Title: METHOD AND SYSTEM FOR MANUFACTURING COSMETIC PROSTHESSES

Abstract: A process for manufacturing a custom prosthetic prosthesis that substantially matches the amputated limb both anatomically and aesthetically is presented. The process generally comprises the capture and collection of anatomical and aesthetic information about the amputated limb, the capture of anatomical information about the remaining sound limb, the production of a computerized model of the amputated limb using the electronic capture of anatomical information, the production of positive and negative molds based on the computerized model, the molding of the prosthetic prosthesis, and the customization of the prosthetic prosthesis.
Title of the Invention

Method and System for Manufacturing Cosmetic Prostheses

5 Cross-Reference to Related Applications


Field of the Invention

[0002] The present invention generally relates to methods and systems for manufacturing prostheses.

Background of the Invention

[0003] When an amputee wishes to replace his/her amputated limb with a cosmetic prosthesis, it generally has three choices of cosmetic prosthesis: 1) an off-the-shelf cosmetic prosthesis, 2) a semi-customized cosmetic prosthesis, or 3) a fully customized cosmetic prosthesis.

[0004] As the name implies, an off-the-shelf prosthesis is a generic prosthesis available in predetermined sizes and predetermined colors. Though these prostheses are more economical when compared to semi-custom and full-custom cosmetic prostheses, their main deficiencies are the lack of custom fit and aesthetics. Indeed, when an amputee chooses such a prosthesis, the choice will be based on a best-fit approach, that is the amputee will choose the size and color that provides the best fit for the amputated limb and the best match for the sound limb. Understandably, the fit and match can be less than what the amputee would otherwise desire.
[0005] Semi-custom prostheses provide a better fit and look than off-the-shelf prostheses. There are varying degrees of fit and match with these cosmetic prostheses but they are essentially devices that will offer a wider choice of standard skin colors, sizes and anatomical styles than with off-the-shelf devices. Basically, they are selected on the basis of best fit for skin colors (or tones), sizes and anatomical styles and may in some cases be touched up within the limits of the mold.

[0006] Finally, full-custom cosmetic prostheses are typically substantially anatomically and aesthetically identical with the amputated limb. However, the main problem with the current processes for producing a fully customized cosmetic prosthesis is the significant amount of human intervention and skills needed in the production and customization of the cosmetic prosthesis.

[0007] In fact, fully customized cosmetic prostheses are still mostly individually handcrafted using a process which is both highly time consuming and very expensive.

[0008] This time consuming and expensive process prevents the vast majority of amputees from obtaining fully customized cosmetic prostheses. Indeed, for most amputees, a fully customized cosmetic prosthesis is simply too expensive.

[0009] Unfortunately, it is generally known that amputees will more readily accept their condition and their cosmetic prostheses if they are not only realistic-looking but also resemble the limbs they replace and if they retain some basic functionality.

[0010] Hence, in view of the foregoing, there is clearly a need for a better process for manufacturing fully customized cosmetic prostheses which will mitigate at least some of the shortcomings of the current process.

Summary of the Invention

[0011] At least some of the shortcomings in prior art systems and methods for manufacturing cosmetic prostheses are mitigated by a method, and related system, in which a fully customized cosmetic prosthesis can be manufactured with reduced human interventions.
[0012] A process for manufacturing a fully customized cosmetic prosthesis in accordance with the principles of the present invention generally starts with a consultation between the amputee and a certified prosthetist or another prosthetic or medical professional.

[0013] During this consultation, the prosthetist will gather or collect several types of anatomical and aesthetical information about the amputee, about the amputated limb the prosthesis will replace, and also about the remaining sound limb since the amputated limb is no longer available to provide complete anatomical and aesthetical data.

[0014] Certain elements of this information will concern personal data on the individual amputee. For example, it may include the gender, age (or age group), lifestyle, activity level and expectations in term of the final look and functionality of the prosthesis. The amputee information will also include size and weight of the amputee, the side and extent of the amputation, the range of motions of the amputated limb, etc.

[0015] With respect to the amputated limb itself, the level of information collected is much more comprehensive since this information will be used in the fabrication and customization of the cosmetic prosthesis. Hence, the anatomical and aesthetical information generally includes the basic skin color, changes in colors/pigmentations, and the location(s), dimension(s) and color(s) of color transitions, freckles (if any), nails (if any), veins (if any), wrinkles (if any), knuckles (if any), hairs (if any), deformities and scars (if any). In this respect, the more detailed the collected information, the more realistic the prosthesis will be in appearance.

[0016] In typical yet non-limitative embodiments of the process, anatomical information is collected using forms (e.g. manual and/or computerized forms) and the aesthetical information is collected using color samples, photographs and/or videos of the amputated limb and/or of the remaining sound limb.

[0017] During the same or a different consultation, the prosthetist will perform an electronic capture of the anatomical information (e.g. overall shape) of the remaining
sound limb. This electronic capture is generally performed using one or more 3D electronic digital scanners.

[0018] The anatomical information collected during the electronic capture is then sent to a computer system to generate a computerized model of the detailed exterior shape of the remaining sound limb. Since the electronic capture of the anatomical information is performed on the remaining sound limb, a mirror image of the computerized model is then generated such that the computerized model represents the amputated limb.

[0019] Before or after the generation of the mirror computer image, and if necessary, the computerized model can be modified to add, remove and/or correct aesthetical and/or anatomical details.

[0020] Once the computerized model is aesthetically and anatomically satisfying to the prosthethist, and more importantly to the amputee, the computerized model is used to produce a tridimensional ("3D") positive mold of the amputated limb.

[0021] In some embodiments, the 3D positive mold is used to produce the final 3D negative mold that will be used to produce the final prosthesis.

[0022] In some other embodiments, the 3D positive mold is used to produce a first 3D negative mold which will be used to produce a second 3D positive mold made from very fine and malleable material (e.g. plasticine). In these embodiments, the second 3D positive mold can be further modified to add, remove and/or correct aesthetical and/or anatomical details. This second 3D positive mold is then used to produce the final 3D negative mold that will be used to produce the final prosthesis.

[0023] Once the final 3D negative mold is ready, the prosthetic raw material is prepared and colored using pigment(s) to match the basic skin color of the amputated limb which has been documented and typically digitally captured earlier by the prosthethist. The cosmetic prosthesis is then molded using the colored prosthetic raw material and the final 3D negative mold.

[0024] Finally, the detailed color elements previously collected and documented and captured are applied to the molded cosmetic prosthesis either by a coloring technician
using known methods, or by a computer-controlled coloring process. If necessary and required, nails and hairs may be added to the prosthesis.

[0025] By reducing the number of human interventions in the process of manufacturing a fully customized cosmetic prosthesis, a manufacturing process in accordance with the principles of the present invention generally increases the manufacturing speed while generally reducing the manufacturing costs of fully customized prostheses. In addition, it greatly simplifies the accurate capture and collection of the necessary information to fabricate and dispense a fully customized cosmetic prosthesis.

[0026] Other and further aspects and advantages of the present invention will be obvious upon an understanding of the illustrative embodiments about to be described or will be indicated in the appended claims, and various advantages not referred to herein will occur to one skilled in the art upon employment of the invention in practice.

Brief Description of the Drawings

[0027] The above and other aspects, features and advantages of the invention will become more readily apparent from the following description, reference being made to the accompanying drawings in which:

[0028] Figure 1 is a flowchart of an embodiment of a method for manufacturing a cosmetic prosthesis in accordance with the principles of the present invention.

[0029] Figure 2 is a flowchart of another embodiment of a method for manufacturing a cosmetic prosthesis in accordance with the principles of the present invention.

Detailed Description of the Preferred Embodiment

[0030] A novel method and related system for manufacturing custom cosmetic prostheses will be described hereinafter. Although the invention is described in terms of specific illustrative embodiments, it is to be understood that the embodiments described herein are by way of example only and that the scope of the invention is not intended to be limited thereby.
[0031] Referring to Fig. 1, the main steps of an embodiment of the method 10 to manufacture a custom cosmetic prosthesis are illustrated in a flow chart.

[0032] The method 10 generally starts at 100 with an initial consultation between the patient (or amputee) and a certified prosthetist or other prosthetic or medical professional.

[0033] During this initial consultation, the certified prosthetist will generally obtain three groups of information concerning the individual patient, the remaining sound limb and, the amputated limb.

[0034] First, the certified prosthetist will gather all the relevant basic data with respect to the individual patient (step 110). This basic data generally includes the patient’s gender, age group, lifestyle, level of physical activity, aesthetic expectations with respect to the prosthesis, etc.

[0035] This data is important since it will assist the certified prosthetist in the selection of the most appropriate material or grade of material with which the cosmetic prosthesis will be manufactured. For example, a patient who is highly active will require a more durable prosthesis than a more sedentary patient.

[0036] Second, the certified prosthetist will obtain and document anatomical and aesthetic information or data about the patient (e.g. weight, height) and about the amputated limb under consideration (step 120).

[0037] With respect to the anatomical information, the certified prosthetist will document the side (e.g. left or right) of the amputated limb, the extent of the amputation, the estimated range of motion of the limb and/or of its subcomponents (e.g. the range of motion of a hand and any fingers), etc.

[0038] The aesthetic information or data generally includes two types: color information (step 130) and anatomical information (step 140) of the amputated limb.

[0039] In the present embodiment, the color information that is gathered and documented typically includes the basic skin color and also changes in pigmentation.
(location(s), color(s) and dimension(s)), colors transition from one area of the anatomy to the next (location(s), color(s) and dimension(s)), and freckles (location(s), color(s) and dimension(s)). Depending on the actual skin complexion of the limb under consideration of the patient, more or less color information could be collected.

[0040] In the present embodiment, the anatomical information typically includes the locations, colors and dimensions of nails (if any), veins, wrinkles, knuckles (if any), hairs (if any), deformities (if any), wounds (if any), scars (if any), and amputation (if any).

[0041] Since the cosmetic prosthesis intends to resemble as closely as possible the amputated limb, the more aesthetic information that is collected and documented, the more realistic the final cosmetic prosthesis will be. Since the level of detail of the final prosthesis will have an impact on cost, determining the expectations of the patient with respect to the aesthetic aspects of the final prosthesis during the initial consultation (step 110) will allow the certified prosthetist to decide how much aesthetic data to collect. There is generally no need to collect data about aesthetic aspects the limb under consideration if these aspects will not be replicated in the final prosthesis.

[0042] In the present embodiment, the color and aesthetic information or data is generally collected using still photography and video cameras. Since colors will play an important role in making the final prosthesis more realistic, the cameras used to document the color and aesthetic information will generally be calibrated for colors before their use. In some cases, specialized color analysis devices could be used to improve the accuracy of the data capture.

[0043] In addition, since the amputated limb is no longer available, most of the aesthetic information is collected from the remaining sound limb. In that sense, it might make sense for some aesthetic information to be ignored (e.g. scars, wounds, freckles, etc.) in order to avoid manufacturing a prosthesis which is too symmetrical with the remaining sound limb. Feedback from the patient is generally required during the collection of anatomical, color and aesthetic information to guide the certified prosthetist in collecting relevant information and ignoring irrelevant information.
[0044] If the patient wishes to add color or aesthetic information, such as tattoos, which are not present on the remaining sound limb, this additional information could be provided by photographs of the amputated limb before the amputation.

[0045] In the process of making a full custom cosmetic prosthesis, the final appearance of the cosmetic prosthesis may be as important as its functionality. Some patients will require a cosmetic prosthesis which is as realistic as possible even though the final cosmetic prosthesis includes the same physical imperfections as the amputated limb.

[0046] All these various anatomical, color and aesthetic information which is collected in the previous steps will be used, at least in part, during the molding and final customization of the prosthesis. Therefore, the level of detail of the collected information will have a significant impact on the exactness of the final appearance of the cosmetic prosthesis.

[0047] Third, once all the basic data, anatomical and aesthetic information has been properly captured, collected and documented, the certified prosthetist will generally proceed with the electronic capture of the remaining sound limb with respect to which the manufacture of the cosmetic prosthesis will be based (step 150).

[0048] This electronic capture of the remaining sound limb is generally performed using one or more 3D scanners (e.g. Creaf orm™, Artec™, Rodin™, etc.) in order to properly capture all the detailed and comprehensive anatomical shape information about the remaining sound limb (step 160). The more detailed the anatomical information, the more realistic the prosthesis will be.

[0049] In order to fully capture all the anatomical shape information about the remaining sound limb, several scans of the remaining sound limb may be performed in which the position of the remaining sound limb would be changed. For instance, if the remaining sound limb is a hand, then the remaining sound hand would be scanned opened, closed, partially closed, with the fingers close to each other, with the fingers spread out, etc. By scanning the hand in various positions, more detailed anatomical information can be captured.
[0050] Even though the final prosthesis may not be able to function or move as the remaining sound limb, the capturing of its detailed anatomical information will assist in designing a prosthesis which will be more realistic in appearance.

[0051] Once the remaining sound limb has been properly electronically captured, the 3D limb data is transferred to a computer system in order for the 3D limb data to be processed in order to extract exact dimensions of the remaining sound limb (step 170). Depending on the sound limb and on its configuration, the extracted dimensions may include lengths, circumferences, arcs, radii, diameters, surface areas, etc. These dimensions are extracted using computer-assisted design ("CAD") software.

[0052] Since the prosthesis must fit the anatomy of the amputee, it is generally preferable to extract precise dimensions of the remaining sound limb as these dimensions will be used later on in the manufacturing steps of the cosmetic prosthesis.

[0053] Though the extraction of the dimensions of the remaining sound limb based on the 3D limb data could be determined by the computer software, it is generally desirable to validate at least some of the extracted dimensions in order to ensure that the computer model of the remaining sound limb properly matches the actual remaining sound limb. If any discrepancies are found, they can be corrected.

[0054] Once the dimensions of the remaining sound limb have been properly extracted from the 3D limb data and validated, the 3D limb data and the extracted dimensions are used to generate a 3D computer model of the remaining sound limb using 3D modeling computer software (e.g. Solidworks™, Rhino™, etc.) (step 180).

[0055] If necessary, the 3D computer model can be edited and/or modified by the certified prosthetist (or by a technician) to correct, add or remove details (e.g. adding or removing a scar), to correct defect(s), to take into account preferences of the amputee (e.g. smaller knuckles), etc.

[0056] If the 3D computer model of the remaining sound limb is correct, then no further modifications are necessary.

[0057] At this point, a mirror image of the 3D computer model is generated to take into account the fact that the 3D computer model was based on the remaining sound
limb and not on the amputated limb (step 190). Since the mirror 3D computer model is still a computer model, additional modification of the model can be performed at this step.

[0058] For instance, the amputee, after seeing the 3D model for the replacement of the amputated limb, might wish to add anatomical details that the amputated limb had that the remaining sound limb does not have. For example, the amputee might want to add a scar, a deformity, a bump, etc. such that the mirror 3D model more precisely resembles the amputated limb. Although a more realistic prosthesis will generally reduce unwanted external attention; it will also allow the amputee to personalize the prosthesis. In other words, a more realistic prosthesis has positive psychological personal and social benefits for the amputee.

[0059] Once the mirror 3D computer model of the remaining sound limb has been finalized and accepted, the 3D computer model data is sent to an automated manufacturing machine such as a computer numerical controlled (“CNC”) machine, a 3D printer, etc. to produce a high-definition (“HD”) 3D positive mold of the mirror of the remaining sound limb (step 200). This HD 3D positive will preferably be made from ceramic or plaster materials as it will form the basis of a HD 3D negative mold of the mirror of the remaining sound limb.

[0060] As indicated above, the HD 3D positive mold produced using the 3D computer model data is then used to produce a HD 3D negative mold of the mirror of the remaining sound limb (step 210). In the present embodiment, the HD 3D negative mold is made from high definition casting material such as plaster, ceramic materials or other materials having the ability to produce high definition 3D negative mold.

[0061] Using the HD 3D negative mold, a second high-definition 3D positive mold is produced (step 220). However, the second HD 3D positive mold is made from very fine and malleable material. In the present embodiment, the second HD 3D positive mold is made from material such as plasticine or alginate.

[0062] Due to the malleability of the material from which it is made, the second HD 3D positive mold can be slightly modified to add any anatomical details that could have been missed from the initial electronic capture, to remove any erroneous and/or
unwanted anatomical details, and/or to correct any anatomical details for aesthetic and/or physiological purposes.

[0063] The second HD 3D positive mold can also be slightly modified to assist in the production of the second high definition 3D negative mold (step 230). For example, finer details such as wrinkles could be slightly amplified (e.g. made deeper) to avoid the loss of fine details in the final prosthesis.

[0064] Using this second HD 3D positive mold, a second HD 3D negative mold is produced, this time with a more rigid material such as Plaster of Paris (step 240).

[0065] In the present embodiment, this second HD 3D positive mold is the mold that will be used to produce the main body of the cosmetic prosthesis.

[0066] At this point, once the second HD 3D positive mold is ready, the basic material of the prosthesis can be prepared (step 250). In the present embodiment, the basic material of the prosthesis will be medical grade silicone, or any other material that will have the necessary properties to produce a functional high definition cosmetic prosthesis, which is colored using pigment or combination of pigments which match the main color of the remaining sound limb as previously determined in step 130.

[0067] The preparation of the colored basic material could be done automatically in a computer-controlled mixing apparatus in which the recipes for preparing the various colors (e.g. quantity of base color, quantity and type of each pigment(s) to be added, etc.) are stored.

[0068] In the present embodiment, two molding processes can be used to produce the main body of the prosthesis with the colored silicone material.

[0069] In the first molding process, the second HD 3D positive mold is sequentially filled with liquid colored silicone and then emptied. At each iteration, a thin layer of colored silicone remains in the mold, adding to any previously deposed layers. Once the layers reach a predetermined thickness, the molding process is stopped. Notably, some color elements of the final cosmetic prosthesis could be added during the production of these layers.
[0070] In the second molding process, the second HD 3D positive mold is partially filled with liquid colored silicone and then rotated for a predetermined length of time. As the mold is rotated, thin layers of silicone will adhere to the interior surface of the mold and then on any previous layers. This second molding process is generally known as "roto-molding". Again, some color elements of the final cosmetic prosthesis could be added during the production of these layers.

[0071] Once the molding process is completed, the molded prosthesis is cured to solidify the silicone.

[0072] The resulting molded prosthesis is typically a single-colored prosthesis having the shape of the mirror image of the remaining sound limb. However, depending on the molding method used, the molded prosthesis could comprise more than one (e.g. 2 or 3) basic colors. However, at this point, the prosthesis does not contain all of the color elements (captured in step 130) and anatomical elements (captured in step 140).

[0073] At this point, before proceeding with the final customization of the prosthesis, the patient and the certified prosthelist will validate that the prosthesis properly resembles the amputated limb, at least with respect to its anatomical shape. Should the prosthesis fail to match the appearance of the amputated limb, there would be no need to proceed with the final customization steps.

[0074] If the molded prosthesis is approved by the patient, then the process continues with the final customization steps.

[0075] Using the color element data collected in step 130, colors are then applied to the prosthesis to match the color element data previously collected (step 260).

[0076] Although the color matching could be performed by a coloring technician using known techniques, in the present embodiment, the colors are applied using a computer-controlled 3D coloring process.

[0077] In other embodiments, the main color elements could be applied using a computer-controlled 3D printer (i.e. a printer capable of printing on a 3D surface)
while the finer color elements could be added afterwards by a coloring technician using known techniques.

[0078] Finally, the anatomical details are added to the prosthesis (step 270). These anatomical details typically include hairs and nails though they could also include other elements depending on the amputated limb the prosthesis replaces.

[0079] In reference to Fig. 2, another embodiment of a process 20 in accordance with the present invention is shown. The embodiment of Fig. 2 is broadly similar to the embodiment of Fig. 1. The main difference is the absence of steps 210, 220 and 230 in the process 20.

[0080] The process 20 comprises less molding steps than the process 10. The process 20 may be used in circumstances in which the final prosthesis does not involve the geometric complexities of a hand or a foot which would typically require additional molding steps as in process 10. For instance, when molding an ear or a nose, the geometric complexities are generally much lower. An ear or a nose is simpler and generally more static a limb compared to a hand or a foot which is more complex and dynamic.

[0081] When a prosthesis is made in order to replace simpler limbs (e.g. ear, nose, etc.), the process 20 can be employed to reduce the number of steps and/or to speed up the manufacturing process.

[0082] Alternatively, depending on the molding technology available to the certified prosthetist, the process 20 could be employed.

[0083] For example, if the molding technology available to produce the first positive 3D mold in step 200 allows for the molding of a high-definition 3D positive mold, then steps 210 to 230 could be avoided altogether.

[0084] Depending on the complexity of the limb to replace and/or on the molding technology available to the certified prosthetist, the certified prosthetist may decide to employ either process 10 or process 20.
[0085] In the end, the resulting prosthesis is more realistic as it substantially matches the amputated limb both anatomically and aesthetically. Furthermore, by reducing the number of human interventions in the process, the processes in accordance with the principles of the present invention generally reduce the processing time to manufacture fully customized prosthesis while reducing the manufacturing costs.

[0086] While illustrative and presently preferred embodiments of the invention have been described in detail hereinabove, it is to be understood that the inventive concepts may be otherwise variously embodied and employed and that the appended claims are intended to be construed to include such variations except insofar as limited by the prior art.
Claims

1) A method to manufacture a cosmetic prosthesis to replace an amputated limb, the method comprising:
   a) producing a positive mold of a mirror image of a remaining sound limb corresponding to the amputated limb using a mirror image of a tridimensional computer model of the remaining sound limb;
   b) producing a negative mold of the mirror image of the remaining sound limb;
   c) molding the cosmetic prosthesis using the negative mold;
   d) customizing the molded cosmetic prosthesis using aesthetical and anatomical information of the amputated limb and/or of the remaining sound limb.

2) A method as claimed in claim 1, further comprising acquiring the anatomical and aesthetical information concerning the amputated limb and/or the remaining sound limb.

3) A method as claimed in claim 2, wherein at least part of the anatomical and aesthetical information is acquired with still photograph and/or video images.

4) A method as claimed in any of claims 1 to 3, further comprising generating the tridimensional computer model of the remaining sound limb using tridimensional anatomical information of the remaining sound limb.

5) A method as claimed in claim 4, further comprising capturing the tridimensional anatomical information of the remaining sound limb.

6) A method as claimed in claim 4, wherein the tridimensional anatomical information of the remaining sound limb is captured with at least one tridimensional electronic digital scanner.

7) A method as claimed in any of claims 1 to 6, wherein producing the positive mold comprises machining the positive mold using a computer-controlled machining apparatus.
8) A method as claimed in any of claims 1 to 6, wherein producing the positive mold comprises printing the positive mold using a computer-controlled tridimensional printing apparatus.

9) A method as claimed in any of claims 1 to 8, wherein the aesthetical information comprises color elements and anatomical composition elements.

10) A method as claimed in claim 9, wherein customizing the molded cosmetic prosthesis comprises applying at least one color element to the molded cosmetic prosthesis.

11) A method as claimed in claim 10, wherein the at least one color element is a change in pigmentation, a color transition, or at least one freckle.

12) A method as claimed in any of claims 10 to 11, wherein applying the at least one color element comprises printing the at least one color element using a computer-controlled printing apparatus.

13) A method as claimed in any of claims 9 to 12, wherein customizing the molded cosmetic prosthesis comprises applying at least one anatomical element to the molded cosmetic prosthesis.

14) A method as claimed in claim 13, wherein the at least one anatomical element is a nail, a vein, a wrinkle, a knuckle, a deformity, a wound, a scar, or a hair.

15) A method as claimed in any of claims 1 to 14, wherein the positive mold is a first positive mold, and wherein the negative mold is a second negative mold, and wherein the method further comprises producing a first negative mold of the mirror image of the remaining sound limb using the first positive mold, and producing a second positive mold of the mirror image of the remaining sound limb using the first negative mold, and wherein the second negative mold is produced using the second positive mold.

16) A cosmetic prosthesis made in accordance with the method as claimed in any of claims 1 to 15.
17) A method to manufacture a cosmetic prosthesis to replace an amputated limb, the method comprising:
   a) capturing tridimensional anatomical information of a remaining sound limb corresponding to the amputated limb;
   b) generating a tridimensional computer model of the remaining sound limb using the captured tridimensional anatomical information;
   c) generating a mirror image of the tridimensional computer model of the remaining sound limb;
   d) producing a positive mold of the mirror image of the remaining sound limb using the mirror image of the tridimensional computer model of the remaining sound limb;
   e) producing a negative mold of the mirror image of the remaining sound limb using the positive mold;
   f) molding the cosmetic prosthesis using the negative mold;
   g) applying at least one aesthetical element to the molded cosmetic prosthesis using aesthetical and anatomical information of the amputated limb and/or of the remaining sound limb.

18) A method as claimed in claim 17, wherein the at least one aesthetical element comprises at least one color element and/or at least one anatomical composition element.

19) A method as claimed in claim 18, wherein the at least one color element is a change in pigmentation, a color transition, or at least one freckle.

20) A method as claimed in claim 19, wherein applying the at least one color element comprises printing the at least one color element using a computer-controlled printing apparatus.

21) A method as claimed in claim 18, wherein the at least one anatomical element is a nail, a vein, a wrinkle, a knuckle, a deformity, a wound, a scar, or a hair.
22) A method as claimed in any of claims 17 to 21, further comprising acquiring the anatomical and aesthetical information concerning the amputated limb and/or the remaining sound limb.

23) A method as claimed in claim 22, wherein at least part of the anatomical and aesthetical information is acquired with still photography and/or video images.

24) A method as claimed in any of claims 17 to 23, wherein the tridimensional anatomical information of the remaining sound limb is captured with at least one tridimensional scanner.

25) A method as claimed in any of claims 17 to 24, wherein producing the positive mold comprises machining the positive mold using a computer-controlled machining apparatus.

26) A method as claimed in any of claims 17 to 24, wherein producing the positive mold comprises printing the positive mold using a computer-controlled tridimensional printing apparatus.

27) A method as claimed in any of claims 17 to 26, wherein the positive mold is a first positive mold, and wherein the negative mold is a second negative mold, and wherein the method further comprises producing a first negative mold of the mirror image of the remaining sound limb using the first positive mold, and producing a second positive mold of the mirror image of the remaining sound limb using the first negative mold, and wherein the second negative mold is produced using the second positive mold.

28) A cosmetic prosthesis made in accordance with the method as claimed in any of claims 17 to 28.

29) A method to manufacture a cosmetic prosthesis to replace an amputated limb, the method comprising:
   a) acquiring anatomical and aesthetical information concerning the amputated limb and/or a remaining sound limb corresponding to the
amputated limb, the anatomical and aesthetical information comprising several aesthetical elements;

b) capturing tridimensional anatomical information of the remaining sound limb corresponding to the amputated limb;

c) transforming the captured tridimensional anatomical information into a tridimensional computer model of the remaining sound limb;

d) generating a mirror image of the tridimensional computer model of the remaining sound limb;

e) producing a positive mold of the mirror image of the remaining sound limb using the mirror image of the tridimensional computer model of the remaining sound limb;

f) producing a negative mold of the mirror image of the remaining sound limb;

g) molding the cosmetic prosthesis using the negative mold;

h) applying at least one aesthetical element to the molded cosmetic prosthesis.

30) A method as claimed in claim 29, wherein the aesthetical elements comprise color elements and anatomical composition elements.

31) A method as claimed in claim 30, wherein the color elements comprise at least one change in pigmentation, at least one color transition, at least one freckle, or combination thereof.

32) A method as claimed in claim 30, wherein the anatomical elements comprise at least one nail, at least one vein, at least one wrinkle, at least one knuckle, at least one deformity, at least one wound, at least one scar, at least one hair, or a combination thereof.

33) A method as claimed in claims 29 or 30, wherein at least part of the anatomical and aesthetical information is acquired with still photography and/or video images.
34) A method as claimed in any of claims 29 to 33, wherein capturing the tridimensional anatomical information of remaining sound limb comprises tridimensionally scanning the remaining sound limb.

35) A method as claimed in any of claims 29 to 34, wherein capturing the tridimensional anatomical information of the remaining sound limb is performed with at least one tridimensional scanner.

36) A method as claimed in any of claims 29 to 35, wherein producing the positive mold comprises machining the positive mold using a computer-controlled machining apparatus.

37) A method as claimed in any of claims 29 to 36, wherein producing the positive mold comprises printing the positive mold using a computer-controlled tridimensional printing apparatus.

38) A method as claimed in any of claims 29 to 37, wherein the positive mold is a first positive mold, and wherein the negative mold is a second negative mold, and wherein the method further comprises producing a first negative mold of the mirror image of the remaining sound limb using the first positive mold, and producing a second positive mold of the mirror image of the remaining sound limb using the first negative mold, and wherein the second negative mold is produced using the second positive mold.

39) A cosmetic prosthesis made in accordance with the method as claimed in any of claims 29 to 38.
Step 10 - Consultation between patient and CP

Step 110 - Obtain and document the basic data: gender, age group, lifestyle of patient (personal, recreational, professional), activity level, expectations for the cosmetic prosthesis in terms of aesthetics, functionality, maintenance, etc.

Step 120 - Obtain and document the anatomical information - side, extent of amputation, range of motion of the limb under consideration and in general, weight and height of patient.

Step 130 - Capture and document the Color Elements using electronic technologies.

Basic skin color, changes in pigmentation - location, color and dimensions, color transition from one area of the anatomy to the next - location, color and dimensions, freckles - location, color and dimensions.

Step 140 - Capture and document the Anatomical Composition Elements using electronic technologies.

Nails - location, color and dimensions; Veins - location, color and dimensions; Wrinkles - location, color and dimensions; Knuckles - location, color and dimensions; Deformities - location, color and dimensions; Wounds - location, color and dimensions; Scars - location, color and dimensions; Amputations - location, color and dimensions; Hairs - location, color and dimensions.

Step 150 - Electronic capture of detailed and comprehensive anatomical information of the sound limb and its proximal boundaries to reproduce as a mirror image.

Step 160 - Capture the 3D anatomical shape of the sound limb and its anatomical part(s) using scanning technologies.

Step 160 - Generate a 3D electronic model of the sound limb and its anatomical part(s) using scanning technologies.

Step 170 - Produce the Dimensions of anatomical part(s) in terms of lengths, circumferences, arcs, radii, diameters, surface areas, etc. using an adapted CAD software.

Step 180 - Generate a 3D mirror image electronic model of the sound limb with the modified dimensions.

Step 190 - Generate a 3D mirror image electronic model of the sound limb with the modified dimensions.

Step 200 - Generate a 3D positive likeness of the mirror image of the sound limb model using data produced in step 190.

Step 210 - Produce a High Definition 3D Negative shape using high definition material (e.g. plaster).

Step 220 - Produce a High Definition 3D Positive shape using a very fine and malleable material (e.g. plasticine).

Step 230 - Adapt the Positive to the Anatomical Information captured in step 120 by integrating in the malleable Positive all the details that may have been missed in the electronic capture of anatomical information (step 160).

Step 240 - Produce a High Definition 3D Negative using the adapted High Definition Positive made of malleable material.

Step 250 - Produce the replicate of the Anatomical Part in a synthetic material using the Negative produced in step 240.

Integrate the basic color (captured in step 130) in the synthetic material.

Produce the replicate of the Anatomical Part using the colored synthetic material and the Negative produced in step 240.

Step 260 - Apply additional coloring techniques to conform to the data from the capture of the Anatomical Information in steps 130 and 140.

Step 270 - Apply texturing techniques to conform to the data from the capture of the Anatomical Information in step 140.

Fig. 1
Step 100 - Consultation between patient and CP

Step 110 - Obtain and document the basic data: gender, age group, lifestyle of patient (personal, recreational, professional), activity level, expectations for the cosmetic prosthesis in terms of aesthetics, functionality, maintenance, etc.

Step 120 - Obtain and document the Anatomical Information - side, extent of amputation, range of motion of the limb under consideration and in general, weight and height of patient.

Step 130 - Capture and document the Color Elements using electronic technologies.
Basic skin color, changes in pigmentation - location, color and dimensions, color transition from one area of the anatomy to the next - location, color and dimensions, freckles - location, color and dimensions.

Step 140 - Capture and document the Anatomical Composition Elements using electronic technologies.
Nails - location, color and dimensions; Veins - location, color and dimensions; Wrinkles - location, color and dimensions; Knuckles - location, color and dimensions; Deformities - location, color and dimensions; Wounds - location, color and dimensions; Scars - location, color and dimensions; Amputations - location, color and dimensions; Hairs - location, color and dimensions.

Step 150 - Electronic capture of detailed and comprehensive anatomical information of the sound limb and its proximal boundaries to reproduce as a mirror image.

Step 160 - Capture the 3D anatomical shape of the sound limb and its anatomical part(s) using scanning technologies.

Step 170 - Produce the dimensions of anatomical part(s) in terms of lengths, circumferences, arcs, radii, diameters, surface areas, etc. using an adapted CAD software.

Step 180 - Generate a 3D electronic model of the sound limb with dimensions and modify the model as required.

Step 190 - Generate a 3D mirror image electronic model of the sound limb with the modified dimensions.

Step 200 - Generate a 3D positive likeness of the mirror image of the sound limb model using data produced in step 190.

Step 240 - Produce a High Definition 3D Negative using the adapted High Definition Positive made of malleable material.

Step 250 - Produce the replicate of the Anatomical Part in a synthetic material using the Negative produced in step 240.

Integrate the basic color (captured in step 130) in the synthetic material.

Produce the replicate of the Anatomical Part using the colored synthetic material and the Negative produced in step 240.

Step 260 - Apply additional coloring techniques to conform to the data from the capture of the Anatomical Information in steps 130 and 140.

Step 270 - Apply texturing techniques to conform to the data from the capture of the Anatomical Information in step 140.

Fig. 2
INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2013/001012

A. CLASSIFICATION OF SUBJECT MATTER
IPC: A61F 2/76 (2006.01), A61F 2/59 (2006.01)

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: A61F 2/76 (2006.01), A61F 2/59 (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)
Full text databases using the search tool EPOQUE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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<tr>
<td>X</td>
<td>EP0947899 A2 (FERRONE) 06 October 1999 (06-10-1999) - refer to paras. 0012, 0013, 0023-0031, 0038-0044, 0056, 0059, 0063, 0064</td>
<td>1-39</td>
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<td>A</td>
<td>US2004/0260402 A1 (BALDINI et al.) 23 December 2004 (23-12-2004) - refer to fig. 1, abstract, paras. 0004-0006, 0019, 0023-0027, 0036</td>
<td>1, 17, 29</td>
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☑ Further documents are listed in the continuation of Box C. ☑ See patent family annex.

“*” Special categories of cited documents:
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Date of the actual completion of the international search
28 March 2014 (28-03-2014)

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Facsimile No.: 001-819-953-2476

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<td>GB2357725 A (BOUCHIER-BLEASE et al.) 04 July 2001 (04-07-2001) - refer to entire document</td>
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