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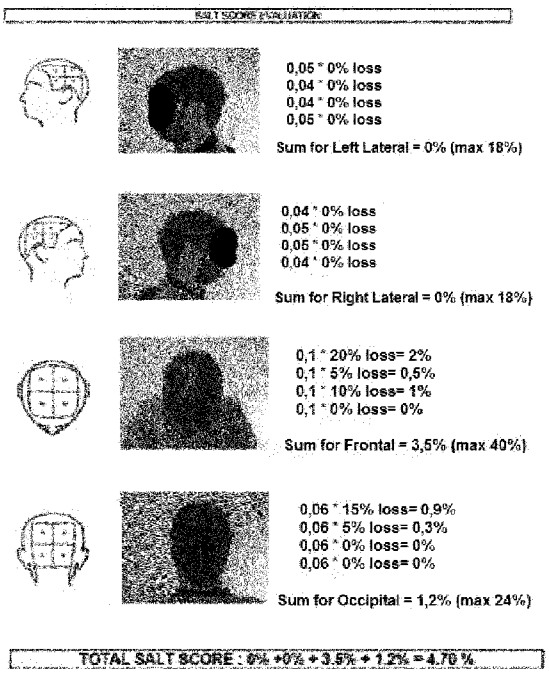
(54) Title: METHOD FOR ASSESSING HAIR LOSS AND SCALP DISORDERS

FIG. 7



(57) Abstract: This invention generally relates to devices and methods for hair and scalp image analysis, and more specifically, to devices and methods for assessing hair loss and scalp disorders.

WO 2019/134760 A1

METHOD FOR ASSESSING HAIR LOSS AND SCALP DISORDERS

TECHNICAL FIELD

This invention generally relates to devices and methods for hair and scalp image analysis, and more specifically, to devices and methods for assessing hair loss and scalp disorders.

BACKGROUND OF THE INVENTION

Alopecia areata (AA) is an autoimmune disease that results in hair loss that ranges in presentation from circular patches on the scalp that can often undergo spontaneous resolution to complete hair loss that may persist for life.

Chemotherapy-induced alopecia (CIA) is a common side effect of chemotherapy regimens, affecting around 65% of chemotherapy patients. In the course of CIA, the rapidly growing and dividing cell populations in anagen phase are damaged by the systemic chemotoxic agents and undergo unwanted apoptosis, consequently causing anagen effluvium, leading to a complete or partial baldness period in cancer patients for 20 weeks on average, i.e. from maximum hair loss to the start of hair regrowth. CIA is considered by the sufferers as the most visible and emotionally distressing consequence of cancer therapies, giving negative repercussions on various aspects of quality of life. There are no approved pharmacologic treatments available for preventing or reducing the impact of CIA.

Androgenetic alopecia (AGA) is the most common form of hair loss in humans, occurring both in men and women. In men, this condition is commonly known as male pattern baldness (MPB), as hair is lost in a well-defined pattern, beginning above both temples. Over time, the hair thins at the crown (near the top of the head), often progressing to partial or complete baldness. In Caucasians, MPB is noticeable in about

20% of men aged 20, and increases steadily with age, so that a male in his 90s has a 90% chance of having some degree of MPB. In women, onset of androgenetic alopecia tends to occur later and in a milder form. The pattern of hair loss in women also differs from male-pattern baldness. In women, the hair becomes thinner all over the head, and the hairline does not recede. Androgenetic alopecia in women rarely leads to total baldness. A familial tendency to MPB and racial variation in the prevalence is well recognized, with heredity accounting for approximately 80% of predisposition. Normal levels of androgens are sufficient to cause hair loss in genetically susceptible individuals.

The key pathophysiological features of AGA are alteration in hair cycle development, follicular miniaturization and inflammation. In general, hair growth occurs in a cycle that can last from a few months (e.g. for shorter terminal length hairs such as those in the eyebrow) to several years. Hair is produced in the anagen or growth phase where cell division takes place in the matrix of the hair bulb outside the dermal papilla. Keratinocytes then move up into the thinner part of the hair follicle, differentiating into the layers of the hair and its surrounding sheath. Melanocytes in the bulb also transfer pigment to the hair keratinocytes to give the hair color. Anagen is followed by a short regressive phase called catagen which is a transitional phase that lasts 2-3 weeks. The final stage is called telogen which is a resting phase that can last about 2-3 months.

Androgens also play significant roles in hair growth. Interestingly, their relative roles differ depending on the type of hair. For example, androgens have almost no impact on the growth of eyelashes, while having significant impact on beard growth.

Treatment of AGA currently involve the use of topical minoxidil and oral finasteride which are approved by the Food and Drug Administration (USA) for the treatment of AGA. Both medications prevent further hair loss, but only partially reverse

baldness, and require continuous use to maintain the effect. Topical minoxidil is well tolerated as a 5% solution and acts as a potassium channel agonist and vasodilator, potentially increasing blood supply to the hair follicle. Finasteride is a potent and selective antagonist of type II 5a-reductase, thus preventing the conversion of testosterone into 5a-dihydrotestosterone (DHT). Both treatments are not completely effective however. For example, Minoxidil is most effective on small areas of hair loss, and in patients under 40 years of age who have only recently started losing hair, but loss returns when Minoxidil use is stopped. There are currently no treatments that work for everyone with hair loss and scalp disorders, new treatments have been proposed.

For example, document WO 2008/113912 describes compositions comprising an extract of Allium species, an extract of Citrus species, an extract of Paullinia species and an extract of Theobroma species having effects on excessive hair loss and insufficient hair growth.

Considering the unpredictable nature of spontaneous regrowth and lack of a uniform response to various therapies, these variables have made clinical trials in hair loss and scalp disorders difficult to assess.

Although there are numerous methods and devices available for visually measuring hair count and hair shaft thickness at any particular point in the scalp, there exists no standardized method or automated process or device to process the data such that hair bulk assessments can be measured accurately for different sections of the scalp, or for the same section of the scalp over different time periods.

For example, The Severity of Alopecia Tool (SALT) has served as a guideline for alopecia research and for following progression of alopecia (Alopecia areata investigational assessment guidelines -Part II, J Am Acad Dermatol 2004). The SALT score

is a global severity score that captures percentage of hair loss. Estimating percentage for a SALT score, however, is time consuming, not easily done consistently with a quick visual assessment. Moreover, calculation mistakes can easily occur. Despite the relevance of SALT score in the diagnosis, prognosis and follow-up, this method is poorly used in clinical practice due to the above-mentioned limitations.

Given the lack of devices designed for this purpose, it is common that no precise monitoring of the evolution of hair loss and scalp disorders is performed.

Hence, there is a need to have a means to interpret and analyze hair loss or hair growth in the context of hair loss and scalp disorders and its treatment in a consistent and straightforward manner that provides improved accuracy over existing methods. What is desired is an easy and consistent methodology to capture and store the images, to provide assistance to the evaluator, to automatically evaluate/calculate the quantity of hair loss or hair growth, for example the SALT score, and to generate a customized general report.

The present invention is aimed at solving said need.

The digital imaging system and methods described herein help to reduce the impact of human subjectivity (and also the expertise of the person making the hair loss and scalp disorders assessment) and visual acuity as variables, thereby resulting in improved measurement accuracy. This enables faster evaluation, reduced training requirements, allows the evaluation to be performed at any time and any place. As an example of the functionality of the invention, a picture taken at subject's home can be evaluated remotely by a Physician afterwards.

BRIEF DESCRIPTION OF THE INVENTION

An object of the present invention is to provide a practical solution to the aforementioned problems of the state of the art, providing novel devices and methods that enable a measurement system allowing an accurate evaluation of hair loss and scalp disorders to be carried out.

Said object of the invention is obtained by means of a device for the monitoring of hair loss and scalp disorders comprising:

- a camera with autofocus capability that adjusts for slight differences in focal distance and thus compensates for differences in patient position and distance,

-a filter/counting grid positioned on the screen of the digital camera to be adjusted to a patient's head in order to frame one of the 4 zones of interest of a patient's head,

-optionally a filter holder to place the filter/counting grid in front of the camera lens, if not positioned on the screen of the camera,

-optionally an image processing controller which includes a central processing unit (CPU) or processor, a memory or storing unit in order to process the images of the four zones of interest of a patient's head,

- an image analysis program to treat the said images, calculate and assess the hair loss and scalp disorders,

-a display screen.

A method of the present invention uses the afford mentioned device for the monitoring of hair loss and scalp disorders in a reproducible automated way to evaluate or calculate the percentage scalp surface area involved in hair loss or hair growth.

DESCRIPTION OF THE FIGURES

FIG. 1 is a schematic representation of a system embodiment of this invention showing the image capture device (A) and the four filters/counting grids (B) corresponding to the four zones of interest of a patient's head (a: left side, b: right side, c: frontal (top) and d: occipital (back).

FIGS. 2 shows how the filter is framed on the patient's head. Positions A and B are wrong, position C is right. The filter/grid is adjusted.

FIGS. 3 shows how the patient's head is positioned during the image recording.

FIGS. 4/5 show the operating conditions during the image recording. Camera is at the same level as the patient's head.

FIG. 6 is a schematic view of a frontal zone bearing the counting grid associated with the image of the same zone to be evaluated.

FIG. 7 is a schematic view of the SALT score evaluation.

DETAILED DESCRIPTION OF THE INVENTION

A method of assessing hair loss and scalp disorders comprising:

a) capturing at least one image of a zone of interest of a patient's head by using a camera equipped with a filter/counting grid to be adjusted to a patient's head in order to frame one of the four zones of interest of a patient's head,

b) processing the images with an image analysis program to treat said images,

c) quantifying or evaluating the percentage of hair loss or hair growth in a patient using said program.

Various particular embodiments of the present invention concern:

-The method of assessing hair loss and scalp disorders, wherein the filter/counting grid comprises or consists in i) a filter/counting grid positioned on the screen of the camera on the display screen of a digital camera, or ii) a filter/counting grid positioned in front of the camera lens, or iii) a virtual grid integrated to the display of the camera.

-The method of assessing hair loss and scalp disorders, wherein the filter/counting grid is adjusted to the patient's head independently of the size of the head and the distance between the photographer and the patient.

-The method of assessing hair loss and scalp disorders, wherein the method further comprises storing the images of the four zones of interest of a patient's head, in a database.

-The method of assessing hair loss and scalp disorders, wherein the processing of the images comprises:

detecting and calculating the density of the hairs based on the images of the at least one of the four zones of interest of a patient's head.

-The method of assessing hair loss and scalp disorders, wherein the method further comprises calculating the percentage of hair loss or hair growth in the four images of the scalp corresponding to the left and right side of a patient's head, the top of the head and the back of the head.

-The method of measuring the hair loss or hair growth, wherein the method is able to detect and quantify the pigmentation of hair.

-A method of assessing hair loss and scalp disorders comprising, using a device that includes both a digital camera and a display screen, the method comprising the steps of:

a) installing a filter/counting grid on the display screen of a digital camera or in front of the camera lens or virtual grid integrated to the display of the camera;

b) capturing a first image of a patient's head with the device camera by framing the grid having at least one cell with the area of interest of the patient's head,

c) capturing a second image of said patient's head with the said device camera in the same conditions but at a different time;

d) comparing the images to make a prognosis concerning the loss or the growth of hair in the said patient

-A system for detecting the scalp treatment efficacy of by means falling under data processing of image of the patient's head comprising:

a) subjecting a patient with a treatment for hair loss and scalp disorders,

b) installing a filter/counting grid on the display screen of a digital camera or in front of the camera lens;

c) capturing a least one image of a patient's head with the device camera by framing the grid having at least one cell with the area of interest of the patient's head,

d) producing at least one information related to the sensitivity of a person to a treatment against hair loss and scalp disorders.

-A method of measuring the hair loss or hair growth from image data obtained from images taken of the four views of a patient's head comprising the steps of:

a) determining the number of pixels in an image having relatively dark intensities compared to other pixels in an image,

b) determining pixel number thresholds to quantify scoring, and

c) comparing the number of relatively dark pixels with the thresholds and/or a previous image and scoring the hair loss or hair growth in accordance therewith.

d) optionally measuring the variation or the difference between two images taken at different dates, and

e) deducing from said measure, the prognosis of the hair loss or hair growth.

The device in accordance with the principles of this invention contains a digital recording device (camera or equivalent), an access to the program, or a device that acquires a digital signal through other means. A zone of interest of a patient's head is imaged. When the method is applied, the end result will be a measurement or an assessment of hair loss or hair growth in at least one zone of interest of a patient's head.

In a particular embodiment of the present invention, the method of measuring the hair loss or hair growth is focused on at least one, two, three or four zone(s) of the patient's head.

Counting Grid

The counting grid defines areas for cell counting. FIG. 1 shows four designs of the counting grid that is suitable for cell counting. These four designs correspond to the four zones of interest: the left and right side of a patient's head, the top of the head and the back of the head.

In a particular embodiment, the counting grid is divided in at least 4 cells as shown in Fig.1 and the grid cells have either the same or different size or surface. The number of

cells per grid is comprised from 1 to 1000, preferably, 1, 2, 4, 10, 16, 20, 25, 50, 100, 200, 500 or 1000. For ease of manufacture, preferably the counting grid is incorporated into a grid film. The grid film is a transparent film with a grid pattern that defines the counting area. The most economical material for the grid film is a plastic film. The grid pattern may be formed by marking a plastic film or its equivalent by any techniques that are well known to those skilled in the art.

In a further embodiment the grid has a shape to adjust or frame one of the 4 parts of interest, chosen among the left or right side of the patient's head, the top of the head and the back of the head.

The grid is placed on the camera's screen or on the lens of the camera. The grid is either a disposal part of the camera or an integrated-application of the camera.

The counting grid filter or film thickness ranges from 10 micrometers to 1000 micrometers.

In another aspect, the present invention provides methods for measuring the hair loss or hair growth characterized in that it includes one or more of the following steps: (1) providing a digital image of at least one of the four zones of a patient's head; and (2) determining the amount of hair loss or hair growth by comparing or calculating any difference of the mass/density of hair in at least one of the four zones of a patient's head.

According to the present invention, the term "density" refers to the hair volume or global hair coverage

A particular and very important aspect of the invention is the use of the filter/counting grid of the invention in such a way to allow a standardization of the method, i.e the adjustment of the filter/counting grid independently of the size of the head and the distance between the photographer and the patient.

Another interest of the standardization of the image taking with filters/counting grids is that the homogeneity of the image will allow an automated analysis by an algorithm or artificial intelligence (machine learning).

The digital image of the patient's head may be displayed on a computer screen, and may preferably be manipulated using image processing software to enhance the accuracy of the methods described herein. The computer may then calculate the hair density based on the number of pixels that are attributed to the presence of hairs versus total number of pixels attributable to the entire image comprising areas without hairs.

In a particular embodiment of the invention, the layout and automatic adjustment of the filter/counting grid on the image is carried out by auto detection of the contours of the head without the need to do it manually by the investigator before the assessment of hair loss and scalp disorders.

In another embodiment of the invention, the assessment of hair loss and scalp disorders is carried out by the software using for example pixel contrast variation or more generally any automatic method known to the skilled artisan.

By "computer screen" is meant any manner of displaying a digital image. Other visible format that may be used to display the image include any type of electronic or light-based visualization system, including but not limited to, projection images, pixel-based imaging, high density imaging, and the like.

The term "image processing software" refers to a program that is capable of manipulating the elements making up a digital image. Numerous image processing programs are known to the skilled artisan.

A digital image of the patient's head to be analyzed may be provided by any suitable means. Persons of ordinary skill in the art are aware of various electronic devices,

usually associated with digital cameras or other magnifying devices, that are able to provide a digital image of the patient's head. While the data presented here were generated using specific instrumentation and image analysis software, persons of ordinary skill in the art will realize that equivalent instrumentation and image processing software with the same capabilities is available and known in the art. These instruments and software are also contemplated as embodiments of the present invention. The person of ordinary skill in the art will also realize that the image need not be displayed at all, but may be present within the computer, and analyzed by an automated or other process without being visually presented to the operator.

In order to be able to compare images taken over long periods of months and sometimes years, all images should have the same parameters, for example the picture size should be the same for all pictures to be comparable, preferably to a minimum of 500x 333-pixel per image, more preferably not less than 166x500-pixel per image.

In various embodiments, the digital image may be expressed as pixel elements or areas, and may preferably be displayed on a computer screen or other visual representation provided to the operator.

The present invention provides a semi-automated procedure for measuring the hair loss or hair growth from image data. A high degree of precision is attainable with the present methods, and coefficients of variation of less than 20% more preferably less than 10, 5 or 1% may easily be achieved. The methods are easily and rapidly performed, often with less than 1 minute per image being required. The present methods may also be performed at relatively modest cost making it accessible both in terms of costs and in terms of reach.

Indeed, the method may reach populations living in remote areas of the world allowing them to connect with hair science specialists in other parts of the world not available in such regions Thus another embodiment of the present invention is to provide a telemedicine solution to populations in need.

According to the present invention, the term “telemedecine” is the one defined by the WHO hereafter: “The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities”.

One of the particularities of the present method is to allow an easy, fully anonymized and secured storage of image files. Other than providing for a comparative evaluation, the present method represents a valuable tool for the scientific community involved in hair loss and scalp disorders. This method may serve potentially as an international collaborative database helping scientist in the field to build-up knowledge and exchange with their fellow researchers around the world.

The present invention provides a semi-automated or an automated method of measuring the hair loss or hair growth from image data characterized in that it includes determining the percent scalp hair loss or hair growth by determining the number of relatively dark image pixels compared to relatively bright image pixels and scoring the percent scalp hair loss or hair growth in accordance with the magnitude of the number of relatively dark pixels.

Practically, the determination of the percent scalp hair loss or hair growth is based on the combination of extent and density of scalp hair loss or hair growth. The score is determined by visually determining the amount of hair loss or hair growth in each of the four views of the scalp and adding these together with a maximum score of 100%.

When the image is processed, the number of relatively dark image pixels may be determined by transforming the image data to a different image space having an intensity image and counting the number of pixels having intensities below a predetermined intensity threshold.

The images captured by the camera according to the method of the invention, are processed by a computer or equivalent, more particularly by an image processing controller which includes a central processing unit (CPU) or processor, a memory, a user input device, a display, and an interface device which are coupled together. The processor in the image processing controller executes a program of stored instructions for one or more aspects of the present technology as described and illustrated by way of the examples and described with reference to FIG. 7, although other types and numbers of processing devices and logic could be used and the processor could execute other numbers and types of programmed instructions.

The memory in the image processing controller stores these programmed instructions for one or more aspects of the present technology as described and illustrated herein, although some or all of the programmed instructions could be stored and executed elsewhere. A variety of different types of memory storage devices, such as a random access memory (RAM) or a read only memory (ROM) in the system or other computer readable medium which is read from and written to by a magnetic, optical, or other reading and writing system that is coupled to the processor in the image processing

controller, can be used for the memory in the image processing controller. Data (images, report) may also be stored in the “cloud".

The user input device in the image processing controller is used to input data and/or selections, although the user input device could be used to input other types of requests and data and interact with other elements. The user input device can include keypads, touch screens, and/or vocal input processing systems although other types and numbers of user input devices can be used. The display in the image processing controller is a computer monitor, although other types and numbers of displays could be used. The interface device in the image processing controller is used to operatively couple and communicate between the image processing controller and the image capturing device.

Although an example of an image processing controller is described herein, it could be implemented on any suitable computer system or computing device. It is to be understood that the device of the example described herein is for exemplary purposes, as many variations of the specific hardware and software used to implement the examples are possible, as will be appreciated by those skilled in the relevant art(s).

Furthermore, the examples herein may be conveniently implemented using one or more general purpose computer systems, microprocessors, digital signal processors, and micro-controllers, programmed according to the teachings of the examples, as described and illustrated herein, and as will be appreciated by those ordinary skill in the art.

Image processing

The system and method for assessing hair loss and scalp disorders according to the present invention generally begins with acquiring at least one image preferably four images of the zones of interest of a patient’s head using any appropriate image acquisition device, for example a digital camera or a smartphone. The image acquisition

device may produce a digital image, such as that produced by a digital camera. The images of FIG. 6 and 7 are images of a section of human scalp.

The resulted digital images are processed using well-known image processing techniques to produce a segmented image. One example of a segmented image is a binary image. The segmented image is not limited to creating a binary image, but may also be multi-modal, i.e. differentiated into more than two different image codes corresponding to different features. The segmented image provides an improved and clearer image of the patient's head, however, it is still likely to contain certain "noise" that requires further filtering (e.g.: objects and artifacts that do not correspond to hair or scalp zone (zone lacking hair).

In order to assess the percentage or the quantity of hair loss or hair growth, the image processing controller may be able to identify and quantify areas of hair loss or hair growth in connection with a previous set of images of a given patient's head. An image database is created by taking at least four photographs of each patient using the standardized approach of the present invention to capture images.

The image processing controller is able to detect the pigmentation of the hair.

Because, hair pigmentation is a characteristic of the hair regrowth in alopecia areata, the possibility to detect unpigmented or pigmented hair re-growth may have prognostic implications

When the image is acquired, a region of interest could be the entire image or a selected sub-area of the entire image. In the example described herein, the selected region of interest is the image consisting of at least one cell of the counting grid of the present invention, or preferably a part or the entire filter/counting grid.

The region of interest may be selected by an operator or the selection may be automated by the system.

In another aspect, the present invention may provide an automated method of measuring the hair loss or hair growth from image data obtained from images taken of the four views of the patient's head characterized in that it includes the steps of:

a) determining the number of pixels in an image having relatively dark intensities compared to other pixels in an image,

b) determining pixel number thresholds to quantify scoring, and

c) comparing the number of relatively dark pixels with the thresholds and/or a previous image and scoring the hair loss or hair growth in accordance therewith.

d) optionally measuring the variation or the difference between two images taken at different dates, and

e) deducing from said measure, the prognosis of the hair loss or hair growth

In another aspect, the present invention comprises determining a diagnosis and/or prognosis for a patient with hair loss and scalp disorders by determining the hair density according to the methods of the present invention, and utilizing the said hair density or the calculated SALT score to determine the prognosis for a patient with hair loss and scalp disorders. In a preferred embodiment, a continuous regrowth of hairs may indicate a positive prognosis and a low regrowth of hairs may indicate a negative prognosis.

The phrase "determining the prognosis" as used herein refers to methods by which the skilled artisan can predict the course or outcome of a condition in a patient. The term "prognosis" does not refer to the ability to predict the course or outcome of a condition with 100% accuracy. Instead, the skilled artisan will understand that the term

"prognosis" refers to an increased probability that a certain course or outcome will occur; that is, that a course or outcome is more likely to occur in a patient exhibiting a given condition, when compared to those individuals not exhibiting the condition.

In another aspect of the present invention, the hair loss and scalp disorders are chosen among, but not limited to alopecia areata, androgenic alopecia, chemotherapy-induced alopecia, scarring alopecia, telogen or anagen effluvium, congenital hair disorders or other forms of hair loss, scalp tumors, hair pigmentation, disorders, psoriasis, seborrheic dermatitis, dandruff or other forms of scaly scalp, and scalp erythema.

The foregoing illustrated and described embodiments of the invention are susceptible to various modifications and alternative forms, and it should be understood that the invention generally, as well as the specific embodiments described herein, are not limited to the particular forms or methods disclosed, but to the contrary cover all modifications, equivalents and alternatives falling within the scope of the appended claims. By way of non-limiting example, it will be appreciated by those skilled in the art that the advantages obtained by the present invention in comparison with the SALT manual evaluation (as shown in Table 1) are considered within the scope of this invention as described and defined in the claims.

EXAMPLES of the use of the invention in a clinical trial on paediatric alopecia areata

1. Standardization of the photography for reliable, repeatable and reproducible SALT evaluations

For each patient, we collected four images representing different viewpoints (top, back, right, and left scalp), following the photographic guidelines given by the SALT score

The same parameters were used for all image views.

1.1. Global photographs of the four areas of the scalp will be taken at Visits 1, 2, 3, 4 and 5

Standardized and good quality photos are very important because:

- it makes software use easier
- It allows inter-and intra-individual comparisons

1.2. Subject's framing: Head position (Fig 3)

Four sides of scalp must be taken:

- The picture should be closely framed from the top of the head to the bottom of the chin
- Head angle:

  Vertical line between forehead and chin

  Keep looking straight ahead

1.3. Subject's framing with filters

Aim of filters:

-To standardize the framing independently of the distance

-To facilitate SALT grid adjustment during evaluation with the software

- In case where framing with filter is not possible, prefer to frame the whole head (from top to the chin) rather than adjust the grid

To adjust the grid, each corner should be adjusted to edge of the head, as far as possible

1.4. Subject –Photographer position (Fig 4/5)

Camera should be at same level of the subject head

(i.e. photographer sits on a chair)

1.5. Subject's hair style

Wear a hair-dressing cape or uniform blue patient gown.

•Long hair in a low ponytail. If areas of hair loss are hidden, change the grooming to make bald spots visible using hair clips.

Taking time to comb the hair is very important so that the location and relative size of the areas of hair loss can be tracked at subsequent visits

Ask to subject to remember grooming for next visits and Check last image to reproduce the same grooming

As much as possible, advice subject to try to keep comparable hair styling (hair color, hair length) during study

No earrings or glasses

Face anonymization is automatically done by the software

2. Determination of the SALT score (FIG 6/7)

SALT scoring – This calculation is based on a scoring system.

Scalp is divided into four areas: left side of scalp representing 18% of the scalp surface area, right side of scalp – 18% of scalp surface area; top - 40% of scalp surface area and back - 24% of scalp surface area. The percentage of hair loss in each of the four scalp areas is determined independently, each multiplied by its coefficient (left and right side: 0.18 each; top: 0.40 and back 0.24). The coefficient of each area varies according to the

location. Then the resulting hair loss percentages of all four areas are summed up for a final total % hair loss, designated as the SALT score. This method is suitable for clinical practice.

Olsen et al. also described a more precise SALT score assessment, more suitable for clinical trials. Each area is further subdivided into four quadrants (5%+4%+4%+5%; 10%+10%+10%+10% or 6%+6%+6%+6%) according to the scalp area, see Figure 7.

The percentage of hair loss in each quadrant is determined independently, each multiplied by its coefficient (0.04, 0.05, 0.06 or 0.1). The coefficient of each quadrant varies according to the location (Figure 7). Then the resulting hair loss percentages of all four areas (16 quadrants) are summed up for a final total percentage of hair loss, designated as the SALT score.

Due to the numerous calculation to obtain final SALT score and due to the variation of the coefficient depending on the area, manual SALT scoring is at risk of errors. Thanks to the software all calculations are automatic.

As an example of a patient (Figure 7)

Quadrant	% of hair loss estimated by the evaluator	Multiplier (= scalp surface)	Score in %
Left side (top picture)	0	0.05	0
	0	0.04	0
	0	0.04	0
	0	0.05	0
Right side (second picture)	0	0.04	0
	0	0.05	0
	0	0.05	0
	0	0.04	0
Top (third picture)	20	0.1	2
	5	0.1	0.5
	10	0.1	1
	0	0.1	0
Back (bottom picture)	15	0.06	0.9
	5	0.06	0.3
	0	0.06	0
	0	0.06	0
Total SALT Score			**4.7%**

Table 1: Comparison of the present invention with the manual evaluation

Criteria	Current SALT evaluation (manual)	SALT II (manual)	Invention
Standardization	• Not possible	• Not possible	• Grid to take picture • Software to assess
Duration of the assessment	• Quick image evaluation • Complex and time-consuming calculation	• Long image evaluation • More complex and time-consuming calculation	• Requires taking and uploading pictures • Quick image evaluation (and even quicker with the automatic

			evaluation module) • Quick and automatic calculation • Telemedicine possible: Remote evaluation (e.g. countryside…)
Risk of error in calculation	• High	• Very high	• None (automatic)
Scientific validation	• SALT score was published and is used as a validated endpoint in clinical trial	• Not validated	• Based on SALT score published and used as a validated endpoint in clinical trial
Repeatability and reproducibility	• Good if evaluation done by the same evaluator	• Must be done by the same evaluator	• Good if evaluation done by the same evaluator • Improved by the support of the virtual grid • Evaluation based on pictures allows the evaluator to carefully adjust the grid and assess the area

			• Allows double-checking by another evaluator (i.e in clinical trial) and/or re-evaluation
Follow-up	• Does not allow tracking individual lesions or small changes in density • Does not allow understanding whether SALT score at follow-up visits involves new untreated bald areas or just bald areas present since baseline	• Allows tracking individual lesions or small changes in density • Allows understanding whether SALT score at follow-up visits involves new untreated bald areas or just bald areas present since baseline	• Thanks to pictures, it allowstracking individual lesions or small changes in density • Allows understanding whether SALT score at follow-up visits involves new untreated bald areas or just bald areas present since baseline
Confidentiality	• No photo taken	• No photo taken	• Automatic anonymization of the subject
Comfort for Evaluator	• Not comfortable, the evaluator has to imagine the grid and take	• Not comfortable, the evaluator has to imagine a complex grid and	• Comfortable because the grid is virtually applied on the

	notes and calculate	take notes and calculate	pictures
Comfort for Subject	• Needs subject's presence	• Needs subject's presence • Longer consultation	• Subject's presence not needed since the evaluation is based on pictures
Storage	• No storage, no archives	• No storage, no archives	• Photos and report archived on any type of drive and available for consultation anytime anywhere

CLAIMS

1. A method of assessing hair loss and scalp disorders comprising:

a) capturing at least one image of a zone of interest of a patient's head by using a camera equipped with a filter/counting grid to be adjusted to a patient's head in order to frame one of the four zones of interest of a patient's head,

b) processing the images with an image analysis program to treat said images,

c) quantifying or evaluating the percentage of hair loss or hair growth in a patient using said program.

2. The method of assessing hair loss and scalp disorders according to claim 1, wherein the filter/counting grid comprises or consists in i) a filter/counting grid positioned on the screen of the camera on the display screen of a digital camera, or ii) a filter/counting grid positioned in front of the camera lens, or iii) a virtual grid integrated to the display of the camera.

3. The method of assessing hair loss and scalp disorders according to claim 1, wherein the filter/counting grid is adjusted to the patient's head independently of the size of the head and the distance between the photographer and the patient.

4. The method of assessing hair loss and scalp disorders according to claim 1, wherein the method further comprises storing the images of the four zones of interest of a patient's head, in a database.

5. The method of assessing hair loss and scalp disorders according to claim 1, wherein the processing of the images comprises:

detecting and calculating the density of the hairs based on the images of at least one of the four zones of interest of a patient's head.

6. The method of assessing hair loss and scalp disorders according to claim 1, wherein the method further comprises calculating the percentage of hair loss or hair growth in the

four images of the scalp corresponding to the left and right side of a patient's head, the top of the head and the back of the head.

7. The method of measuring the hair loss or hair growth according to claim 1, wherein the method is able to detect and quantify the pigmentation of hair.

8. A method of assessing hair loss and scalp disorders comprising, using a device that includes both a digital camera and a display screen, the method comprising the steps of:
a) installing a filter/counting grid on the display screen of a digital camera or in front of the camera lens or virtual grid integrated to the display of the camera;
b) capturing a first image of a patient's head with the device camera by framing the grid having at least one cell with the area of interest of the patient's head,
c) capturing a second image of said patient's head with the said device camera in the same conditions but at a different time;
d) comparing the images to make a prognosis concerning the loss or the growth of hair in the said patient

9. A system for detecting the scalp treatment efficacy of by means falling under data processing of image of the patient's head comprising:
a) subjecting a patient with a treatment for hair loss and scalp disorders,
b) installing a filter/counting grid on the display screen of a digital camera or in front of the camera lens;
c) capturing a least one image of a patient's head with the device camera by framing the grid having at least one cell with the area of interest of the patient's head,
d) producing at least one information related to the sensitivity of a person to a treatment against hair loss and scalp disorders.

10. A method of measuring the hair loss or hair growth from image data obtained from images taken of the four views of a patient's head comprising the steps of:
a) determining the number of pixels in an image having relatively dark intensities compared to other pixels in an image,

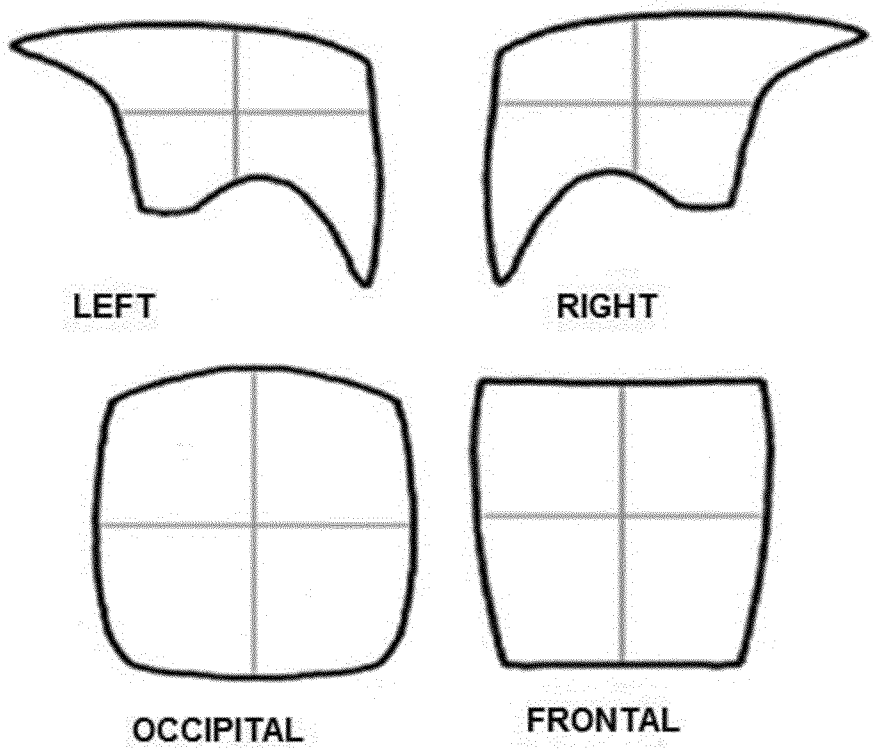
b) determining pixel number thresholds to quantify scoring, and

c) comparing the number of relatively dark pixels with the thresholds and/or a previous image and scoring the hair loss or hair growth in accordance therewith.

d) optionally measuring the variation or the difference between two images taken at different dates, and

e) deducing from said measure, the prognosis of the hair loss or hair grow

A



B

FIG.1

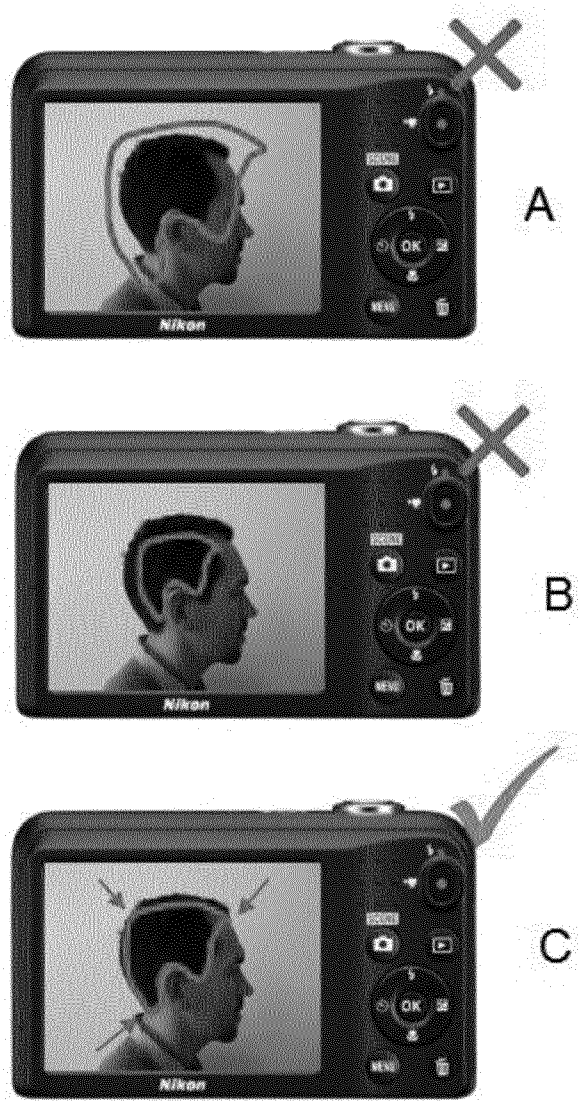
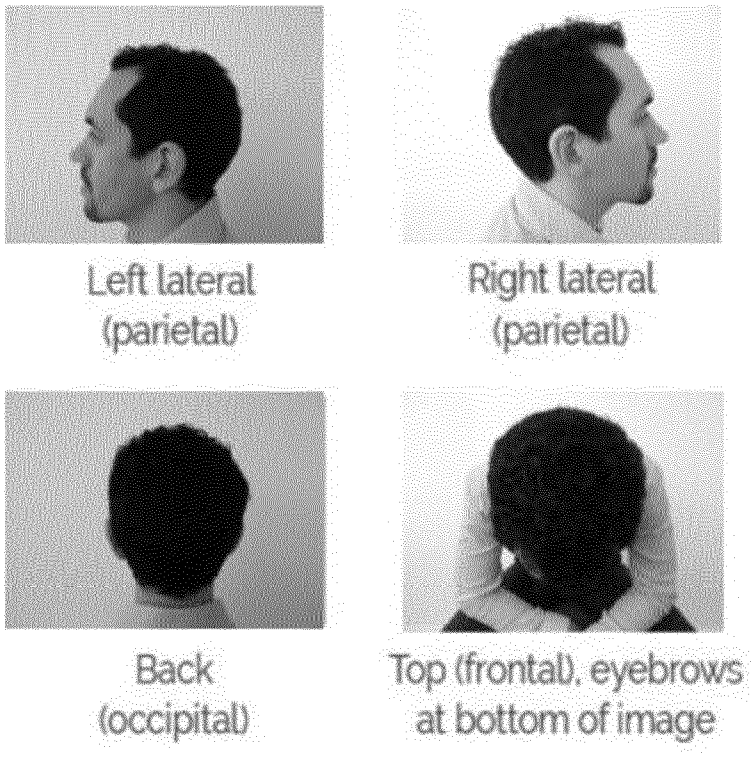


FIG. 2


Left lateral
(parietal)
Right lateral
(parietal)
Back
(occipital)
Top (frontal), eyebrows
at bottom of image

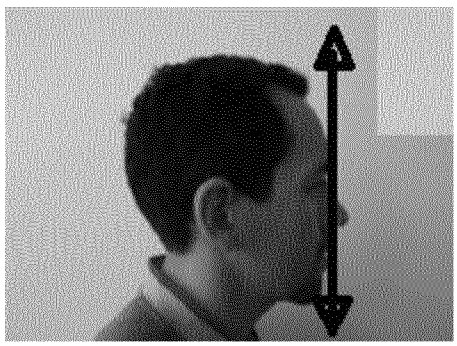
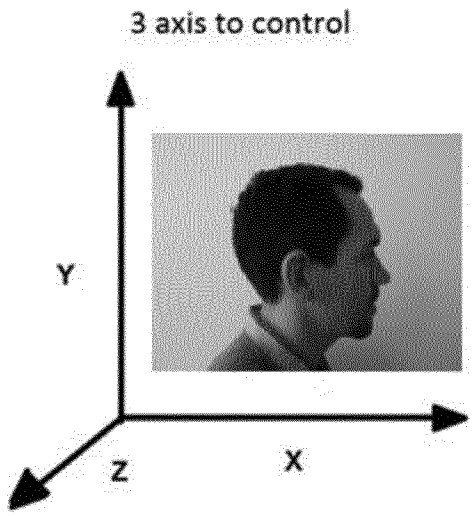


FIG. 3



X axis Y axis Z axis

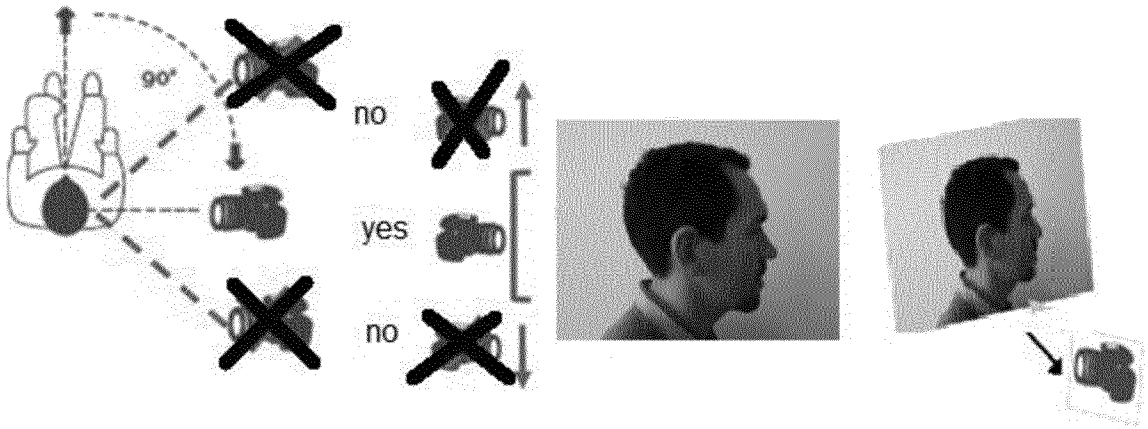


FIG. 4

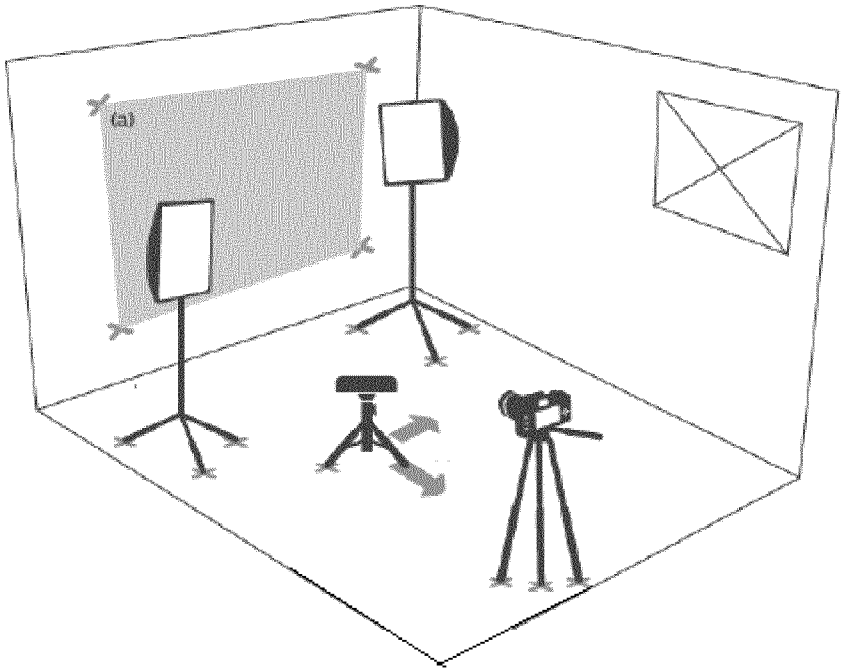


FIG. 5

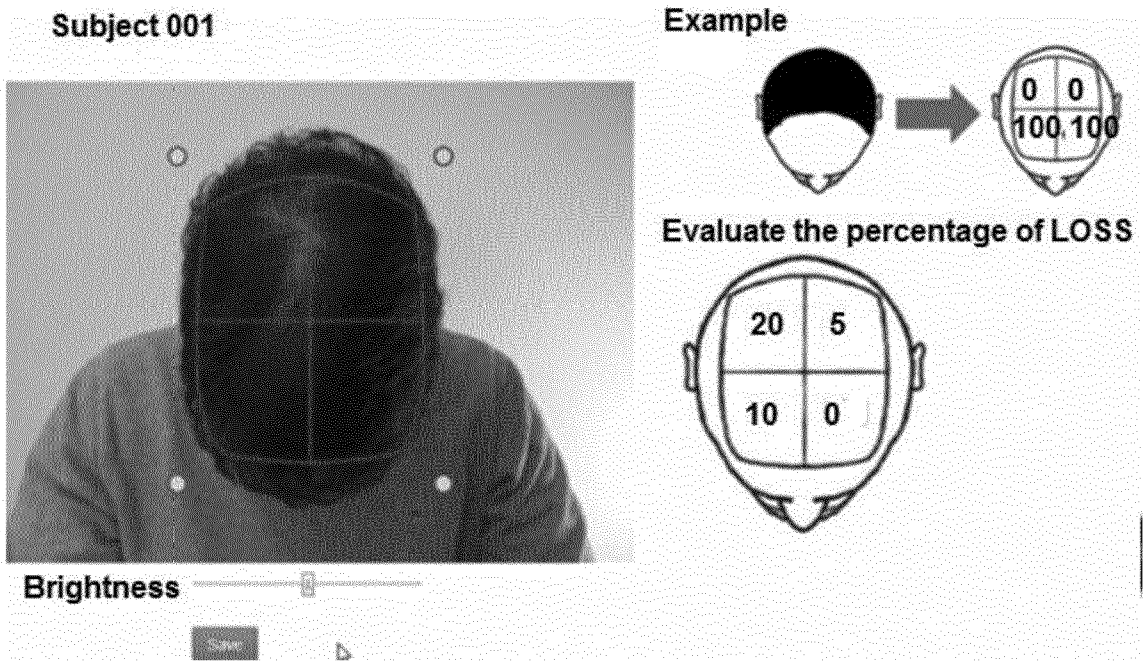

Subject 001
Brightness
Example
0 0
100 100
Evaluate the percentage of LOSS
20 5
10 0

FIG. 6

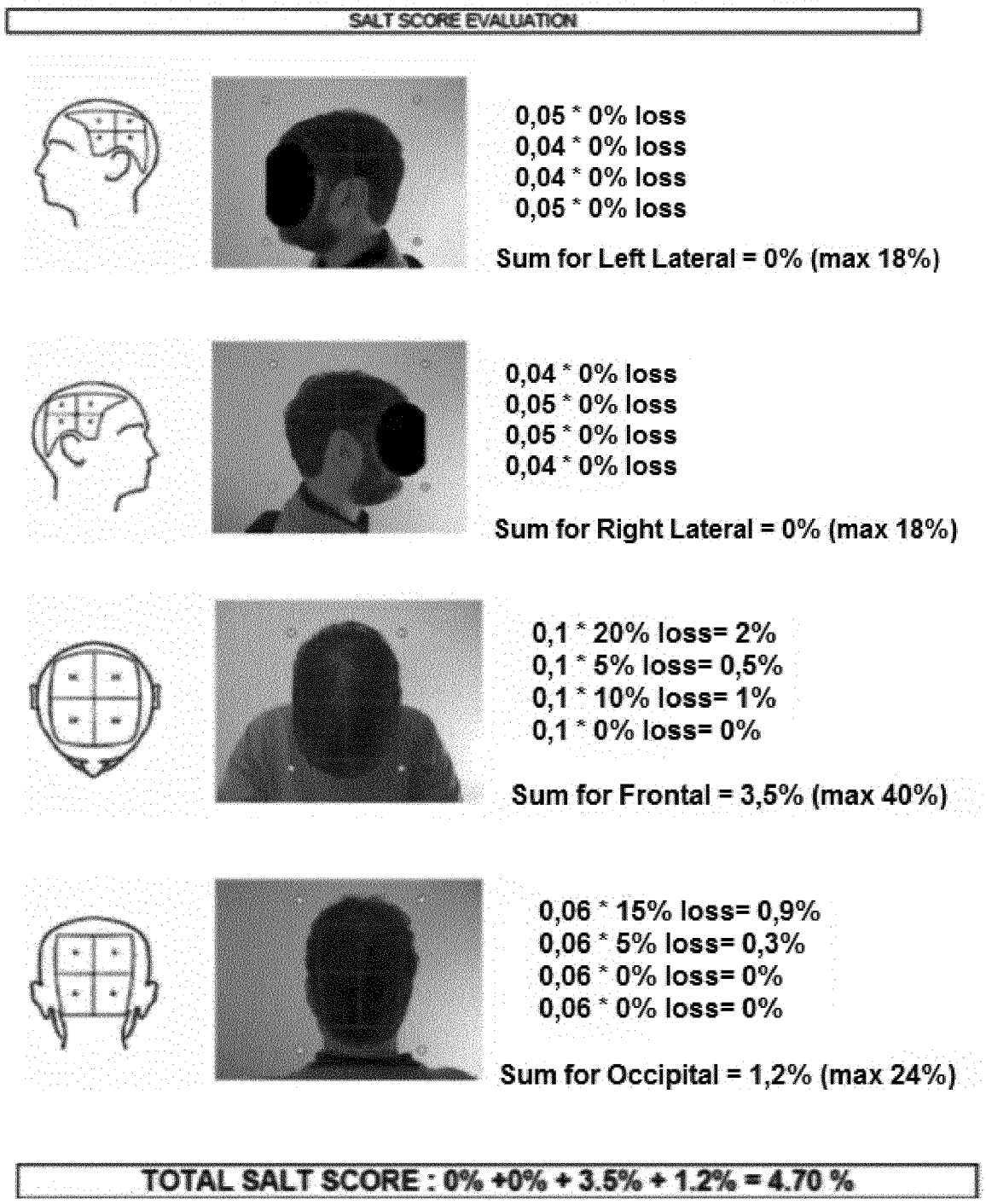

SALT SCORE EVALUATION
0,05 * 0% loss
0,04 * 0% loss
0,04 * 0% loss
0,05 * 0% loss
Sum for Left Lateral = 0% (max 18%)
0,04 * 0% loss
0,05 * 0% loss
0,05 * 0% loss
0,04 * 0% loss
Sum for Right Lateral = 0% (max 18%)
0,1 * 20% loss= 2%
0,1 * 5% loss= 0,5%
0,1 * 10% loss= 1%
0,1 * 0% loss= 0%
Sum for Frontal = 3,5% (max 40%)
0,06 * 15% loss= 0,9%
0,06 * 5% loss= 0,3%
0,06 * 0% loss= 0%
0,06 * 0% loss= 0%
Sum for Occipital = 1,2% (max 24%)
TOTAL SALT SCORE : 0% +0% + 3.5% + 1.2% = 4.70 %

FIG. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2018/050364

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00
ADD.

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)
A61B

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	OLSEN E A ET AL: "Alopecia areata investigational assessment guidelines-Part II", JOURNAL OF THE AMERICAN ACADEMY OF DERMATOL, MOSBY, INC, US, vol. 51, no. 3, 1 September 2004 (2004-09-01), pages 440-447, XP004561275, ISSN: 0190-9622, DOI: 10.1016/J.JAAD.2003.09.032 figure 2 paragraphs [0A.4], [00C.], [0D.3], [0D.6]	1-8
X	US 2017/032223 A1 (ZINGARETTI GABRIELE [US] ET AL) 2 February 2017 (2017-02-02) figure 4 paragraphs [0056], [0062]	1-8

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" 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)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" 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

"X" 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

"Y" 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

Date of the actual completion of the international search	Date of mailing of the international search report
21 September 2018	07/12/2018

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Brendemühl, S

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2018/050364

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	OLSEN ELISE A ET AL: "SALT II: A new take on the Severity of Alopecia Tool (SALT) for determining percentage scalp hair loss", JOURNAL OF THE AMERICAN ACADEMY OF DERMATOLOGY, MOSBY, INC, US, vol. 75, no. 6, 12 November 2016 (2016-11-12), pages 1268-1270, XP029808565, ISSN: 0190-9622, DOI: 10.1016/J.JAAD.2016.08.042 figure 1 -----	1

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2018/050364

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-8

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-8

   filter or grid; to aid identifying the four views
   ---

2. claim: 9

   produce information related to sensitivity to treatment; to detect scalp treatment efficacy
   ---

3. claim: 10

   calculate number of pixels with darkness above a threshold, compare over time; to produce a prognosis of hair loss
   ---

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2018/050364

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2017032223 A1	02-02-2017	US 2017032223 A1	02-02-2017
		US 2018271456 A1	27-09-2018
		WO 2017019437 A1	02-02-2017