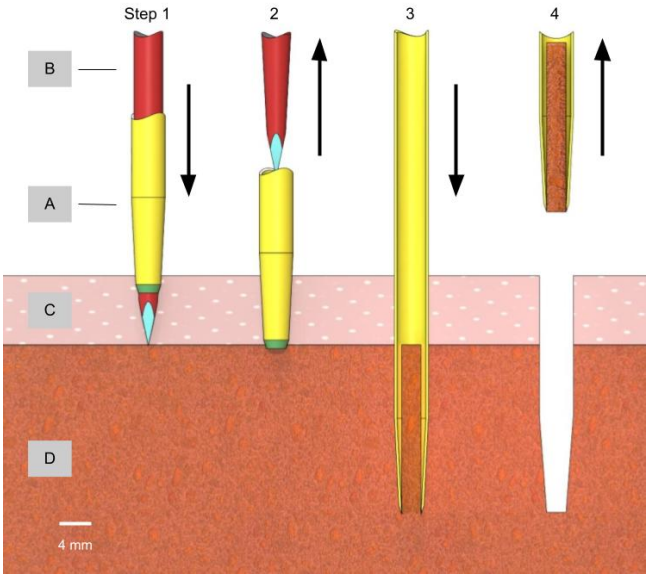


Figure 1: The four steps of a needle bone biopsy procedure. With A showing the cannula, B showing the trocar, C indicating the cortical layer of bone and D indicating the cancellous bone. To enhance clarity, the instruments have been sectioned at varying locations and angles.

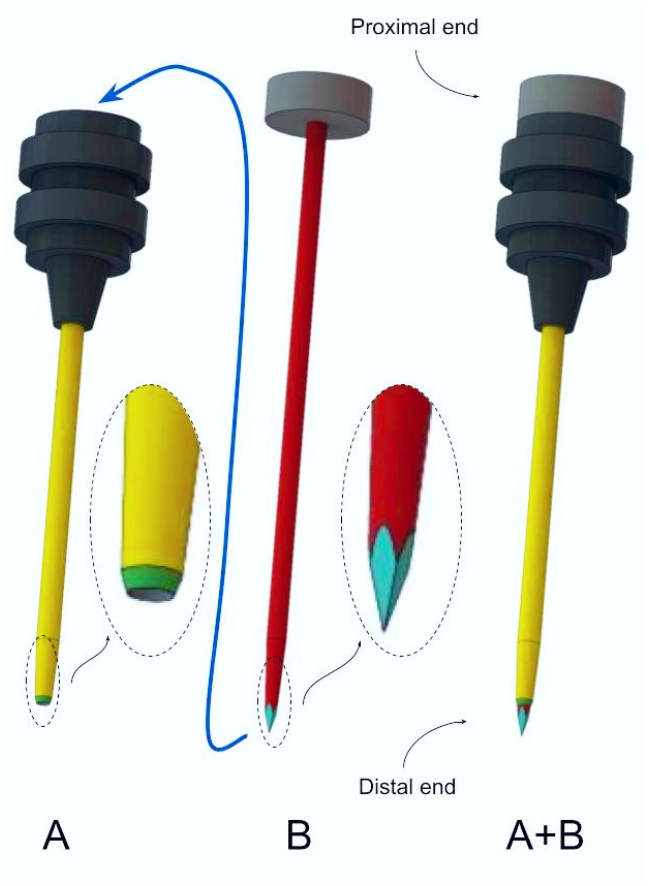


Figure 2: A common type of bone biopsy needle, shown in three configurations with colors to enhance clarity. Configuration A is a cannula, shown in yellow with its handle colored black and the edges designed for cutting the cancellous bone shown in green. Configuration B is a trocar, shown in red. Its handle is colored dark gray and its distal edges designed for cutting the cortical bone shown in light blue. Configuration A+B shows the cannula and trocar assembled into a single instrument.

whole is taken out. After this, the sample can be ejected from the cannula and analyzed further. In the figure, the steps are shown in order.
Step 1 shows the trocar breaching the cortical bone, with the cannula moving along with it in the indicated direction.
Step 2 shows how the trocar is removed, once the cannula has reached the cancellous bone.
Step 3 shows the cannula proceeded into the cancellous bone to envelop the tissue which is to be sampled.
Step 4 shows how the cannula is removed along with the sample.

B. Problem definition

Minimally invasive cancellous bone biopsy instruments have been developed for quite a long time, but they still suffer from a range of complications. As shown in Figure 1, at step four, the ideal situation would be to take the cannula straight out with the sample inside. However, between step three and step four, the sample is still connected to the surrounding tissue at the distal end. The conventional way to sever the bone biopsy, is to rotate the cannula and move the distal end radially in the hopes of severing the sample from the surrounding tissue. The main problem is that this movement directly damages the surrounding tissue, which causes complications for the patient.

Even if the sample is sufficiently severed from the surrounding tissue, there are still other forces which may cause the sample to slide out of the cannula while extracting. The most common strategy of combating this problem is to design the cannula to be tapered toward the distal end. This design choice was first implemented by Iranian haemotologist Khosrow Jamshidi [3], [4]. Since then, this design has become the golden standard and the Jamshidi needle is widely applied. The design is also visible on the yellow colored cannula in previous figures. This tapering effectively allows a sample to enter, which is smaller than the lumen of the cannula. In reaction, the sample of cancellous bone expands slightly to fill this open space. The expanded sample will recieve forces in the axial direction by the tapered portion of the cannula when extracting.

Even still, these two measures may sometimes not be enough to succesfully extract the sample. When this happens, the surgeon will need to retry the operation at a different location. Since this procedure causes a serious amount of long-lasting pain in patients, this effect is very undesirable [5].

Furthermore, due to crushing artifacts and other non-optimal effects of the biopsy procedure, on average 25% of the sample is unusable in its analysis [6]. This can not easily be addressed by taking a larger sample, since the minimum adequate sample length of 1.5 cm is already quite an imposing length which may not always be possible to

expand due to the bone anatomy. One of the causes of this uselessness of a piece of the sample is the generation of crushing artifacts in the sample. Another is because of the use of a trocar to breach the cortical bone.

A study by Bain reports a 0.08% of complications from procedures using such instruments [7]. Important to note is that this study is limited to the report of serious long-term complications, and does not report regular failure of a biopsy procedure with the adverse effects mentioned above. Minor complications are not widely reported, and only found in anecdotal evidence, therefore is difficult to estimate the size of the problems caused.

C. Goal and structure

The goal of this study is to provide a comprehensive overview of the patent literature on minimally invasive cancellous bone biopsy instruments. To achieve this goal, relevant patents were classified into categories of clear, distinctive strategies. These strategies are discussed in Section II, after which the results of this classification method are discussed in Section III. After a factual comparison of the different strategies, a more subjective comparison is presented in Section IV, along with interesting findings, an address of the limitations of this study and recommendations for future research. Finalizing the patent review will be a conclusion presented in Section V.

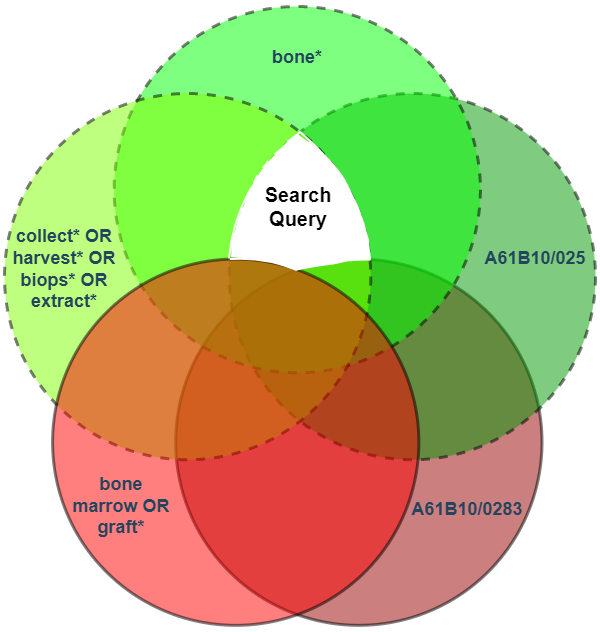


Figure 3: Venn diagram illustrating the search query. In green, the search terms have been visualized which were included as AND terms. Only patents which contained all three of these terms were included in the study. In red, the search terms are visualized which were excluded using NOT terms. All patents containing one or both of these terms were excluded. This results in the search query visualized in white.

II. Method

A. Search method

To gather the relevant patents needed to provide a comprehensive overview of the current bone biopsy instruments, a search was conducted in the database of the European patent office, Espacenet, as it includes most patents published worldwide. A further argument for using this database is its thorough integration of the CPC classification system, which makes filtering patents much easier.

Two CPC classification symbols are of note in this review: A61B10/025 and A60B10/0283. The first, A61B10/025, concerns pointed or sharp biopsy instruments for taking bone, marrow or cartilage samples. This classification alone contains 747 patents and should contain all patents this review is focused on. However, the A61B10/025 classification symbol also contains biopsy instruments specifically focused on marrow and cartilage, which are not relevant for this review. These instruments are filtered out with further addition of search terms.

This is where A61B10/0283 helps out. This classification symbol contains biopsy instruments specifically using vacuum aspiration for obtaining the sample. This strategy is used primarily for bone marrow aspirates, therefore it is deemed appropriate to exclude patents classified as A61B10/0283 from this review. A quick check pointed out that the amount of useful bone biopsy instruments denied by excluding the A61B10/0283 classification symbol is negligible, further validating this assumption.

To further filter the 623 results left, several search terms were introduced. The first was the addition of the ”bone” search term in either the title or the abstract. This term assures the exclusion of biopsy instruments not designed to extract bone biopsies. Secondly, the addition of the term biopsy in the title or the abstract excluded the patents which were not concerned with gathering a sample. To avoid excluding instruments which do gather a sample but do not call it a biopsy, the synonyms collect, harvest and extract were added as included terms. Third, to further exclude patents overly focused on the aspiration of bone marrow in contrast to bone, the term ”bone marrow” was to be excluded. However, to exclude as few instruments as possible which are able to extract a useful bone biopsy along with a bone marrow aspiration, this search term was solely excluded from the title, not the abstract. Some of the patents still included describe instruments which harvest several smaller pieces of bone, which are used mostly to perform autologous transplants and are not usable as a biopsy. This process is also called ’grafting’. Therefore, the term ”graft” was to be excluded from the title and abstract.

Full search query: cpc = A61B10/025 AND ta = (bone* AND (collect* OR harvest* OR biops* OR extract*)) NOT (cpc = A61B10/0283 OR ti = bone marrow OR ta = graft*)

To improve comprehension, a venn diagram has been made and included in Figure 3. The resulting patents were filtered on language, leaving only patents available in English. Finally, a total of 142 patents were left after these filters.

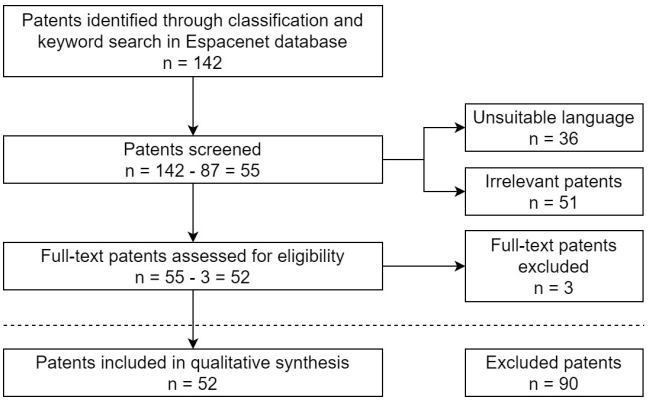


Figure 4: A PRISMA flow diagram illustrating a schematic overview of the patent selection process.

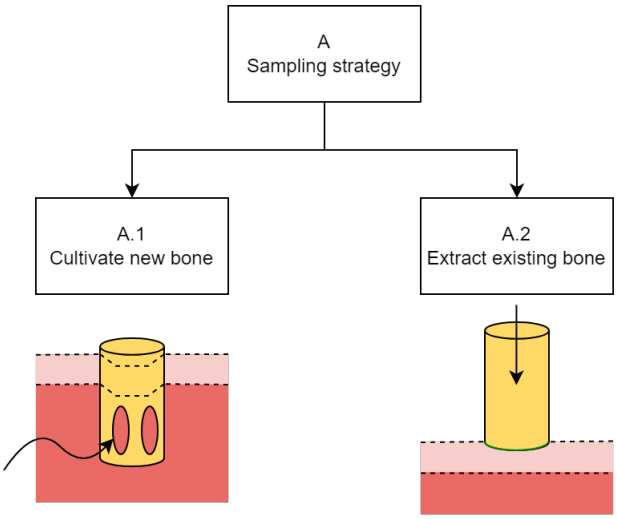


Figure 5: Classification tree showing the first separation of patents in two categories. Its numbering corresponds to its location in the Results section.

B. Selection criteria

The 142 patents found in the CPC classification and keyword search query described above have been subjected to several inclusion and exclusion criteria by manually checking them. These stages are shown in Figure 4. The first criterion is to check that the patent is written in English. Of the 142 patents, 36 were only available as a computer translated version and therefore were not included in this review. The resulting 106 patents were to be checked with more thorough selection criteria, which are listed below:

1) The patent must concern a device capable of extracting a cancellous bone biopsy
2) The penetrating or extracting function of the device must be a focus of the design
3) Devices focused on aspiration of bone marrow are excluded
4) Devices which produce a graft or otherwise damage the sample are excluded

These criteria were first applied on a superficial level, by checking the title and abstract of these patents. Of these 106 patents, six patents still proposed an instrument specifically designed to aspirate bone marrow from a biopsy site. 19 patents proposed a grafting instrument or other instrument which cuts the bone into smaller pieces. 11 patents describe an instrument designed to collect bone graft in one way or another, some by attaching to a grafting instrument or drill and some by filtering the bone-blood mixture generated by regular bone surgery. Six patents were found not to describe an instrument but a method of either using an instrument or a more general method of performing a bone biopsy. Five patents were excluded because they described a specific part of a biopsy instrument which was not relevant to the strategy and lastly, four patents were excluded because they describe an instrument not capable of extracting a bone biopsy.

After applying these criteria, 51 patents were deemed not relevant to this review, leaving 55 patents to read fully. After a full-text screening, it was discovered that three patents did not comply with the selection criteria, resulting in a final 52 patents included in this review. These 52 patents are outlined in Table I.

C. Patent classification

1) Sampling strategy: The patents found in the database are classified according to their described instruments' working principles. Three classifications were deemed necessary to logically divide the patents. The first division is between instruments which extract a biopsy from a patient's bone in a single operation and instruments in which the target tissue is cultivated which can then be extracted from the instrument. As shown in Figure 5, these two strategies are classified as *extract existing bone* and *cultivate new bone*. The large difference in size of these two groups calls for further classification of only the extract existing bone category.

Extracting bone in the conventional way, which means the extract existing bone-category, is done in two stages. The bone is penetrated with the instrument, which results in the instrument being located within the bone and simultaneously the sample being located within the instrument. This is called the *penetrating bone* stage. Hereafter the instrument needs to be extracted from the patient, while keeping the sample in the instrument. This stage is called the *severing sample* stage. The strategy of the penetrating bone stage has little influence on the strategy used in the severing sample stage. These stages will therefore be discussed independently.

2) Penetrating bone: The first step of extracting a sample from the existing bone is to move an instrument into the bone. The goal of this stage is to achieve a clear difference between the targeted sample being situated within the instrument and the surrounding bony tissue which is not part of the sample. Each patent that describes an instrument which extracts the existing bone describes some version of a hollow needle, or cannula, which is axially forced into the bone. Therefore, the strategy designation is limited to the ways in which such a cannula is axially inserted into bone while encapsulating a sample.

Inventor(s)	Title	Country	Year	Strategies		Reference
Fox *et al.*	Analytic bone implant	US	1990	Cultivate new bone		[8]
Fox	Bone biopsy implant	US	1996	Cultivate new bone		[9]
Fox	Method and implant for surgical manipulation of bone	US	1999	Cultivate new bone		[10]
Swaim	Biopsy hand tool for capturing tissue sample	US	1997	B.1.a	C.1.a	[11]
Aakerfeldt *et al.*	Device for biopsy sampling	EP	1995	B.1.a	C.1.a	[12]
Casula	Device for transcutaneous biopsy	EP	2002	B.1.a	C.1.a	[13]
Zambelli	Bone biopsy device and process for making the same	EP	2003	B.1.a & B.2.a	C.1.a & C.2.a	[14]
Cook	Apparatus and method for harvesting bone	US	2019	B.1.a	C.2.a	[15]
Rodriguez & Snyder	Biopsy needle assembly and guide	US	1995	B.1.a	C.2.a	[16]
Byrne *et al.*	Biopsy needle assembly	US	1996	B.1.a	C.2.a	[17]
Tretinyak	Biopsy needle	US	1983	B.1.a	C.2.a	[18]
Rodriguez *et al.*	Needle device with improved handle	US	1996	B.1.a	C.2.a	[19]
Mehl	Biopsy needle	CA	1982	B.1.a	C.2.a	[20]
Mehl	Biopsy needle	US	1994	B.1.a	C.2.a	[21]
Mehl	Biopsy needle	CA	1984	B.1.a	C.2.a	[22]
Hirsch *et al.*	Cannula for extracting and implanting material	US	2004	B.1.a	C.2.a	[23]
Laughlin *et al.*	Tissue coring device	US	2020	B.1.a	C.2.a	[24]
Globerman & Beyar	Integrated bone biopsy and therapy apparatus	EP/IL	2008	B.1.a	C.2.a	[25]
Ward	Biopsy instrument	US	1988	B.1.a	C.2.b	[26]
Slama & Zerazhi	Osteomedullar biopsy trocar	FR	2006	B.1.a	C.2.b	[27]
Avaltroni	Biopsy device	IT/EP	2000	B.1.a	C.3.a	[28]
Ackroyd	Dual needle core biopsy instrument	US	2016	B.1.b	C.1.a	[29]
Entrekin *et al.*	Bone harvest system	US	2007	B.1.b	C.1.a	[30]
Krueger	Bone biopsy instrument having improved sample retention	EP	2003	B.1.b	C.1.a & C.1.b	[31]
Krueger	Bone biopsy instrument having improved sample retention	EP	2003	B.1.b	C.1.a & C.1.b	[32]
Dunker *et al.*	Biopsy holder for a biopsy cannula	EP/DE	2004	B.1.b	C.1.b & C.3.b	[33]
Miller & Ireland	Biopsy extractor	US	2001	B.1.b	C.2.b	[34]
Johanson *et al.*	Method and apparatus for harvesting and implanting bone plugs	US	2004	B.1.b	C.3.b	[35]
Johanson *et al.*	Method and apparatus for harvesting and implanting bone plugs	US	2001	B.1.b	C.3.b	[36]
Fumex & Masseglia	Biopsy Trocar	US	2015	B.2.b	C.1.a	[37]
Hoffmann & Matusch	Biopsy needle for the histological examination of body tissue	EP/DE	2006	B.2.b	C.1.a	[38]
Islam	Biopsy needle	US	2017	B.2.b	C.1.a	[39]
Islam & Bevan	Biopsy needle	GB/US	1985	B.2.b	C.1.a	[40]
Miller *et al.*	Biopsy devices and related methods	US	2008	B.2.a & B.2.b	C.2.a	[41]
Miller *et al.*	Biopsy devices and related methods	US	2008	B.2.a & B.2.b	C.2.a	[42]
Miller & Eisbrenner	Vertebral Access System and Methods	US	2019	B.2.a & B.2.b	C.2.a	[43]
Madhumathi *et al.*	Bone biopsy system and method	US	2021	B.2.b	C.2.a	[44]
Doppelt	Bone biopsy apparatus	US	1989	B.2.b	C.2.a	[45]
Matthews	Counter rotating biopsy needle	US	1981	B.2.b	C.2.a	[46]
Gray	Bone biopsy needle	US	1991	B.2.b	C.2.a	[47]
Elias & Elias	Bone biopsy instrument and method	US	1974	B.2.b	C.2.a	[48]
Turkel	Infusion and biopsy needle	GB	1949	B.2.b	C.2.a	[49]
Masseglia & Fumex	Perforating trocar	US	2008	B.2.b	C.2.a	[50]
Masseglia & Fumex	Perforating trocar	US	2006	B.2.b	C.2.a	[51]
Peliks *et al.*	Bone biopsy device and related methods	US	2021	B.2.b	C.2.b	[52]
Vilaghy & zellerman	Bone biopsy instrument kit	US	1977	B.2.a	C.2.a	[53]
Zambelli	Bone biopsy device	EP/IT	2010	B.2.a	C.1.a	[54]
Negroni	Biopsy assembly	US	2004	B.2.a	C.1.a & C.2.a	[55]
Peliks *et al.*	Bone biopsy device and related methods	US	2021	B.2.a	C.2.a	[56]
Zambelli	Bone biopsy device	EP/IT	2018	B.2.a	C.2.b	[57]
Sachse & Sachse	Oscillating bone harvesting device	DE	1999	B.2.a	C.3.a	[58]
Avaltroni	Improved needle instrument for taking osteomedullary bioptical samples	EP/IT	2004	B.2.a	C.3.a	[59]

TABLE I: Relevant patents found in the Espacenet database. The numbers representing the strategies correspond to the numbers found in Figures 6 and 8.

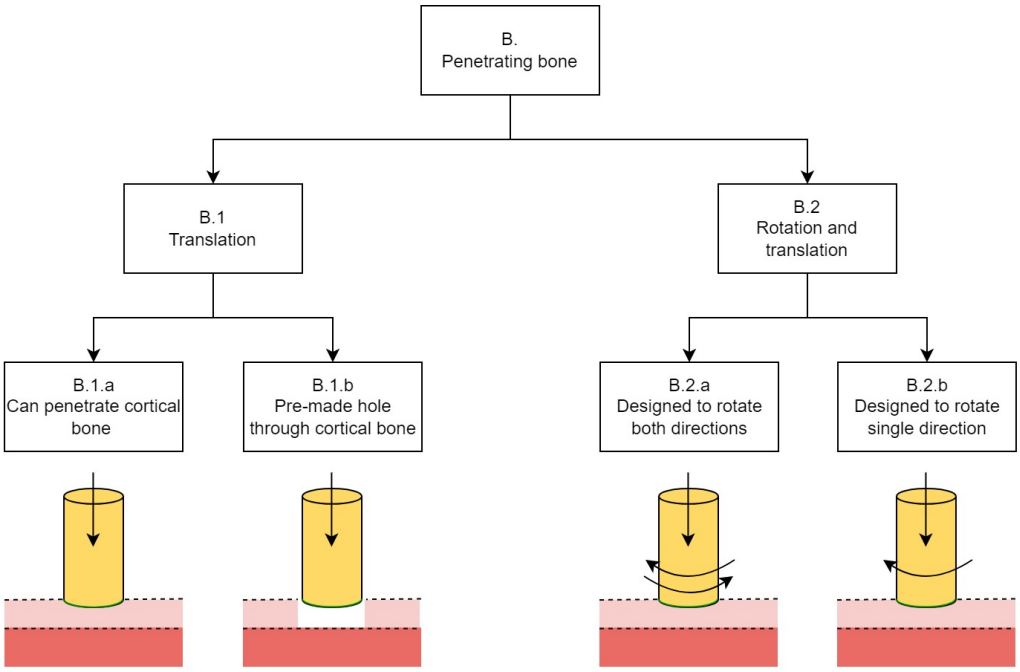


Figure 6: Classification tree separating the strategies found in the patents regarding the *penetrating bone* stage. The numbers of the strategies correspond to their location in the Results section.

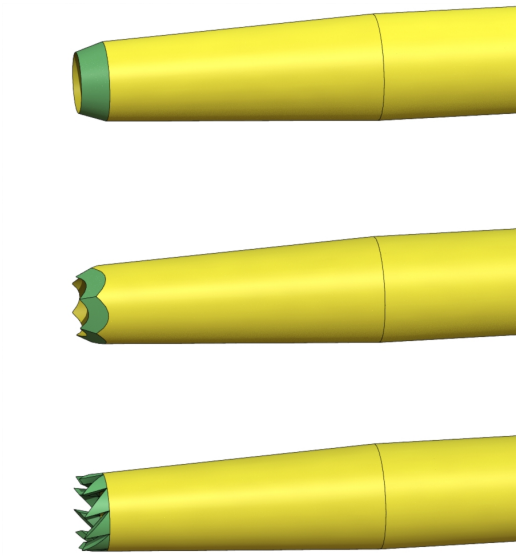


Figure 7: A comparison of the distal ends of three different cannula. On top is shown the same cannula as in Figure 1 and Figure 2. The middle is an example of a cannula designed to rotate in both directions. On the bottom is shown an example of a cannula designed to rotate in a single direction.

The found strategies are split in two main groups, each with two subgroups. This division is shown in Figure 6. The *translation* group consists of the patents describing an instrument designed to be pushed into the bone without any movement other than axial movement. These instruments are recognized by the smooth distal end of the cannula. This group is split into instruments which contain a strategy for penetrating the layer of cortical bone and instruments which rely on a hole in the cortical bone through which they are inserted.

Instruments belonging to the *rotation and translation* group, on the other hand, all have some sort of rotating motion prescribed for the penetrating stage. Most of these instruments can be recognized by non-straight distal edges of the cannula, which can resemble the teeth of a saw blade. These teeth along with the rotating movement aid the instrument in its movement through the bone. This group is split into patents describing cannulas with teeth designed to rotate in a single direction and teeth designed to rotate in both directions. A comparison of such different types teeth can be seen in Figure 7.

3) Severing sample: When the instrument has entered the bone and a sample is inside, it is time to remove the instrument along with the sample. Because of the factors described in the Problem definition section, there is a tendency for the sample to slide out of the instrument while extracting.

Several strategies exist to make sure these factors are negated. These strategies are separated in Figure 8. In this figure, a distinction is made between three main strategies. Since each strategy prescribes a force applied in a certain direction, the distinction is made in the direction of the force applied on the instrument: the first direction, *axial force*, concerns the force applied by pulling the instrument out of the bone. The second direction, *radial force*, means a force applied perpendicular to the axle of the cannula. The third direction, *tangential force*, concerns forces resulting in rotation of the cannula along its axis.

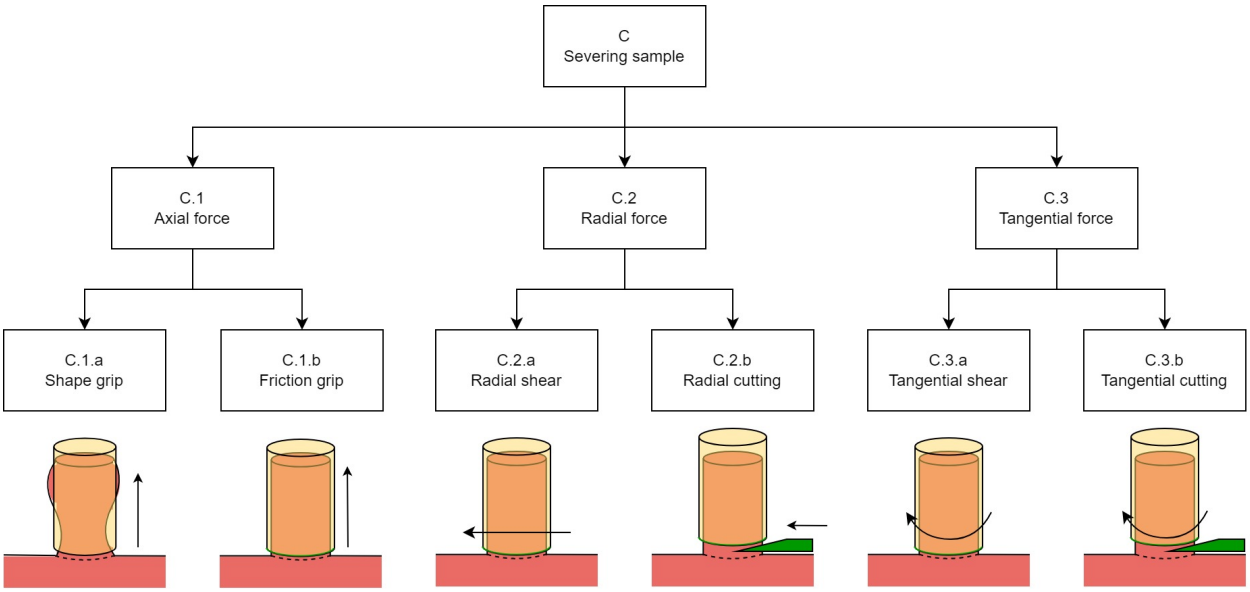


Figure 8: Classification tree separating the strategies found in the patents regarding the *severing sample* stage. The numbers of the strategies correspond to their location in the Results section.

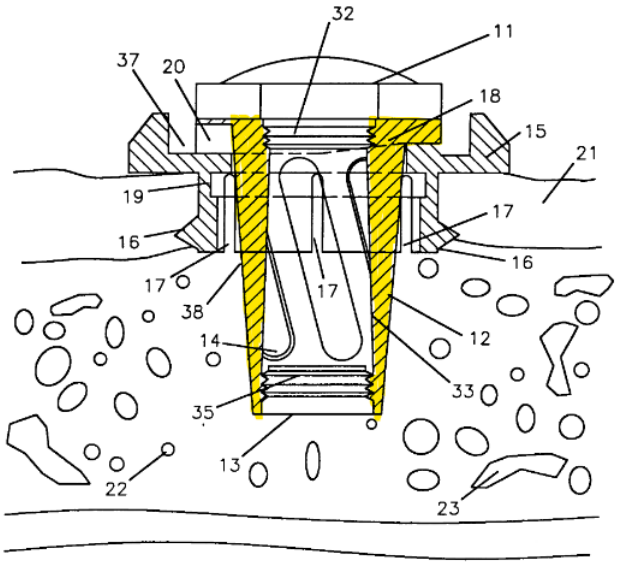


Figure 9: Figure adapted from the patent by Fox [9]. Indicated in yellow is the part of the instrument with a function comparable to a cannula.

III. Results

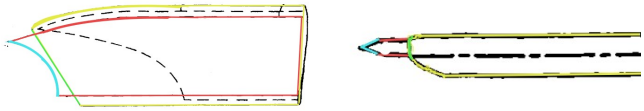
A. Sampling Strategy

1) Cultivate new bone: Of the total 52 patents, three described instruments designed to cultivate new bone which can be extracted afterwards [8]–[10]. See the first category of Figure 5. These three describe instruments which facilitate the growth of new bone, which will form the sample. When this new bone tissue is sufficiently grown, the whole or part of the instrument is extracted, taking with it the sample.

The instruments described in the patents are hollow, cylindrical or semi-cylindrical shaped devices with holes in their perimeter which allow bone to grow into the instrument, forming the sample. See Figure 9 for an example of such a device. When the instrument is extracted, the sample is taken with it. Since these devices are not designed to be drilled into existing bone, they require a pre-drilled hole in the bone, into which they are placed. After this hole is drilled, a semi-permanent implant is fastened in place. This implant, most thoroughly described in [10], is essentially a vessel in which a temporary implant can be inserted. This temporary implant is the acquiring vessel which will hold the sample. When the sample has grown into this temporary implant, the temporary implant will be removed along with the sample, leaving the permanent implant in place. The permanent implant facilitates follow-up insertions of another temporary implant or other intra-osseous operations without the need of a different operating site. When several biopsies are needed from the patient at different points in time, the need of but a single, reusable hole in bone forms a large advantage for the patient.

All three of these devices share a common inventor, namely William Casey Fox, which would indicate a single project resulting in several patents. Indeed, two of these patents ([9], [10]) share a priority number. More closely inspecting these patents gives the impression that the semi-permanent implant part of [9] might be the instrument described in patent [10], albeit more thoroughly detailed.

2) Extract existing bone: The other 49 patents not covered by the previous section describe devices which are designed to extract a sample from the already-present bone [11]–[59]. See the second category of Figure 5 As mentioned before, since this group is so big in comparison to the cultivate new bone category, it is described in further



(a) Figure adapted from the patent by Swaim [11].

(b) Figure adapted from the patent by Slama and Zerazhi [27].

Figure 10: Two figures adapted from patents, showing different configurations of the trocar located within a cannula. The trocar is colored red, with its cutting edge light blue. The cannula is colored yellow, with its opening in green.

detail in Sections III-B and III-C.

These devices all employ the strategy discussed before: move a cannula into the bony tissue which is to be sampled, which results in a sample located within the cannula. After this, a part of or the whole instrument is removed from the sampling location, taking the sample with it.

B. Penetrating Bone

1) Translation:

a) Can penetrate cortical bone: 18 patents have been classified as describing devices which translate into the bone and are able to penetrate cortical bone [11]–[28]. See the first category of Figure 6. These devices generally comprise at least one cannula and a trocar. Refer back to Figure 2 for a configuration common among patents in this category. As seen in the figure, the trocar often ends in a centered point. However, the trocar does not always have to be shaped with a centered point. For example, see the trocars in Figure 10. The trocar by Swaim is shaped such that it functions in a unique way. The trocar by Slama and Zerazhi is located off-center because of the shape of the distal end of their cannula.

Irrespective of the shape of the trocar, most patents in this category should penetrate the bone in the same way as has been described in the Introduction. Some instruments, when the trocar is removed, introduce an inner cannula into the, now, outer cannula. These inner cannulas are often useful when extracting the sample, but offer no real advantage while penetrating the bone.

The patent by Globerman and Beyar describes an instrument whose cannula is located within the trocar [25]. The distal opening is located on the side of this trocar, and a flexible inner cannula is designed to be able to protrude from this opening and encapsulate a sample. The proposed instrument is shown in Figure 11. This is the only patent found which proposes a method to extract a sample in the radial direction.

b) Pre-made hole through cortical bone: In contrast to the patents described in the previous paragraph, some patents describe instruments which require a pre-made hole in the cortical bone before the instrument is inserted. How such a hole is made is oftentimes not specified, but can be made by either a separate trocar or drill. In this category, eight patents are classified [29]–[36]. See the second category of Figure 6.

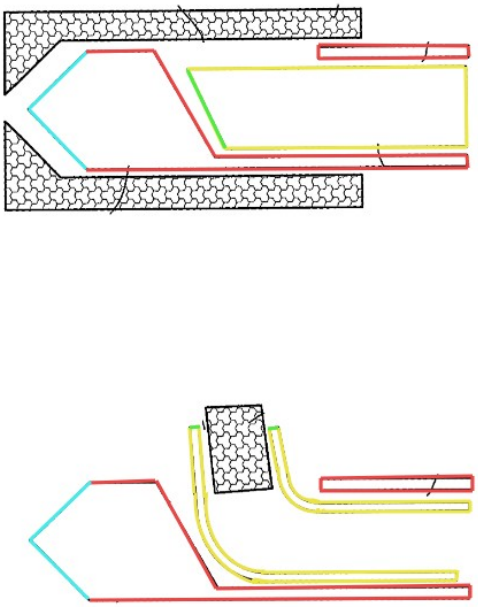
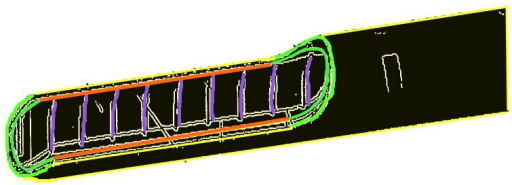


Figure 11: Figure adapted from the patent by Globerman and Beyar [25]. Showing a section view of the side of the trocar cannula assembly proposed by Globerman and Beyar. In red, shown the trocar, with its cutting edge light blue. The cannula is colored yellow, with its opening in green. The top figure shows the surrounding bone tissue around the assembly. The bottom figure does not show the surrounding tissue, but does show a part of this tissue located within the cannula as a sample.

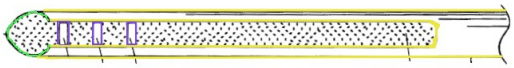
This category of instruments is in essence more limited in function than the category of instruments which can penetrate the cortical bone. However, the instruments do not need to be concerned with allowing a trocar through the cannula. This allows for a more complex internal area of the cannula, as seen in the patent by Entrekin *et al.* and in Figure 12a, which describes a multi-layered cannula with grooves perpendicular to the axis [30]. These grooves do not help with entering the bone, but will be further discussed in the severing sample section.

Similarly, the instruments described by Krueger also contain canullas with non-standard shape and openings as seen in Figure 12b [31], [32]. These could negatively impact the bone penetration function, but may help the other functions of these devices, such as sample extraction.

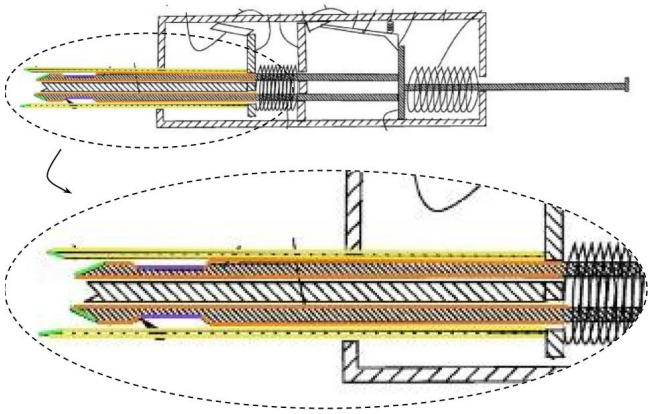
Another instrument which is not designed to be used before penetrating the cortical bone is described in the patent by Ackroyd [29]. The instrument proposed in this patent comprises a spring-loaded double-walled cannula which is forced into the target tissue by the spring, first the inner cannula and then the outer cannula. See **??**. This instrument is designed to finely tune the depth of penetration, making sure that the cannula does not continue too deep on accident.



(a) Figure adapted from the patent by Entrekin *et al.* [30].



(b) Figure adapted from the patent by Krueger [32]. The inside of the cannula is dotted, indicating the friction enhancing surface texture.



(c) Figure adapted from the patent by Ackroyd [29]. This instrument contains a pair of inner cannulas within its outer cannula.

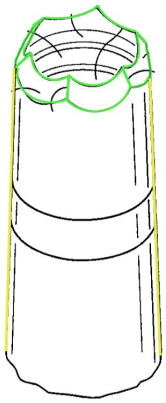
Figure 12: In each figure, the cannula is outlined in yellow, if applicable an inner cannula is outlined in orange and their cutting edges are lined with green. Structures intended for sample retention are lined with purple.

Furthermore, the patent proposes the same instrument but with two of these cannulas connected next to each other. With one push of the button, both inner cannulas will spring forward simultaneously and encapsulate two samples. This strategy allows for the extraction of two separate samples very close to one another, which would otherwise be very difficult or require the holes to be further apart, increasing the damage to the patient. This might be useful if the targeted tissue is of uncertain quality or too shallow, when a single sample would not be enough.

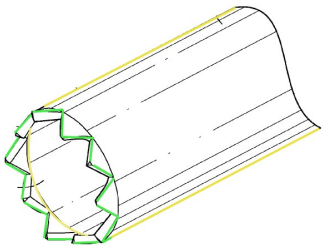
2) Rotation and Translation:

a) Designed to rotate in both directions: There are several devices designed to utilize a rotating motion in order to more efficiently penetrate the bone. These devices are characterized by the distinctive shape of the distal end of their cannula. These distal ends all contain saw-like teeth which work when an axial rotation is initiated. This distal end dictates whether the device should rotate in one or both directions. These teeth are designed to perform a drilling, sawing or scraping function when the cannula is rotated while it is pushed axially into the bone.

These devices are separated in two categories, depending on the shape of their teeth. 11 devices are classified in the category with teeth designed to function in either direction [14], [41]–[43], [53]–[59]. See the third category of Figure 6. Whether or not the teeth are rotationally symmetrical clearly distinguishes devices which are designed to rotate in one or both directions. Figure 13 clearly shows two devices which are rotationally symmetrical. Both function clockwise just as well as counterclockwise.



(a) Figure adapted from the patent by Miller *et al.* [42].



(b) Figure adapted from the patent by Peliks *et al.* [56].

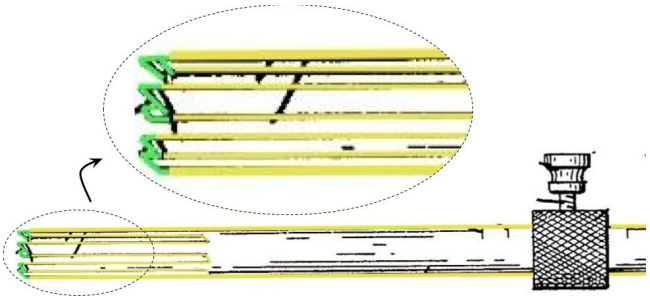
Figure 13: Both figures feature a side view of their cannula's teeth, clearly showing their symmetry. In yellow, the cannula is outlined, with the cutting teeth colored green.

Most patents in this category propose devices with teeth as shown in Figure 13a. These teeth are shaped to a sharp point as well as shaped inward to have the teeth perform a cutting motion. The slope of the teeth being outward avoids excessive inward pressure on the sample and also makes sure that most of the debris caused by cutting the bone moves outward away from the sample.

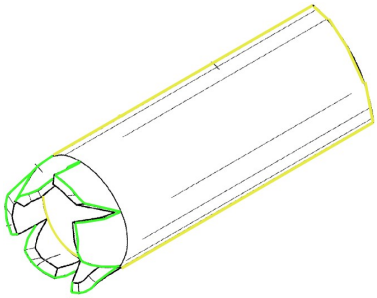
Many of these devices do not describe in detail the shape of their teeth at the distal end of the cannula. However, some patents do not specify the shape of their teeth at all. In the patent by Vilaghy and Zellerman, the teeth are merely illustrated with a serrated line [53]. Another patent which does not illustrate or describe the shape of the teeth is by Sachse and Sachse [58]. While they neglect the shape of the teeth, they do illustrate a very interesting use of their instrument. It is designed such, that it should enter the bone using an oscillating motion, never rotating more than a few degrees. The effect of this motion is a shape of the sample, which will be useful in the severing sample stage.

b) Designed to rotate in a single direction: 16 patents were classified in this category [37]–[52]. See the fourth category of Figure 6.

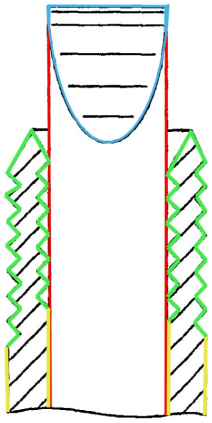
The teeth present on devices designed to rotate in a single direction are all non-symmetrical. This means that the teeth perform differently, depending on the direction of rotation. Three examples of such teeth are shown in Figure 14. The first of this figure, Figure 14a, shows a cannula with recesses on its side, with teeth at the distal end between the recesses. The function of these recesses is to provide a way outward for any bone debris caused by cutting into the bone. The



(a) Figure adapted from the patent by Doppelt [45].



(b) Figure adapted from the patent by Peliks *et al.* [52].



(c) Figure adapted from the patent by Hoffmann and Matusch [38].

Figure 14: These figures illustrate three different configurations of devices designed to rotate in a single direction. The cannula is shown in yellow with its cutting edge in green. b) shows a trocar shown in red, with its cutting edge in blue.

second figure, Figure 14b, shows how a unique shape of the teeth. The teeth on this cannula are alternatively bent inward and outward. This design is also generated to nudge the bone debris outward away from the sample. The third figure, Figure 14c, shows a cannula with helical thread on the inside and outside. The thread should enhance the function of penetrating bone, pulling itself inward when the instrument is rotated.

The patents which propose a motorized apparatus actuating the cannula are often designed to be able to use a cannula designed to rotate in a single direction. This motorized actuation allows a very specific ratio of axial rotation speed to axial translation speed. This would allow a tooth design which would not be useful if the axial translation speed would not be coupled to the axial rotation speed. One patent discussing such a coupling is the one by Madhumathi *et al.* [44]. It describes a powered driver coupled to a cannula with helical thread on the outside.

C. Severing Sample

1) Axial force:

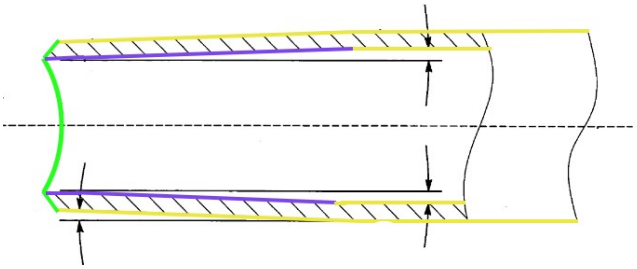
a) Shape grip: Of the total 52 patents, 14 use the shape grip axial force strategy [11]–[14], [29]–[32], [37]–[40], [54]–[56]. See the first category of Figure 8. These patents employ a macro structure, e.g. their shape, to hold on to the sample. These structures are generally recognized on the inside of an instrument's cannula or by the shape of their inner cannula.

The most general type of shape grip is the strategy of pushing the sample past a barrier, which requires more force for the sample to exit, than it took to enter the cannula. Often by using the sample's tendency to expand in size when given the space, due to its elastic nature. This strategy is obvious with instruments whose cannula have a lumen which is smaller at the distal end, and widens gradually as in Figure 15a [12], [55], or abruptly as in Figure 15b [14], [39], [40]. Some devices also use this same elastic behaviour of the sample with a different shape. They use holes in the sides of their cannula into which the sample can expand, see the devices in Figure 12 [29]–[32]. When pulling out, the sample will be dragged along due to macro-shape grip.

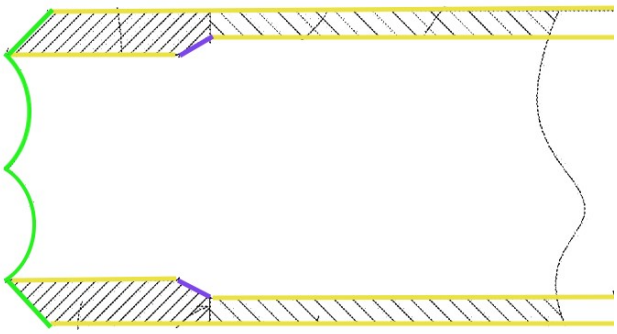
Two devices contain a screw-like thread inside their cannula [37], [38], refer back to Figure 14c. When this cannula is rotationally advanced into the tissue, the thread has little to no effect on the sample. However, when the cannula is being retracted, this thread does provide a surface which adds shape grip on the sample.

The final group of instruments which employ shape grip, all contain an outer and inner cannula. Their inner cannula either turns to add axial grip on the sample [11], [30], or deforms within the outer cannula slightly into the sample [13], [54]. The device by Entrekin *et al.* [30], its distal end of the inner and outer cannulas have a semicylindrical shape, as shown in Figure 12a. When entering, these two halves are aligned as half a cylinder, but once at the sampling location, the inner cannula is rotated around the sample, cutting the sides off from the rest of the tissue. The furrows present in the inner cannula now cut away less of the sample. The sample therefore "sticks out" into the furrows, which adds additional shape grip in the axial direction when extracting the sample. Swaim's device uses partly the same strategy [11], work is shown in Figure 15c. This device also enters the bone with the inner and outer cannula aligned, finally turning the inner cannula when the device is already around the sample. However, this device has a full distal end, which is slightly tapered to one side. When the sample is inside the cannula, it has entered slightly sideways. Therefore, when the inner cannula rotates, the distal end of the sample is partially cut off and the outer cannula's hole is partially covered by the inner cannula. This essentially creates a partial wedge between the sample and the tissue at its distal end, which adds to the axial force imposed on the sample when extracting.

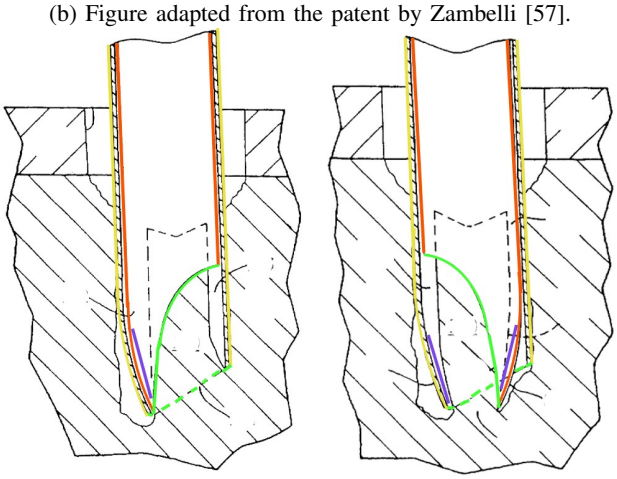
One of the patents which merit further discussion is the only patent which suggests using a vacuum to enhance the sample retention within the cannula, even though using vacuum for the subsequent bone marrow aspiration procedure is common practice. The patent in question concerns an instrument invented by Negroni [55]. The tapered inside of the distal end, which is shown in Figure 15a, classifies it in the shape grip category. Because this tapering can only account for so much force in the axial direction, most such



(a) Figure adapted from the patent by Negroni [55].



(b) Figure adapted from the patent by Zambelli [57].



(c) Figure adapted from the patent by Swaim [11]. The left shows the inner and outer cannula aligned, the right shows the inner cannula rotated 180 degrees.

Figure 15: Figure a) shows a cannula with a gradual tapered lumen. Figure b) shows a cannula with an abrupt tapered lumen. Figure c) shows an inner and outer cannula combination which shows a larger area of shape grip than before rotation. The cannula is shown in yellow, inner cannula in orange, with their cutting edges in green. Areas intended to grip the sample are shown in purple.

instruments also move radially to shear off the sample from the surrounding tissue. Connecting a syringe to the end of the should improve the force in axial direction on the sample, resulting in a lower need of radial shearing the sample and less damage to the surrounding tissue due to this movement.

b) Friction grip: Three patents were found to use friction to directly enhance the sample extracting efficacy [31]–[33]. See the second category of Figure 8. The devices by Krueger were also classified in the shape grip-category [31], [32]. However, the patents very clearly specify the surface inside the cannula to have enhanced friction.

Dunker's patent describes a device whose main part is a wire to be inserted into an existing biopsy cannula [33]. This wire, among other things, enhances the friction with the sample. Therefore it belongs in the friction grip category. It is clear from these three examples, that no patent proposes an instrument relying solely on friction. They all use friction in addition to another strategy.

2) Radial force:

a) Radial shear: This category is the most common strategy among the patents and contains 20 patents [11], [12], [14]–[23], [25], [41]–[51], [55], [56]. See the third category of Figure 8. These devices move the distal end in the radial direction when the sample is fully encapsulated within the cannula, causing the sample's distal end to detach from the surrounding tissue. This step of radial shear would be between step 3 and step 4 of Figure 1.

One patent in particular, by Globerman and Beyar, is of interest because it describes an instrument which is designed to actually encapsulate a sample in the radial direction instead of in the axial direction, as shown in Figure 11 [25]. The instrument features an outer cannula with a drill bit at its distal end, but with a hole in its lumen. The lumen of the outer cannula is designed such, that when a flexible inner cannula is inserted, it bends sideways and extends from the outer cannula in the radial direction. The distal end of the inner cannula is stiff enough to penetrate the cancellous bone and encapsulate a sample. When the outer cannula is rotated a small angle, it moves the inner cannula such that the sample is sheared off from the surrounding tissue.

b) Radial Cutting: Five patents were classified in this category [26], [27], [34], [52], [57]. See the fourth category of Figure 8. The devices in this paragraph all move a part within their outer cannula in order to perform a cutting movement in the radial direction. This movement functions in severing the sample from the tissue on its distal end, but also often serves in holding the sample when extracting the inner cannula from the outer cannula.

The patents by Miller and Ireland, Zambelli, Ward, and Slama and Zerazhi describe devices consisting of an inner and outer cannula [26], [27], [34], [57]. The outer cannula is shaped like a regular cannula, except for having a lumen with a smaller diameter at the distal end. Often this change in diameter is gradual, but over a very small distance as shown by the pruple areas in Figure 15b. The inner cannula is advanced into the outer cannula until it reaches this change in diameter. When the sample is inside the outer cannula and within the inner cannula, the inner cannula is advanced against the purple areas with force. The inner cannula is designed such, that it will deform and perform a radial cutting movement at the distal end of the sample, as shown in Figure 16a. When the sample is retained in the deformed inner cannula, the inner cannula is extracted, with the sample inside. The outer cannula can often be left for following operations.

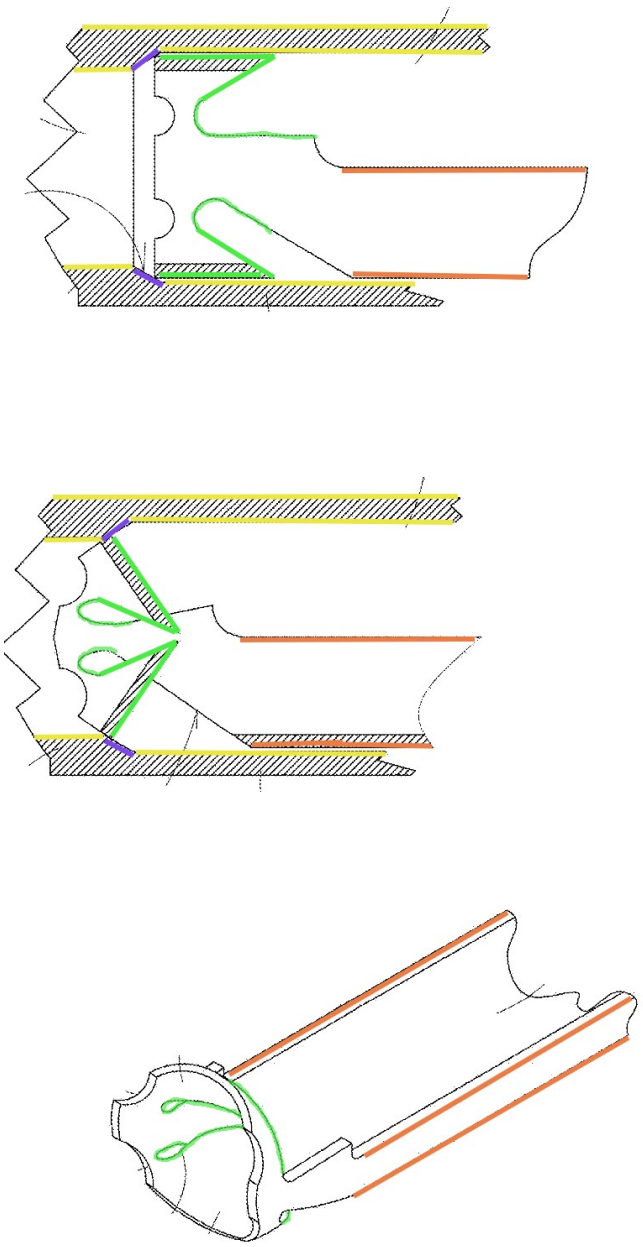
One patent is different from the others in this category, the one by Peliks *et al.* [52]. This patent describes a device which contains a cannula, and a deforming plate situated at its outside, as shown in Figure 16b. This plate is advanced toward the distal end of the cannula when a sample is inside. The plate will encounter a hole in the side of the cannula and, because of its deformed spring-like nature, will enter the hole in the cannula. This results in a radial cutting movement of the plate into the cannula. At this moment, the cannula can be extracted along with the plate. This makes sure that the sample is contained within by the plate.

3) Tangential force:

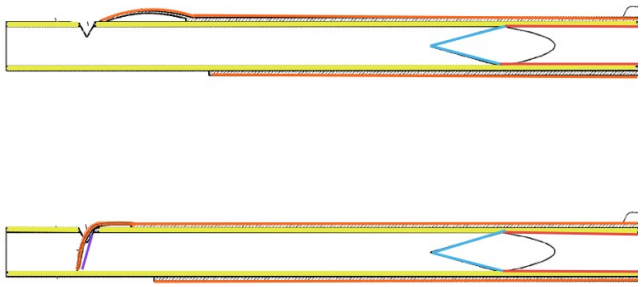
a) Tangential shear: Three instruments function by enacting a tangential force directly on the sample [28], [58], [59]. See the fifth category of Figure 8. These instruments are characterized by their strategy of twisting the whole encapsulated sample along the cannula's axis, in order to sever it from the surrounding tissue. The patent Avaltroni published in 2000, describes an instrument consisting of a regular outer cannula and a special inner cannula [28]. When the outer cannula is situated inside the bone, containing the sample as in step 1 of Figure 17a, the inner cannula is inserted. This inner cannula has a flattened end at least as long as the sample and when inserted, it sticks through the middle of the sample. The flat end of this inner cannula is shown from the side in step 2 of Figure 17a. In step 3, the inner cannula is turned 90 degrees, turning the sample with it. This causes the sample to sever from the surrounding tissue. Then the entire instrument is removed from the patient with the sample inside the outer cannula.

Avaltroni published a different patent in 2004 [59]. This patent describes an instrument with a similar strategy, although using a different technique. The device is shown in Figure 17b. The inner cannula proposed in this patent does not puncture through the middle of the sample, but rather between the sample and the outer cannula. As seen in the figure, the distal end of the inner cannula is split in two halves opposite each other, both forming about a quarter of the original circumference. Where the previous instrument's inner cannula held the sample from the middle, this instrument's inner cannula holds the sample from its outside. The intended effect is the same: When the inner cannula rotates, the sample rotates together with it.

The device by Sachse and Sachse takes a different approach [58] to a similar solution. The device contains two protrusions on the inside of the cannula, as shown in Figure 17c. Because of this, the device should be advanced into the bone in a rotationally oscillating fashion, never rotating more than a few degrees back and forth. This motion generates an encapsulated sample with a shape as shown in the figure, with indentations where the protrusions have moved. Just like the instrument by Avaltroni, if the device makes a larger rotation, the protrusions push on the sides of the sample. While making a full rotation, this tangential force causes the sample to shear off from the surrounding tissue at the distal end of the cannula.

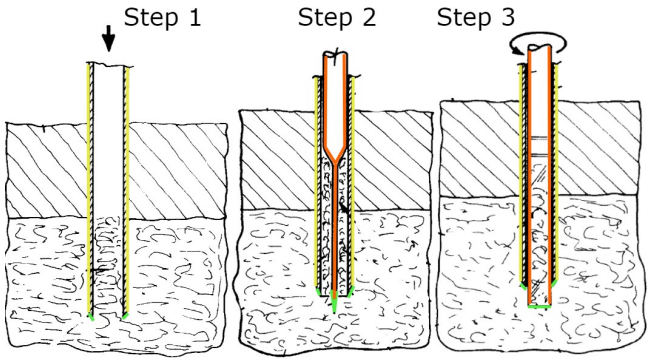


(a) Figure adapted from the patent by Zambelli [57]. The outer cannula is the same as the one pictured in Figure 15b.

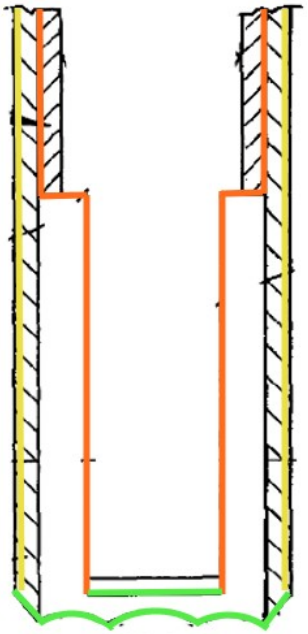


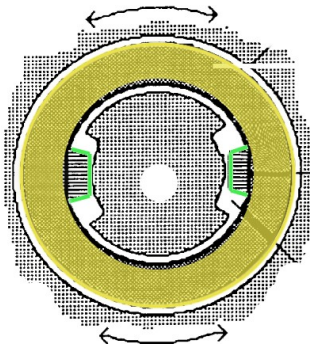
(b) Figure adapted from the patent by Peliks *et al.* [52].

Figure 16: These figures illustrate two instruments with a deforming inner cannula, performing a radial cutting motion. The rigid, outer cannula is shown in yellow, the deforming inner cannula is shown in orange, with cutting edges shown in green. b) shows a trocar, outlined in red with a cutting edge in light blue. The lowest figure also shows a purple area, which indicates the area which will help with retaining the sample.

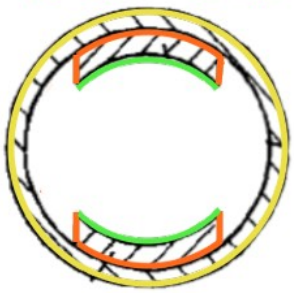


(a) Figure adapted from the patent by Avaltroni [28].





(c) Figure adapted from the patent by Sachse and Sachse [58].



(b) Figure adapted from the patent by Avaltroni [59].

Figure 17: Three figures illustrating the devices in the tangential cutting category. The outer cannulas have been outlined in yellow, the inner cannulas in orange, with their cutting edges outlined in green.

b) Tangential cutting: In this category, three patents have been classified [33], [35], [36]. See the sixth category of Figure 8. The two patents by Johanson *et al.* describe two very similar devices, with only minor differences [35], [36]. The instument proposed in these patents is designed to perform a bone plug transplant. This bone plug, however, could also be used as a biopsy. As shown in Figure 18a, the cannula of this instrument includes a tooth at its distal end. It is therefore important, that this instrument is inserted into the bone tissue without rotating it, to ensure most of the sample remains undamaged. When the sample is fully inside the cannula however, the outer cannula should be rotated a full circle before extracting the instrument. With this rotation, the tooth separates the sample from the surrounding tissue with a tangential cutting motion.

The patent by Dunker *et al.* describes an instrument to be added to a regular outer cannula, consisting of a rod with a straight wire at the end, as shown in Figure 18b. This instrument is inserted into the cannula, after it is inserted into the bone and contains the sample. The wire at the distal end of the instrument is driven between the sample and the inside of the cannula. When the instrument is rotated, the wire moves tangentially along the inside of the cannula, cutting the sample loose from the surrounding tissue. Finally, the patent mentions a possible roughened surface of the wire, providing an additional friction force when extracting the entire instrument with cannula from the body.

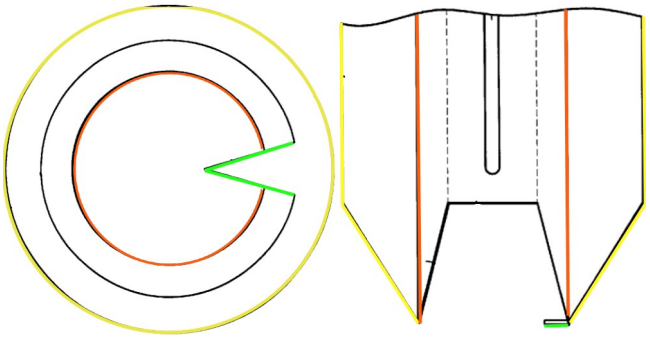
IV. Discussion

A. Main findings regarding sampling strategy

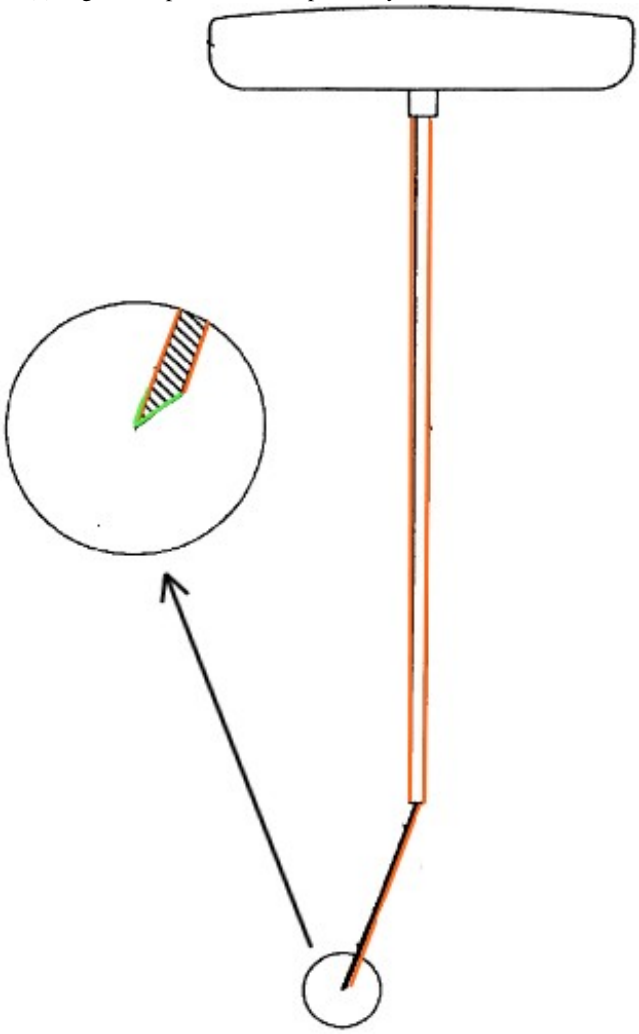
In this review, an overview of the patent literature on cancellous bone biopsy instruments has been provided, separating them into their respective strategies. Of the relevant patents, 50% was published by a company, 48% was published by an independent inventor or a collaboration of multiple independent inventors, and 2% was published by an academic institution.

The overview of Table I, apart from presenting all discussed patents, also shows which strategies their instruments engage in order to first penetrate the cortical bone and subsequently make sure the sample of cancellous bone is severed from the surrounding tissue and is retained when the cannula is withdrawn. Several patents offer variations of the same device, which result in different strategy classifications for each variation, therefore these have been classified with multiple strategies.

Of the 52 discussed patents, three relate to cancelous bone biopsy implants, or 6%. These three patents are certainly interesting because of their unique strategy. However, it is challenging to comment on their effectiveness, since such devices have only been tested on animals [60]. Interestingly, while all three patents have been invented or co-invented by the same person, William C Fox, only the first chronologically was a collaboration of multiple inventors [8]–[10]. This seems to indicate that Fox was the driving factor in the study of such devices.



(a) Figure adapted from the patent by Johanson *et al.* [36].



(b) Figure adapted from the patent by Dunker *et al.* [33].

Figure 18: These figures illustrate the devices in the tangential cutting category. The outer cannula is shown in yellow, the inner cannula in orange, with their cutting edges in green.

B. Main findings regarding penetrating bone

Of the 49 patents relating to cancellous bone needle biopsy instruments, about half describe instruments with a prescribed rotation and half describe instruments which are not prescribed to rotate or actively discouraged to rotate during insertion. The common standard of cancellous bone biopsy is, as visualized in Figure 2, composed of a cannula with a smooth, sharpened distal edge wherein a trocar can be placed. This standard would fall in the *penetrates cortical bone* category. Most of the patents falling in this category do not deviate from this standard, but rather focus on the severing sample strategy. In other words, they do not offer any uniqueness in terms of their bone penetration strategy and often pay no attention to the shape of the distal end of their cannula. The same is true for the patents in the *hole through cortical bone* category. These patents do not breach the cortical bone themselves, but rely on a different device to facilitate a hole in the cortical bone.

However, this is not true for all of the patents in these categories. 40% propose a cannula with a disinct distal end. However, only 8% of the patents in these two categories describes a cutting edge which actively enhance the bone penetration function.

The more interesting categories concern the devices which rotate in a single or both directions, since these devices all have at least a drawing of the distal end of the cannula which illustrates how a rotating motion would benefit its penetration. Apart from benefiting penetration, 20% of the instruments in these categories are specifically designed such that their penetration of the tissue would generate as little damage to the sample as possible, addressing one of the key problems put forward in the problem definition. This is mainly done by redirecting the bone debris caused by boring the bone away from the sample.

The rotation categories also contain all devices which are specifically designed to be operated using a powered driver, instead of the other instruments which are rotated manually. Six patents, or 14% of the patents in these categories, describe their instrument being actuated by a powered driver. The addition of a powered driver brings very interesting options forward. For example the ability to finely tune the design of the distal end of the cannula with regards to the rotation speed and the velocity of advancing into the bone. The most obvious application of such options would be the addition of a thread on the inside or outside of the cannula. Two of the patents hint at this combination of strategies, but only one describes it in detail.

Several rotating instruments have been classified in rotating both in a single and both directions. This double classification is be explained by the tendency of patented instruments to be applicable in as wide an area as possible without diminishing their particulars. Especially patents which focus on a different factor but whose distal end and its function of penetrating bone tissue are likely to describe several different configurations for this distal end.

To visualize the dates in which patents have been published and their respective strategy, Figure 19 has been

made. Striking from this figure, is the fact that only one patent has been published in the 1940's, with at least 20 years of no publications until the 1970's.

Furthermore, a very clear peak is visible in the years 2000 to 2009. Further dissecting this peak and the years around it shows the following trends: In the 1990's, 70% of the patents were published in the second half, e.g. 1995-1999. In the 2000's, 60% of the patents were published in the first half, e.g. 2000-2004. The years 1995-1999 contain almost as much patents as 2005-2009. This indicates that this perceived peak is strongest in the first half of the 2000's. Several different causes could explain this peak of published patents. The temporarily increased attention to minimally invasive cancellous bone biopsy could be the result of advances in medicine or technology in other fields, political influences, or it could just be a coincidence.

Another trend seen in Figure 19 concerns instruments which do not rotate, and specifically those requiring a hole present in the cortical bone. Patents describing these instruments are almost solely published in the years 2000 to 2010. This could be a contributing factor of the peak visible in these same years. However, it could also be a product of the same causes which led to this peak in the first place.

Lastly, a slight trend begins to form after 2010. Patents describing instruments designed to rotate are significantly more patented after 2010 than instruments which are not specifically prescribed to rotate, while in the three decades prior, the focus seems more on non-rotating instruments. However, the numbers compared here are so small, that deducing anything tangible on this basis would be unwise.

C. Main findings regarding severing sample

Of the 49 patents relating to cancellous bone needle biopsy instruments, about half describe an instrument using a radially shearing force in order to sever the sample from the surrounding tissue. As with the non-rotating strategies of the previous section, almost all the patents in the *radial shear* category employ the usual strategy of moving the distal end of the needle sideways in order to sever the distal end of the sample. With a few exceptions, this category also contains the patents which do not specify how their instrument severs the sample from the surrounding tissue or enhances the instrument's sample retention capabilities. These last patents are generally the patents focusing primarily on the penetration strategy. It is no coincidence that the light blue in Figure 20 slightly corresponds with the green colours in Figure 19. Specifically, of the 16 patents classified as rotating in a single direction, 11 also use radial shear.

Thirteen patents describe an instrument which moves or deforms the inner cannula with respect to the outer cannula when it is inserted all the way and reached the sample. Both strategies are employed by a few patents to engage a shape grip. However, it is observed that the instruments which move their inner cannula inside the outer cannula for a sample severing strategy, use this technique by rotating the inner cannula inside the outer cannula. These instruments therefore use tangential force and no radial force strategies. In contrast, the patents proposing a deforming inner cannula all move in the axial direction to perform. These instruments therefore use radial force and no tangential force strategies.

Of the six patents which rotate their inner cannula within the outer cannula, two rotate to create a new shape which grips the sample better than they would without moving [11], [30]. Two others rotate axially, gripping the sample with this motion and tangentially shearing it off from the surrounding tissue [28], [59]. The last two use the cutting tooth located at their distal end to tangentially cut the sample from the surrounding tissue [35], [36].

Of the patents describing instruments which deform their inner cannula, two deform their inner cannula to push it into the sample, creating a greatly enhanced shape grip [13], [54]. The other five deform their inner cannula to form an edge which cuts the distal end of the sample off from surrounding tissue, performing a radial cutting function [26], [27], [34], [52], [57]. A downside of cutting through the sample, is that several of these instruments can not cut at the far end of the sample, effectively leaving the end of the sample behind. This slightly shortens the sample in comparison to other methods, which already is a problem in some cases, as presented in the problem definition.

Furthermore, most of these deforming instruments damage the sample in some way or other. Some by slightly crushing it from the sides and some damaging the locations at which the teeth or edges cut into the sample. It should therefore be considered to which extent a higher chance of a successful extraction of the sample excuses the lower value of the sample itself.

As with the strategies for penetrating the bone, the strategies for severing the sample have been presented with regards to their publication date in Figure 20. As with Figure 19, a very clear peak is visible in the 2000's. However, even more interesting is the clustering of three very different strategies in this single decade. Specifically, the eight patents classified as friction grip, tangential shear and tangential cutting are all published in the six years from 2000 to 2005. This might seem a high number, but three of these patents share at least one inventor with another of these eight. The number of unique projects we are looking at is therefore reduced to five, which could well mean a coincidence to be published within six years. However, as discussed before, there could also be other unknown factors at work which influence the amount of patents published in this relatively short time span.

D. Limitations and recommendations

This review attempts to include all relevant patents regarding cancellous bone biopsy instruments. However, limiting the search to a query in the Espacenet database limited the amount of results obtained. During the investigation of the results, it was found that several of the patents in the Espacenet database lacked a digitized abstract. Therefore, these patents were automatically excluded when they did not include the queried terms in their title. It was found that the patents therefore omitted were mostly older patents, which could help explain the lack of included patents before 1970.

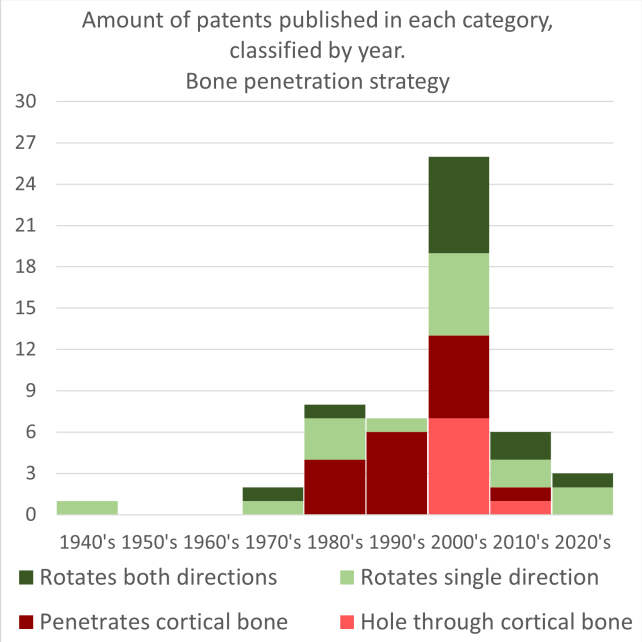


Figure 19: As seen in Table I, some patents have been classified in multiple categories, explaining why the total amount of patents presented in this figure exceeds 49.

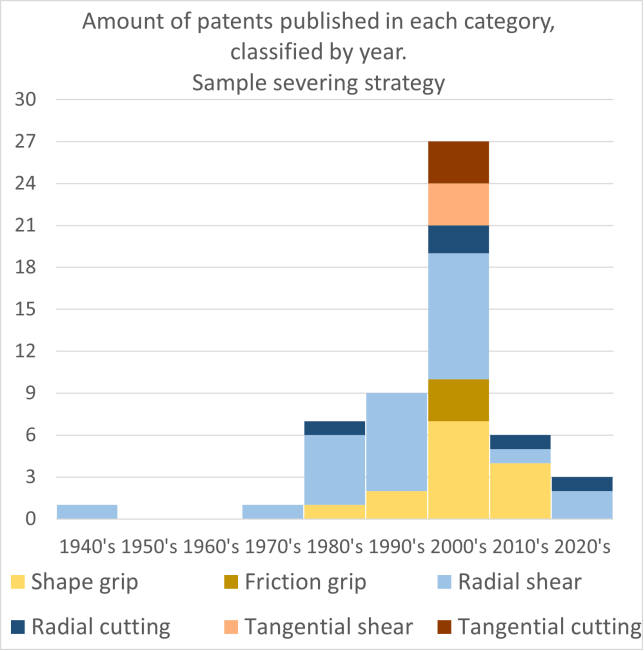


Figure 20: kleuren rood en nog wat ipv groen en blauw. vn beide figuren lettertype wat groter

This issue was not observed in more recent patents, indicating that recent innovations were more completely analyzed in this review. Nonetheless, patents using unconventional terminology could still have been wrongfully excluded.

The next exclusion step concerned a superficial check and full-text screening of the patents to estimate their relevance. Personal biases and mistakes could have lead to excluding patents which arguably could have been included.

It was found that a sizable amount of patents have been excluded because of limiting the language to English only. Of the patents excluded because of their language, only 8% have been published outside of Asia, these were published in German. 67% were published in Chinese. Of these Chinese patents, 78% were published after 2010, indicating the medical industry being a growing one, which soon should not be ignored.

This review only considers patent literature. Academic literature comparing different cancellous bone biopsy instruments with respect to efficiency of sample collection or patient discomfort have only been found sparingly. The articles found have thus only been superficially examined to substantiate findings regarding the patents. Therefore, along with the recommendation to further analyze published academic literature with respect to cancellous bone biopsy instruments, it is recommended to publish research with the aim of more broadly analyzing different biopsy instruments with more generalized comparative regards.

It is also recommended to research the designs not yet discussed in published literature. Also deserving research would be an in-depth study in these different types of instruments and examining a combination of instruments focused on bone penetration compared to instruments focused on severing the sample. This patent review indicates research gaps present in the field of cancellous bone biopsy instruments and may provide inspiration on which strategies should be used jointly to generate more effective designs.

V. Conclusion

This patent literature review provides an analysis on cancellous bone biopsy instruments. The goal was to provide a comprehensive overview of the patent literature, using a strategy classification approach to categorize the various patents.

To find the relevant patents, a search has been conducted in the Espacenet database using search terms and the CPC categories. This search has led to 52 relevant patents. The patents were categorized according to three divisions. 1) which main sampling strategy is used. 2) which strategy is used to penetrate the bone with the instrument. 3) which strategy is used to sever the sample from the surrounding bone and extract it.

Of the first division, two main sampling strategies were found. The amount of patents describing an instrument using a cannula to extract a sample from the existing bone was so much larger, that this strategy was used for the subsequent two divisions. Four different strategies were classified in the second division, concerning penetrating the bone with the instrument. The main differences were

discovered between the instruments which were designed to rotate and those which were not. More variation was found in the third division, between the strategies concerning how to extract the sample. These strategies were classified according to how a force was applied to the sample before or while extracting it from the patient.

While comparing the strategies to one another, it was found that most patents share at least the penetrating bone strategy or the severing sample strategy with the golden standard. However, only 25 percent of the patents propose both of these strategies, meaning that at least 75 percent of the patents propose a design which could be used to provide inspiration for new designs or guide further research in this field.

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