



(51) International Patent Classification:

A61K 8/98 (2006.01) A61K 35/19 (2015.01)
A61K 8/73 (2006.01) A61P 15/00 (2006.01)
A61K 31/728 (2006.01)

(21) International Application Number:

PCT/CA2024/050013

(22) International Filing Date:

05 January 2024 (05.01.2024)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

3214418 27 September 2023 (27.09.2023) CA

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(81) Designated States (unless otherwise indicated, for every

kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CV, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IQ, IR, IS, IT, JM, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, MG, MK, MN, MU, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every

kind of regional protection available): ARIPO (BW, CV, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SC, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, ME, MK, MT, NL, NO, PL, PT, RO, RS, SE,

(54) Title: **HYALURONIC ACID AND PLATELET RICH PLASMA COMBINATION FOR USE IN METHOD FOR PENILE ENHANCEMENT**

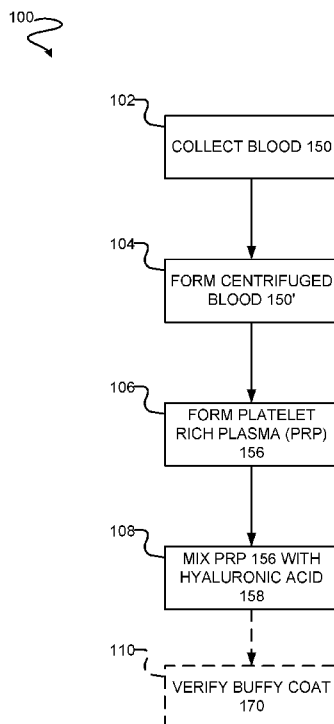


FIG. 1

(57) Abstract: Herein is disclosed a composition and use of said composition in a method for penile enhancement; the composition comprising hyaluronic acid and platelet rich plasma, wherein the hyaluronic acid and the platelet rich plasma are present in the composition in a ratio of about 1:2.

SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN,
GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

HYALURONIC ACID AND PLATELET RICH PLASMA COMBINATION FOR USE IN METHOD FOR PENILE ENHANCEMENT

Cross-Reference to Related Applications

[0001] This application claims priority from Canadian application No. 3214418, filed 27 September 2023. For purposes of the United States, this application claims the benefit under 35 U.S.C. §119 of Canadian application No. 3214418, filed 27 September 2023, and entitled CHEMICAL COMPOSITION AND METHOD FOR PENILE ENHANCEMENT which is hereby incorporated herein by reference for all purposes.

Technical Field

[0002] The present disclosure is directed to chemical compositions suitable for injection into individuals, and methods for preparation and use thereof. More particularly, the present disclosure is directed to chemical compositions and methods for preparation and use thereof for enhancement of an individual's penis.

Background

[0003] The size of an individual's penis and/or the firmness of the individual's penis when erect may affect the individual's sexual health and/or sexual fulfillment. Various factors may negatively impact an individual's penis size and/or a firmness of their erection, for example one or more of genetic disposition, age, and health. Furthermore, many individuals may be unhappy with their natural penis size and/or the firmness of their erection. As such, many individuals desire enhancement of their penis size and/or the firmness of their erection.

[0004] Hyaluronic acid is a glycosaminoglycan sugar found throughout the human body. In skin, hyaluronic acid is a primary component of the extracellular matrix that provides hydration, volume, and supports tissue restructuring and cell regeneration. In part due to these properties, hyaluronic acid is commonly used as an injectable intra-dermal or sub-dermal volumizer.

[0005] Hyaluronic acid is particularly effective and popular as a filler for smaller and/or sensitive body parts, for example lips, cheeks, and penises. When injected sub-dermally into an individual's tissue, hyaluronic acid has a half-life of between 17 and 36 hours. As

such, the half-life of pure hyaluronic acid is too short to be practical as a cosmetic injectable.

[0006] For use as a cosmetic injectable, hyaluronic acid is commonly crosslinked with butanediol diglycidyl ether, which can extend the half-life of hyaluronic acid injected into tissue to up to 6 months.

[0007] Hyaluronic acid can be degraded by the enzyme hyaluronidase, where hyaluronidase will break apart hyaluronic acid within minutes of exposure. As such, hyaluronidase can be effectively used to remove injected hyaluronic acid and reverse the volumizing from injected hyaluronic acid.

[0008] Given the above properties of hyaluronic acid, hyaluronic acid can be injected into an individual to increase the size of body parts such as an individual's penis. Hyaluronic acid can be injected into an individual's penis to increase a size of the individual's penis both when flaccid and when erect. Increasing the size of an individual's erect penis may also increase the firmness of the individual's erection.

[0009] The usefulness of hyaluronic acid is limited by its half-life. The short half-life of hyaluronic acid, even when crosslinked with butanediol diglycidyl ether, necessitates regular injections to maintain the volume created by the hyaluronic acid. Frequent injections of hyaluronic acid increases the amount of recovery time and increases the risk of complications like infections. As such, the use of hyaluronic acid to increase the size of an individual's penis is limited, and many individuals may not be suitable for treatment of their penis with hyaluronic acid due to the requirement for frequent injections.

[0010] There is a general desire for an improved chemical composition suitable for increasing the volume of injected tissue with a longer half-life than prior art chemical compositions. In particular, there is a general desire for an improved chemical composition suitable for increasing the size of an individual's penis.

[0011] The foregoing examples of the related art and limitations related thereto are intended to be illustrative and not exclusive. Other limitations of the related art will become apparent to those of skill in the art upon a reading of the specification and a study of the drawings.

Summary

[0012] Further aspects and example embodiments are illustrated in the accompanying drawings and/or described in the following description.

[0013] One aspect of the invention provides a chemical composition comprising hyaluronic acid and platelet rich plasma, wherein the hyaluronic acid and the platelet rich plasma are present in the chemical composition in a ratio of about 1:2.

[0014] In one or more embodiments:

- the hyaluronic acid and the platelet rich plasma are present in the chemical composition in a ratio of between 1:1.9 and 1:2.1;
- the chemical composition further comprises a local anesthetic;
- the local anesthetic comprises less than 1% of the chemical composition on a weight/weight basis; and/or
- the local anesthetic is selected from the group consisting of lidocaine and xylocaine.

[0015] A further aspect of the invention provides a method for forming the chemical composition as disclosed herein, the method comprising: collecting a volume of blood comprising plasma, platelets, and red blood cells from an individual; separating the plasma and the platelets from the red blood cells, thereby forming a platelet rich plasma; collecting the platelet rich plasma; and mixing the platelet rich plasma with hyaluronic acid, thereby forming the chemical composition.

[0016] In one or more embodiments:

- the volume of blood is collected from one or more of: the cephalic vein of the individual, the basilica vein of the individual, and the median cubital vein of the individual;
- the platelet rich plasma and the hyaluronic acid are mixed in a ratio of between 1:1.9 and 1:2.1; and/or
- the platelet rich plasma is collected by using a WorldPRP™ kit.

[0017] A further aspect of the invention provides a method for enhancing a size of a penis of an individual, the method comprising injecting a volume of the chemical composition as disclosed herein into a shaft of the penis.

[0018] In one or more embodiments:

- injecting the volume of the chemical composition into the shaft of the penis comprises injecting a first portion of the volume of the chemical composition into a dorsal side of the shaft of the penis proximate a base of the penis;
- injecting the volume of the chemical composition into the shaft of the penis comprises injecting a second portion of the volume of the chemical composition and a third portion of the volume of the chemical composition into the shaft of the penis at opposing sides of a hilum of the penis;
- injecting the volume of the chemical composition into the shaft of the penis comprises injecting a fourth portion of the volume of the chemical composition into the dorsal side of the shaft of the penis generally mid-way between the base of the penis and a tip of the penis, wherein the tip of the penis opposes the base of the penis; and/or
- injecting the volume of the chemical composition into the shaft of the penis comprises injecting the chemical composition between a skin of the penis and a corpus cavernosum of the shaft of the penis.

[0019] Some embodiments of the present invention may comprise massaging the shaft of the penis thereby spreading the volume of the chemical composition injected into the shaft of the penis around and along the shaft of the penis.

[0020] Some embodiments of the present invention may comprise injecting a volume of hyaluronic acid into a glans of the penis. Injecting the volume of hyaluronic acid into the glans may comprise injecting a corona of the glans with multiple injections of hyaluronic acid spaced circumferentially around the glans.

[0021] In some embodiment of the present invention, the volume of the chemical composition injected into a penis is between 70 and 72 milliliters, and the volume of hyaluronic acid injected into a glans of the penis is between 9 and 10 milliliters.

[0022] One aspect of the invention provides a method for enhancing a size of a penis of an individual, the method comprising: forming a chemical composition comprising hyaluronic acid and platelet rich plasma, wherein the hyaluronic acid and the platelet rich plasma are present in the chemical composition in a ratio of about 1:2; injecting a first portion of the chemical composition into a dorsal side of the shaft of the penis proximate a base of the penis; injecting a second portion of the chemical composition and a third portion of the

chemical composition into the shaft of the penis at opposing sides of a hilum of the penis; injecting a fourth portion of the chemical composition into the dorsal side of the shaft of the penis generally mid-way between the base of the penis and a tip of the penis, wherein the tip of the penis opposes the base of the penis; massaging the shaft of the penis thereby spreading the first, second, third and fourth portions the chemical composition injected into the shaft of the penis around and along the shaft of the penis; and injecting a corona of the glans of the penis with multiple injections of hyaluronic acid spaced circumferentially around the glans; wherein the first, second, third and fourth portions of the chemical composition injected into the shaft of the penis are together equal to between 70 and 72 milliliters of the chemical composition, and the volume of hyaluronic acid injected into the corona of the glans of the penis is between 9 and 10 milliliters of hyaluronic acid.

[0023] In addition to the exemplary aspects and embodiments described above, further aspects and embodiments will become apparent by reference to the drawings and by study of the following detailed descriptions.

Brief Description of the Drawings

[0024] The accompanying drawings illustrate non-limiting example embodiments of the invention.

[0025] Fig. 1 is a block diagram of a method for preparing a chemical composition in accordance with an embodiment of the present invention.

[0026] Fig. 2A is a block diagram of a method for applying the chemical composition formed in accordance with the method depicted in fig. 1 to a penis.

[0027] Fig. 2B is a schematic diagram of a penis.

Description

[0028] Throughout the following description, specific details are set forth in order to provide a more thorough understanding of the invention. However, the invention may be practiced without these particulars. In other instances, well known elements have not been shown or described in detail to avoid unnecessarily obscuring the invention. Accordingly, the specification and drawings are to be regarded in an illustrative, rather than a restrictive sense.

Chemical Composition

[0029] Human blood comprises, among other things, red blood cells, white blood cells, and platelets, all of which are suspended in liquid plasma. Platelets are cell fragments that perform various functions in the human body directed to healing and growing. In addition to stopping bleeding by clumping together to form blood clots, platelets contain growth factors that can trigger cell reproduction and stimulate tissue regeneration and/or healing. As such, platelets are a critical part of the human body's ability to heal itself.

[0030] Human blood can be processed to remove a portion of the plasma containing a concentrated portion of the non-platelet material, thereby concentrating the platelets within the remaining plasma and forming platelet rich plasma (PRP). PRP can be used in an individual by collecting blood from the individual, processing the collected blood to form PRP, and injecting the PRP into the individual.

[0031] PRP injections are used for a range of conditions including reducing musculoskeletal pain, recovering from injuries, increasing hair growth, and cosmetic procedures. Because PRP is extracted from the individual's blood, the risk of complications from using PRP are substantially lower than use of other products not originating from the individual.

[0032] Hyaluronic acid is commonly used as an injectable intra-dermal or sub-dermal volumizer to increase the size of injected tissue. However, the half-life of hyaluronic acid limits the usefulness of hyaluronic acid, as frequent injections of hyaluronic acid are required to maintain the volume created from the hyaluronic acid.

[0033] By mixing hyaluronic acid with platelet rich plasma (PRP), the half-life of the hyaluronic acid, and accordingly its usefulness in increasing the size of injected tissue, can be substantially increased. A chemical composition comprising hyaluronic acid and platelet rich plasma, wherein the hyaluronic acid and the platelet rich plasma are present in the chemical composition in a ratio of about 1:2, is particularly effective in increasing the size of injected tissue for an extended period.

[0034] When hyaluronic acid is combined with PRP in a molecular-weight ratio of about 1:2, the hyaluronic acid and platelets form a platelet-rich gel matrix (PRGM). When PRGM is injected into an individual's tissue, the hyaluronic acid within the PRGM acts as a filler, thereby volumizing the tissue. Additionally, the growth factors of the platelets within the

PRGM attach to the injected tissue and stimulate production of collagen and fibrillin within the tissue.

[0035] The additional collagen and fibrillin within the tissue extend the half-life of injected PRGM compared to injected hyaluronic acid alone. The noticeable volume created by injected PRGM can last up to between three-years and four-years after injection.

[0036] The combination of PRP and hyaluronic acid to form PRGM does not affect the efficacy of the enzyme hyaluronidase in degrading the hyaluronic acid within PRGM. As such, hyaluronidase can be injected into tissue containing PRGM to breakdown the hyaluronic acid within the PRGM, thereby undoing the volume created by the injected PRGM.

[0037] Given its longer-lasting effect, lower-risk of complications, and reversibility, PRGM is particularly well suited as a volumizer for smaller and/or sensitive body parts, for example lips, cheeks, and penises.

Preparation

[0038] Fig. 1 depicts method 100 for forming PRGM for injection into an individual. Method 100 comprises:

- step 102: collecting volume of blood 150 from the individual;
- step 104: spinning blood 150 in a centrifuge to form centrifuged blood 150', where centrifuged blood 150' comprises a platelet dense portion 152 and a platelet sparse portion 154;
- step 106: separating platelet dense portion 152 from platelet sparse portion 152 to form platelet rich plasma 156;
- step 108: mixing a volume of hyaluronic acid 158 with platelet rich plasma 156 in a molecular-weight ratio of about 1:2 to form PRGM 160.

[0039] In one or more embodiments of method 100:

- step 102 comprises collecting about 20 milliliters of blood from the individual;
- step 102 comprises collecting volume of blood 150 from one or more of: a cephalic vein of the individual, a basilic vein of the individual, and a median cubital vein of the individual;

- step 104 comprises spinning blood 150 in the centrifuge for at least three minutes to form centrifuged blood 150';
- step 106 comprises separating 14 milliliters of platelet dense portion 152 from 6 milliliters of platelet sparse portion 154 to form 14 milliliters of platelet rich plasma 156;
- step 106 comprises separating platelet dense portion 152 from platelet sparse portion 154 by collecting platelet dense portion 152 from centrifuged blood 150' with a syringe;
- step 108 comprises mixing volume of hyaluronic acid 158 with platelet rich plasma 156 by:
 - drawing platelet rich plasma 156 into a first syringe;
 - drawing volume of hyaluronic acid 158 into a second syringe;
 - fluidly connecting the first syringe to the second syringe with a female-to-female connector; and
 - mixing volume of hyaluronic acid 158 with platelet rich plasma 156 by agitating the connected first syringe and second syringe for 30 seconds;
- volume of hyaluronic acid 158 comprises high-molecular-weight hyaluronic acid with a molecular weight of 22 milligrams per milliliter; and/or
- volume of hyaluronic acid 158 comprises 8 milliliters of hyaluronic acid and platelet dense portion 152 comprises between 12 and 13 millimeters of centrifuged blood 150'.

[0040] In some embodiments of method 100, hyaluronic acid 158 comprises a mixture of hyaluronic acid and an anesthetic, for example lidocaine. When injected into tissue, lidocaine acts as a local anesthetic, thereby reducing local discomfort to the tissue. As such, the lidocaine in hyaluronic acid 158 is present within PRGM 160, and thereby reduces discomfort in an individual when PRGM 160 is injected into the individual. In some embodiments, the lidocaine comprises 0.3% lidocaine.

[0041] Some embodiments of method 100 further comprise step 110, verifying buffy coat 170 of centrifuged blood 150'. When a volume of blood is centrifuged, the volume of blood generally separates into three portions:

- a first portion denser in plasma than the other two portions;

- a second portion denser in white blood cells and platelets than the other two portions; and
- a third portion denser in red blood cells than the other two portions.

[0042] The second portion of centrifuged blood, that portion denser in white blood cells and platelets than the other two portions of the centrifuged blood, is known as the buffy coat.

[0043] Step 110 comprises verifying buffy coat 170 of centrifuged blood 150' to confirm that buffy coat 170 contains at least a threshold density of platelets. The threshold density of platelets within buffy coat 170 indicates a threshold level of separation between the three portions required to form PRGM 160 by performing method 100.

Application to Human Penis

[0044] One application of PRGM, for example as prepared in accordance with method 100, as is as a filler for an individual's penis. PRGM may be injected into a human penis to increase the volume of the penis both when flaccid and when erect. The hyaluronic acid within PRGM acts as a volumizer, filling and expanding the penis tissue. The growth factors of the PRP within the PRGM attach to the penis tissue and stimulate production of collagen and fibrillin within the penis tissue. The additional collagen and fibrillin within the penis tissue further volumize the penis tissue. The additional collagen and fibrillin with the penis tissue may also extend the have-life of hyaluronic acid within PRGM.

[0045] Fig. 2A is a block diagram of method 200 for applying PRGM, for example PRGM 160 as prepared in accordance with method 100, to penis 250 of an individual. Fig. 2B is a schematic diagram of penis 250.

[0046] Penis 250 has proximal base 252A and distal tip 252B opposing base 252A. Penis 250 comprises hilum 254 at base 252A, shaft 256 extending from base 252A to tip 252B, and glans 258 at tip 252B. Glans 258 comprises corona 260 extending around shaft 256 at an end of glans 258 opposing tip 252B. Penis 250 has dorsal side 262A and ventral side 262B opposing dorsal side 262A.

[0047] Method 200 comprises:

- step 202, anesthetizing penis 250, for example by one or more of:
 - applying an anesthetic paste to corona 260, for example a paste comprising 2% xylocaine;

- injecting shaft 256 near base 252A with an anesthetic, for example 0.3 milliliters of a solution of 2% xylocaine and 1:100,000 parts epinephrine;
- injecting dorsal side 262A of shaft 256 with an anesthetic, for example 0.4 milliliters of a solution of 2% xylocaine and 1:100,000 parts epinephrine; and
- injecting opposing sides of hilum 254 with an anesthetic, for example 0.3 milliliters of a solution of 2% xylocaine and 1:100,000 parts epinephrine;
- step 204, injecting a first volume of PRGM into dorsal side 262A of shaft 256 proximate base 252A, thereby filling a first volume of shaft 256 with the first volume of PRGM;
- step 206, injecting a second volume of PRGM and a third volume of PRGM into shaft 256 at opposing sides of hilum 254, thereby filling second and third volumes of shaft 256 with second and third volumes of PRGM;
- step 208, injecting a fourth volume of PRGM into dorsal side 262A of shaft 256 generally mid-way between base 252A and tip 252B of shaft 256, thereby filling a fourth volume of shaft 256 proximate to glans 258 with the fourth volume of PRGM; and
- step 210, blending the fourth volume of PRGM filling the fourth volume of shaft 256 proximate to glans 258, for example by massaging the fourth volume of shaft 256 around glans 258.

[0048] The PRGM is injected into shaft 256 beneath a skin of shaft 256 and above a corpus cavernosum of shaft 256.

[0049] Some embodiments of method 200 may further comprise step 212, injecting hyaluronic acid into corona 260, sub-dermally into corona 260 and above an erectile tissue of glans 258. In some embodiments of step 212, corona 260 is injected with multiple injections each of 0.3 milliliters of hyaluronic acid, spaced circumferentially around corona 260. The multiple injections may together inject corona 260 with up to 10 milliliters of hyaluronic acid, for example between 9 and 10 milliliters of hyaluronic acid. In some embodiments, step 212 comprises injecting corona 260 with between 9 milliliters and 10 milliliters of hyaluronic acid. The hyaluronic acid may comprise a hyaluronic acid solution.

[0050] The hyaluronic acid injected into corona 260 may comprise hyaluronic acid with a density of between 20 milligrams per milliliter and 25 milligrams per milliliter. In some

embodiments, the hyaluronic acid may be pre-mixed with a solution of 0.3% lidocaine. The hyaluronic acid may be injected into corona 260 using a needle between 25-gauge and 29-gauge, for example a 27-gauge needle.

[0051] Some embodiments of method 200 may further comprise one or more of:

- step 214, positioning penis 250 and the individual having penis 250, for example positioning the individual supine and penis 250 flaccid;
- step 216, cleansing penis 250 and an area of the individual proximate to penis 250, for example cleansing one or more of penis 250, a mons pubis, a scrotum, and one or more inner thighs of the individual with an antibacterial solution such as 2% chlorhexidine, prior to one or more of steps 202 to 210;
- step 218, circumferentially massaging shaft 256 to smoothly blend the first, second, third and fourth volumes of PRGM injected into shaft 256 around and/or along shaft 256;
- step 220, cleansing penis 250 and the area of the individual proximate to penis 250, for example cleansing one or more of penis 250, a mons pubis, a scrotum, and one or more inner thighs of the individual with an antibacterial solution such as 2% chlorhexidine, following one or more of steps 202 to 210 and 218;
- step 222, applying a topical post injection serum to penis 250 following one or more of steps 202 to 210, 218 and 220;
- step 224, wrapping penis 250 with loose gauze and/or positioning penis 250 as close to straight as possible following one or more of steps 202 to 210 and steps 218 to 222; and/or
- step 226, gently massaging penis 250 up to three times a day and applying a topical post injection serum to penis 250 once per day, each day for seven days following steps 202 to 210.

Some Embodiments

[0052] In some embodiments:

- the ratio of hyaluronic acid and platelet rich plasma in PRGM is between 1:1.9 and 1:2.1;
- the local anesthetic in PRGM comprises less than 1% of the PRGM on a weight/weight basis;

- the PRP is generated using a WorldPRP™ kit, for example an hourglass WorldPRP™ kit;
- method 200 is performed on an individual and completed within 10 minutes of completing method 100;
- method 200 comprises injecting at least 70 milliliters of PRGM into an individual's penis, for example between 70 and 72 milliliters of PRGM;
- method 200 comprises forming one or more injection sites in penis 250 with a 20-gauge trocar;
- method 200 comprises injecting PRGM into an individual's penis with a 22-gauge, 6 centimeter cannula;
- method 200 is performed a first-time on an individual, and a second-time on the individual between one and three weeks after the first-time method 200 is performed on the individual; and/or
- the amount of PRGM injected in method 200 depends in part on one or both of: the existing size of the individual's penis, and the desired final size of the individual's penis.

Interpretation of Terms

[0053] Unless the context clearly requires otherwise, throughout the description and the claims:

- “comprise”, “comprising”, and the like are to be construed in an inclusive sense, as opposed to an exclusive or exhaustive sense; that is to say, in the sense of “including, but not limited to”;
- “connected”, “coupled”, or any variant thereof, means any connection or coupling, either direct or indirect, between two or more elements; the coupling or connection between the elements can be physical, logical, or a combination thereof;
- “herein”, “above”, “below”, and words of similar import, when used to describe this specification, shall refer to this specification as a whole, and not to any particular portions of this specification;
- “or”, in reference to a list of two or more items, covers all of the following interpretations of the word: any of the items in the list, all of the items in the list, and any combination of the items in the list;

- the singular forms “a”, “an”, and “the” also include the meaning of any appropriate plural forms.

[0054] Words that indicate directions such as “vertical”, “transverse”, “horizontal”, “upward”, “downward”, “forward”, “backward”, “inward”, “outward”, “vertical”, “transverse”, “left”, “right”, “front”, “back”, “top”, “bottom”, “below”, “above”, “under”, and the like, used in this description and any accompanying claims (where present), depend on the specific orientation of the apparatus described and illustrated. The subject matter described herein may assume various alternative orientations. Accordingly, these directional terms are not strictly defined and should not be interpreted narrowly.

[0055] For example, while processes or blocks are presented in a given order, alternative examples may perform routines having steps, or employ systems having blocks, in a different order, and some processes or blocks may be deleted, moved, added, subdivided, combined, and/or modified to provide alternative or subcombinations. Each of these processes or blocks may be implemented in a variety of different ways. Also, while processes or blocks are at times shown as being performed in series, these processes or blocks may instead be performed in parallel, or may be performed at different times.

[0056] In addition, while elements are at times shown as being performed sequentially, they may instead be performed simultaneously or in different sequences. It is therefore intended that the following claims are interpreted to include all such variations as are within their intended scope.

[0057] Where a feature (e.g. an anesthetic, needle, trocar, antibacterial agent, etc.) is referred to above, unless otherwise indicated, reference to that feature (including a reference to a “means”) should be interpreted as including as equivalents of that feature any feature which performs the function of the described feature (i.e., that is functionally equivalent), including features which are not structurally equivalent to the disclosed structure which performs the function in the illustrated exemplary embodiments of the invention.

[0058] Various features are described herein as being present in “some embodiments”. Such features are not mandatory and may not be present in all embodiments. Embodiments of the invention may include zero, any one or any combination of two or more of such features. This is limited only to the extent that certain ones of such features are

incompatible with other ones of such features in the sense that it would be impossible for a person of ordinary skill in the art to construct a practical embodiment that combines such incompatible features. Consequently, the description that “some embodiments” possess feature A and “some embodiments” possess feature B should be interpreted as an express indication that the inventors also contemplate embodiments which combine features A and B (unless the description states otherwise or features A and B are fundamentally incompatible).

[0059] It is therefore intended that the following appended claims and claims hereafter introduced are interpreted to include all such modifications, permutations, additions, omissions, and sub-combinations as may reasonably be inferred. The scope of the claims should not be limited by the preferred embodiments set forth in the examples, but should be given the broadest interpretation consistent with the description as a whole.

Claims

1. A chemical composition comprising hyaluronic acid and platelet rich plasma, wherein the hyaluronic acid and the platelet rich plasma are present in the chemical composition in a ratio of about 1:2.
2. The chemical composition of claim 1, wherein the hyaluronic acid and the platelet rich plasma are present in the chemical composition in a ratio of between 1:1.9 and 1:2.1.
3. The chemical composition of either of claims 1 and 2, further comprising a local anesthetic.
4. The chemical composition of claim 3, wherein the local anesthetic comprises less than 1% of the chemical composition on a weight/weight basis.
5. The chemical composition of either of claims 3 and 4, wherein the local anesthetic is selected from the group consisting of lidocaine and xylocaine.
6. A method for forming the chemical composition of any one of claims 1 to 5, the method comprising:
 - collecting a volume of blood comprising plasma, platelets, and red blood cells from an individual;
 - separating the plasma and the platelets from the red blood cells, thereby forming a platelet rich plasma;
 - collecting the platelet rich plasma; and
 - mixing the platelet rich plasma with hyaluronic acid, thereby forming the chemical composition.
7. The method of claim 6, wherein the volume of blood is collected from one or more of: the cephalic vein of the individual, the basilica vein of the individual, and the median cubital vein of the individual.

8. The method of either of claims 6 and 7, wherein the platelet rich plasma and the hyaluronic acid are mixed in a ratio of between 1:1.9 and 1:2.1.
9. The method of any one of claims 6 to 8, wherein the platelet rich plasma is collected by using a WorldPRP™ kit.
10. The method of claim 9, wherein the kit is an hourglass kit.
11. A method for enhancing a size of a penis of an individual, the method comprising injecting a volume of the chemical composition as claimed in any one of claims 1 to 5 into a shaft of the penis.
12. The method of claim 11 wherein injecting the volume of the chemical composition into the shaft of the penis comprises injecting a first portion of the volume of the chemical composition into a dorsal side of the shaft of the penis proximate a base of the penis.
13. The method of either of claims 11 and 12, wherein injecting the volume of the chemical composition into the shaft of the penis comprises injecting a second portion of the volume of the chemical composition and a third portion of the volume of the chemical composition into the shaft of the penis at opposing sides of a hilum of the penis.
14. The method of any one of claims 11 to 13, wherein injecting the volume of the chemical composition into the shaft of the penis comprises injecting a fourth portion of the volume of the chemical composition into the dorsal side of the shaft of the penis generally mid-way between the base of the penis and a tip of the penis, wherein the tip of the penis opposes the base of the penis.
15. The method of any one of claims 11 to 14, wherein injecting the volume of the chemical composition into the shaft of the penis comprises injecting the chemical

composition between a skin of the penis and a corpus cavernosum of the shaft of the penis.

16. The method of any one of claims 11 to 15, further comprising massaging the shaft of the penis thereby spreading the volume of the chemical composition injected into the shaft of the penis around and along the shaft of the penis.
17. The method of any one of claims 11 to 16, further comprising injecting a volume of hyaluronic acid into a glans of the penis.
18. The method of claim 17, wherein injecting the volume of hyaluronic acid into the glans comprises injecting a corona of the glans with multiple injections of hyaluronic acid spaced circumferentially around the glans.
19. The method of either of claims 17 and 18, wherein the volume of the chemical composition injected into the penis is between 70 and 72 milliliters, and the volume of hyaluronic acid injected into the glans is between 9 and 10 milliliters.
20. A method for enhancing a size of a penis of an individual, the method comprising:
 - forming the chemical composition in accordance with any one of claims 6 to 10, wherein the volume of blood is collected from the individual;
 - injecting a first portion of the chemical composition into a dorsal side of a shaft of the penis proximate a base of the penis;
 - injecting a second portion of the chemical composition and a third portion of the chemical composition into the shaft of the penis at opposing sides of a hilum of the penis;
 - injecting a fourth portion of the chemical composition into the dorsal side of the shaft of the penis generally mid-way between the base of the penis and a tip of the penis, wherein the tip of the penis opposes the base of the penis;
 - massaging the shaft of the penis thereby spreading the first, second, third and fourth portions of the chemical composition injected into the shaft of the penis around and along the shaft of the penis; and

injecting a corona of a glans of the penis with multiple injections of hyaluronic acid spaced circumferentially around the glans;

wherein the first, second, third and fourth portions of the chemical composition injected into the shaft of the penis are together equal to between 70 and 72 milliliters of the chemical composition, and the volume of hyaluronic acid injected into the corona of the glans of the penis is between 9 and 10 milliliters.

1/3

100

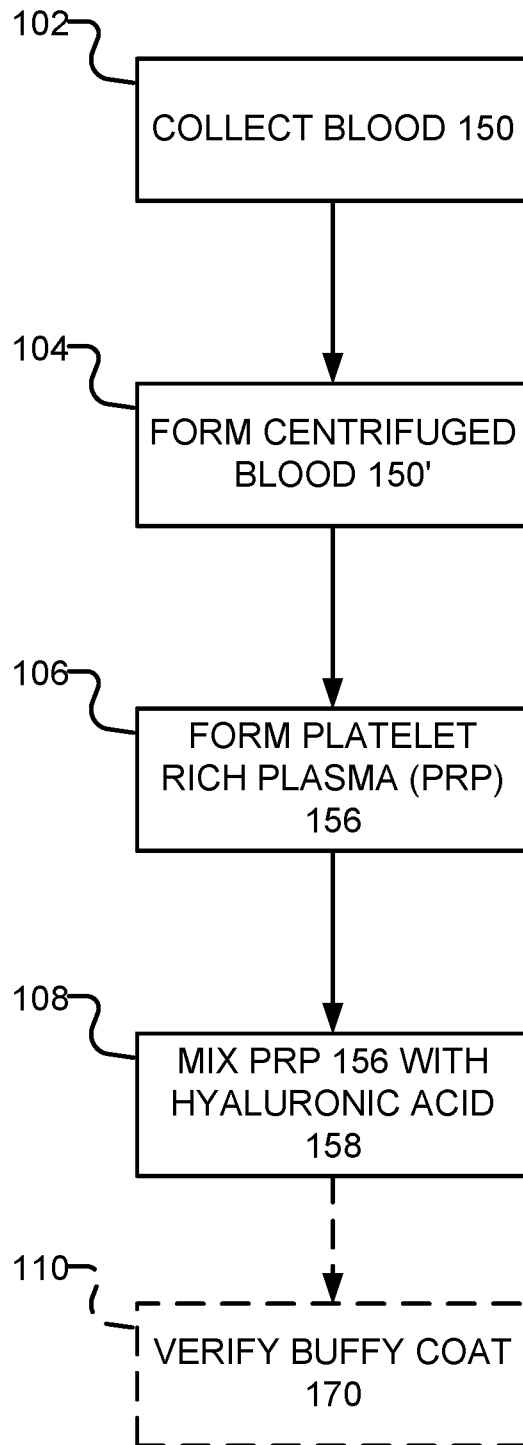


FIG. 1

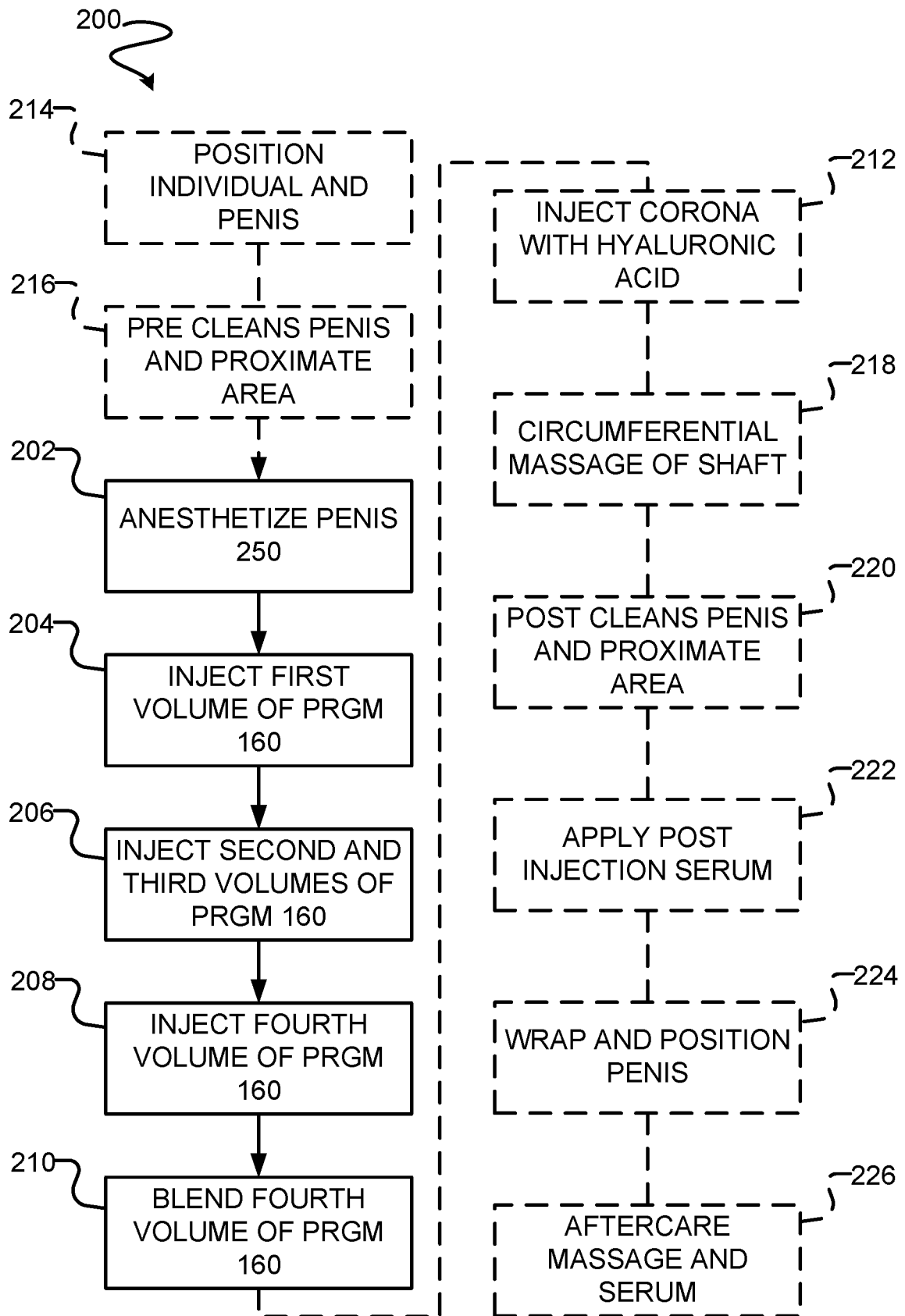


FIG. 2A

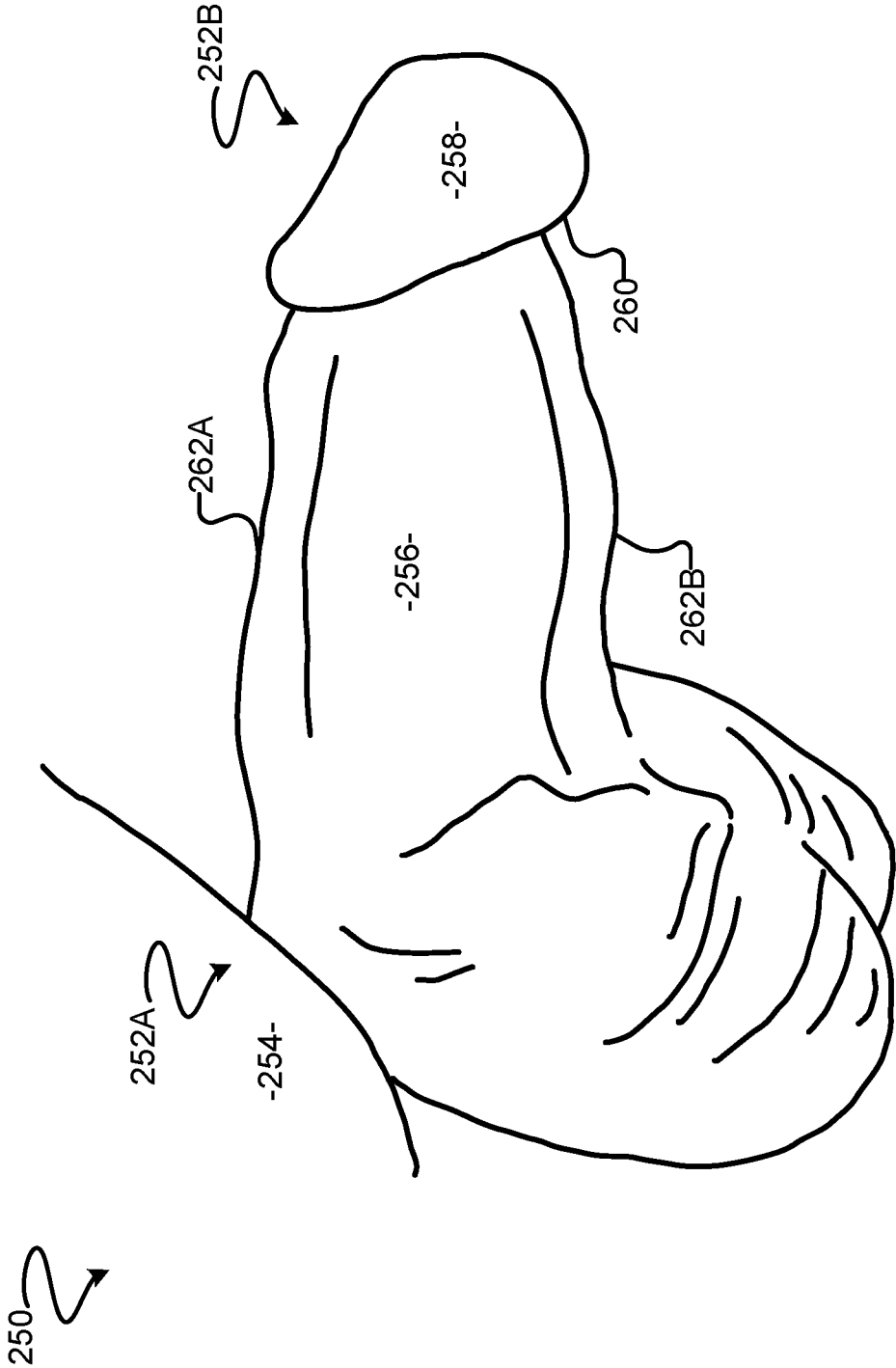


FIG. 2B

INTERNATIONAL SEARCH REPORT

International application No.

PCT/CA2024/050013

A. CLASSIFICATION OF SUBJECT MATTER

IPC: **A61K 8/98** (2006.01), **A61K 8/73** (2006.01), **A61K 31/728** (2006.01), **A61K 35/19** (2015.01),
A61P 15/00 (2006.01)

CPC: **A61K 8/983** (2020.01), **A61K 8/735** (2020.01), **A61K 31/728** (2020.01), **A61K 35/19** (2020.01),
A61P 15/00 (2020.01), **A61Q 90/00** (2023.02) **A61K 2800/91** (2020.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC: A61K 8/98 (2006.01), A61K 8/73 (2006.01), A61K 31/728 (2006.01), A61K 35/19 (2015.01), A61P 15/00 (2006.01)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)

Canadian Patent Database, Questel Orbit, Google Scholar, Google Patents

Keywords: penile augmentation penis enlargement injection hyaluronic autologous platelet plasma [synergistic hyaluronic acid autologous platelet-rich plasma]; Cory TORGERSON Big Shot

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,Y	D1 VIRAG, R. <i>et al.</i> , "Evaluation of the benefit of using a combination of autologous platelet rich-plasma and hyaluronic acid for the treatment of Peyronie's disease", <i>Sex Health Issues</i> , 2017, Vol. 1(1), pp. 1-8 *p. 2, <i>Treatment protocol</i> section; p.5, last paragraph of the left column*	1-20
X	D2 TORGERSON, C., "Big Shot™ Canada's Latest Male Enhancement Treatment", https://drtorgerson.com/ , 29 August 2023 (29-08-2023) [retrieved on 14 March 2024 (14-03-2024)]. Retrieved from the Internet: < https://web.archive.org/web/20230927225925/https://drtorgerson.com/big-shot-canadas-latest-male-enhancement-treatment/ > * <i>The Big Shot™ Penis Enlargement Explained</i> section*	1-20

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* "A" "D" "E" "L" "O" "P"	Special categories of cited documents: document defining the general state of the art which is not considered to be of particular relevance document cited by the applicant in the international application earlier application or patent but published on or after the international filing date document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) document referring to an oral disclosure, use, exhibition or other means document published prior to the international filing date but later than the priority date claimed	"T" "X" "Y" "&"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art document member of the same patent family
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Date of the actual completion of the international search
15 March 2024 (15-03-2024)

Date of mailing of the international search report
08 April 2024 (08-04-2024)

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/CA2024/050013

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	D3 OKABE, K. <i>et al.</i> , "Injectable soft-tissue augmentation by tissue engineering and regenerative medicine with human mesenchymal stromal cells, platelet-rich plasma and hyaluronic acid scaffolds", <i>Cytotherapy</i> , 2009, Vol. 11(3), pp. 307-316 *p.309, whole second paragraph of left column; Table I [HA/PRP], Fig.3.*	11-20
Y	D4 CA 3,155,111 A1 (BROUSSALIAN, E. and YEO, S.-I.) 25 March 2021 (25-03-2021) *the whole document*	9-10

International application No.
PCT/CA2024/050013

Form PCT/ISA/210 (patent family annex) (July 2022) Page 5 of 5