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(54) **Method and system for characterization and mapping of tissue lesions**

Verfahren und System zur Charakterisierung und Abbildung von Gewebeläsionen

Procédé et système pour la caractérisation et la cartographie des lésions de tissu

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- **BALAS C ET AL: "IN VIVO ASSESSMENT OF ACETIC ACID-CERVICAL TISSUE INTERACTION USINGQUANTITATIVE IMAGING OF BACK-SCATTERED LIGHT: ITS POTENTIAL USE FORTHE IN VIVO CERVICAL CANCER DETECTION GRADING AND MAPPING" PROCEEDINGS OF THE SPIE, SPIE, BELLINGHAM, VA , US, vol. 3568, 1 January 1999 (1999-01-01), pages 31-37, XP001011384 ISSN: 0277-786X**

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Description

Field of the Invention

[0001] The present invention is directed to apparatus for the *in vivo*, non-invasive detection and mapping of the biochemical and/or functional pathologic alterations of human tissues.

Background of the Invention

[0002] Cancer precursor signs are the so-called pre-cancerous states, which are often curable if they are detected at an early stage. If left untreated, the pre-cancerous state can develop into invasive cancer, which can subsequently metastasize. At this stage, the possibilities of successful therapy are dramatically diminished. Consequently, the early detection and the objective identification of the severity of the pre-cancerous state are of crucial importance.

[0003] Conventional methods that utilize optical instruments are very limited in their ability to detect cancerous and pre-cancerous tissue lesions. This is due to the fact that the structural and metabolic changes, which take place during the development of the disease, do not significantly and specifically alter the spectral characteristics of the pathological tissue.

[0004] In order to obtain a more accurate diagnosis, biopsy samples are obtained from suspicious areas, which are submitted for histological examination. However, biopsies pose several problems, such as a) a risk for sampling errors associated with the visual limitations in detecting and localizing suspicious areas; b) a biopsy can alter the natural history of the intraepithelial lesion; c) mapping and monitoring of the lesion require multiple tissue sampling, which is subjected to several risks and limitations; and d) the diagnostic procedure performed with biopsy sampling and histologic evaluation is qualitative, subjective, time consuming, costly and labor intensive.

[0005] In recent years, a few methods and systems have been developed to overcome the disadvantages of the conventional diagnostic procedures. These methods can be classified into two categories: a) methods which are based on the spectral analysis of tissues in vivo, in an attempt to improve the diagnostic information, and b) methods which are based on the chemical excitation of tissues with the aid of special agents, which can interact with pathologic tissue and alter its optical characteristics selectively, thus enhancing the contrast between lesion and healthy tissue.

[0006] In the first case, the experimental use of spectroscopic techniques has been motivated by the ability of these techniques to detect alterations in the biochemical and/or the structural characteristics of tissue as the disease progresses. In particular, fluorescence spectroscopy has been extensively used in various tissues. With the aid of a light source (usually laser) of short wave length (blue - ultraviolet range), the tissue is first excited. Next, the intensity of the fluorescent light emitted by the tissue as a function of the wavelength of the light is measured.

[0007] Garfield and Glassman in Patent No. US 5,450,857 and Ramanajum et al. in Patent No. US 5,421,339 have presented a method based on the use of fluorescence spectroscopy for the diagnosis of cancerous and pre-cancerous lesions of the cervix. The main disadvantage of fluorescence spectroscopy is that the existing biochemical modifications associated with the progress of the disease are not manifested in a direct way as modifications in the measured fluorescence spectra. The fluorescence spectra contain limited diagnostic information for two basic reasons: a) Tissues contain non-fluorescent chromophores, such as hemoglobin. Absorption by such chromophores of the emitted light from fluorophores can result in artificial dips and peaks in the fluorescence spectra. In other words the spectra carry convoluted information for several components and therefore it is difficult assess alterations in tissue features of diagnostic importance; and b) The spectra are broad because a large number of tissue components are optically excited and contribute to the measured optical signal. As a result, the spectra do not carry specific information of the pathologic alterations and thus they are of limited diagnostic value. In short, the aforementioned fluorescent technique suffers from low sensitivity and specificity in the detection and classification of tissue lesions.

[0008] Aiming to enhance the sensitivity and specificity of the preceding method, Ramanujan et al. in the Patent No. WO 98/24369 have presented a method based on the use of neural networks for the analysis of the spectral data. This method is based on the training of a computing system with a large number of spectral patterns, which have been taken from normal and from pathologic tissues. The spectrum that is measured each time is compared with the stored spectral data, facilitating in this way the identification of the tissue pathology.

[0009] R.R. Kortun et al, in Patent No. US 5,697,373, seeking to improve the quality of the measured diagnostic information, have presented a method based on the combination of fluorescence spectroscopy and Raman scattering. The latter has the ability of providing more analytical information; however, Raman spectroscopy requires complex instrumentation and ideal experimental conditions, which substantially hinders the clinical use thereof.

[0010] It is generally known that tissues are characterized by the lack of spatial homogeneity. Consequently the spectral analysis of distributed spatial points is insufficient for the characterization of their status.

[0011] Dombrowski in Patent No. US 5,424,543, describes a multi-wavelength, imaging system, capable of capturing tissue images in several spectral bands. With the aid of such a system it is possible in general to map characteristics of diagnostic importance based on their particular spectral characteristics. However, due to the

insignificance of the spectral differences between normal and pathologic tissue, which is in general the case, inspection in narrow spectral bands does not allow the highlighting of these characteristics and even more so, the identification and staging of the pathologic area.

[0012] D.R. Sandison et al., in Patent No. US 5,920,399, describe an imaging system, developed for the *in vivo* investigation of cells, which combines multiband imaging and light excitation of the tissue. The system also employs a dual fiber optic bundle for transmitting light from the source to the tissue, and then from the tissue to an optical detector. These bundles are placed in contact with the tissue, and various wavelengths of excitation and imaging are combined in attempt to enhance the spectral differentiation between normal and pathologic tissue.

[0013] In Patent No. US 5,921,926, J.R. Delfyett et al. have presented a method for the diagnosis of diseases of the cervix, which is based on the combination of Spectral Interferometry and Optical Coherence Tomography (OCT). This system combines three-dimensional imaging and spectral analysis of the tissue.

[0014] Moreover, several improved versions of colposcopes have been presented, (D.R.Craine et al., Patent No. US 5,791,346 and K.L. Blaiz Patent No. US 5,989,184) in most of which, electronic imaging systems have been integrated for image capturing, analysis of tissue images, including the quantitative assessment of lesion's size. For the enhancement of the optical differentiation between normal and pathologic tissue, special agents are used in various fields of biomedical diagnostics, which are administered topically or systematically. Such agents include acetic acid solution, toluidine blue, and various photosensitizers (porphyrines) (S. Anderson Engels, C. Klinteberg, K. Svanberg, S. Svanberg, In vivo fluorescence imaging for tissue diagnostics, Phys Med. Biol. 42 (1997) 815-24). The selective staining of the pathologic tissue arises from the property of these agents to interact with the altered metabolic and structural characteristics of the pathologic area. This interaction enhances progressively and reversibly the differences in the spectral characteristics of reflection and/or fluorescence between normal and pathologic tissue. Despite the fact that the selective staining of the pathologic tissue is a dynamic phenomenon, in clinical practice the intensity and the extent of the staining are assessed qualitatively and statically. Furthermore, in several cases of early pathologic conditions, the phenomenon of temporary staining after administering the agent, is short-lasting and thus the examiner is not able to detect the alterations and even more so, to assess their intensity and extent. In other cases, the staining of the tissue progresses very slowly, resulting in patient discomfort and the creation of problems for the examiner in assessing the intensity and extent of the alterations, since they are continuously changing. The above have as direct consequence the downgrading of the diagnostic value of these diagnostic procedures. Thus, their usefulness is limited to facilitating the localization of suspected areas for obtaining biopsy samples.

[0015] Summarizing the above, the following conclusions are drawn:

a) Various conventional light dispersion spectroscopic techniques (fluorescence, elastic, non-elastic scattering, etc.) have been proposed and experimentally used for the *in vivo* detection of alterations in the structural characteristics of pathologic tissue. The main disadvantage of these techniques is that they provide point information, which is inadequate for the analysis of the spatially non-homogenous tissue. Multi-band imaging has the potential to solve this problem by providing spectral information, of lesser resolution as a rule, in any spatial point of the area under examination. These imaging and non-imaging techniques, however, provide information of limited diagnostic value because the structural tissue alterations, which accompany the development of the disease, are not manifested as significant and characteristic alterations in the measured spectra. Consequently, the captured spectral information cannot be directly correlated with the tissue pathology, a fact that limits the clinical usefulness of these techniques.

b) The conventional (non-spectral) imaging techniques provide the capability of mapping characteristics of diagnostic importance in two or three dimensions. They are basically used for measuring morphological characteristics and as clinical documentation tools.

c) The diagnostic methods that are based on the selective staining of pathologic tissue with special agents allow the enhancement of the optical contrast between normal and pathologic tissue. Nevertheless they provide limited information for the in vivo identification and staging of the disease.

[0016] The selective interaction of pathologic tissue with the agents, which enhance the optical contrast with healthy tissue, is a dynamic phenomenon. It is therefore reasonable to suggest that the measurement and analysis of kinetic properties could provide important information for the *in vivo* detection, identification and staging of tissue lesions. In a previous publication, in which one of the inventors is a co-author, (C. Balas, A. Dimoka, E. Orfanoudaki, E. koumandakis, "In vivo assessment of acetic acid-cervical tissue interaction using quantitative imaging of back-scattered light: Its potential use for the in vivo cervical cancer detection grading and mapping", SPIE-Optical Biopsies and Microscopic Techniques, Vol. 3568 pp. 31-37, (1998)), measurements of the alterations in the characteristics of the back-scattered light as a function of wave-length and time are presented. These alterations occur in the cervix by the topical administration of acetic acid solution. In this particular case, a general-purpose multi-spectral imaging system built around a tun-

able liquid crystal monochromator was used for measuring the variations in intensity of the back-scattered light as a function of time and wavelength at selected spatial points. It was found that the lineshapes of curves of intensity of back-scattered light versus time provide advanced information for the direct identification and staging of tissue neoplasias. Unpublished results of the same research team indicate that similar results can also be obtained with other agents, which have the property of enhancing the optical contrast between normal and pathologic tissue. Nevertheless, the experimental method employed in the published paper is characterized by quite a few disadvantages, such as: The imaging monochromator requires time for changing the imaging wavelength and as a consequence it is inappropriate for multispectral imaging and analysis of dynamic phenomena. It does not constitute a method for the mapping of the grade of the tissue lesions, as the presented curves illustrate the temporal alterations of intensity of the back-scattered light in selected points. The lack of data modeling and parametric analysis of kinetics data in any spatial point of the area of interest restricts the usefulness of the method in experimental studies and hinders its clinical implementation. The optics used for the imaging of the area of interest is of general purpose and does not comply with the special technical requirements for the clinical implementation of the method. Clinical implementation of the presented system is also hindered by the fact that it does not integrate appropriate means for ensuring the stability of the relative position between the tissue surface and image capturing module during the snapshot imaging procedure. This is very important since small movements of the patient (i.e. breathing) are always present during the examination procedure. If, after the application of the agent, micro-movements occur while an image is being recorded, then the spatial features of the captured images may not be accurate. This may substantially reduce the accuracy of the calculation of the curves in any spatial point that express the kinetics of marker-tissue interaction.

Summary of the Invention

[0017] The present invention is defined in the claims.

[0018] In certain embodiments, microscopes used in clinical diagnostic examinations, surgical microscopes and colposcopes may include a reflective objective lens that replaces a refractive lens. The reflective objective lens is contracted so that a second reflection mirror is disposed in the central part of its optical front aperture. In the rear, non-reflective part of this mirror, illumination means are attached from which light is emitted toward the object. With or without illumination zooming and focusing optics, the central ray of the emitted light cone is coaxial with the central ray of the light beam that enters the imaging lens. With the aid of illumination zooming and focusing optics, which may be adjusted simultaneously and automatically with the mechanism for varying the magnification of the optical imaging system, the illuminated area and the field-of-view of the imaging system can vary simultaneously and proportionally. Any decrease in image brightness caused by increasing the magnification is compensated with the simultaneous zooming and focusing of the illumination beam.

[0019] Other features and advantages of the invention will be apparent from the following detailed description and claims.

Brief Description of the Drawing

[0020] Figure 1 illustrates an optical imaging apparatus which comprises a light source located at the central part of its front-aperture.

Detailed Description of the Invention

[0021] The present invention is directed to an optical imaging apparatus comprising a) a reflective objective lens (RO) incorporating a first reflection mirror (1 RM) and a second reflection mirror (2RM) wherein the second reflection mirror (2RM) is disposed in the central part of the optical front aperture of the reflective objective lens (RO); and b) illumination means (LS) disposed at the rear of the second reflection mirror (2RM) in a manner such that the central ray of the light cone emitted from the illumination means (LS) is coaxial with the central ray of the light beam that enters the reflective objective lens (RO) following reflection of the emitted light by a tissue (T) surface under examination.

[0022] Sources of light for illuminating the tissue include light emitting diodes, and lasers.

[0023] For the clinical use of the invention, the different implementations of imaging can be integrated to conventional optical imaging diagnostic devices. Such devices are the various medical microscopes, colposcopes and endoscopes, which are routinely used for the *in vivo* diagnostic inspection of tissues. Imaging of internal tissues of the human body requires in most cases the illumination and imaging rays to travel along the same optical path, through the cavities of the body. As a result, in the common optical diagnostic devices the tissue's surface reflection contributes substantially to the formed image. This limits the imaging information for the subsurface characteristics, which is in general of great diagnostic importance. This problem becomes especially serious in epithelial tissues such as the cervix, larynx, and oral cavity, which are covered by fluids such as mucus and saliva. Surface reflection also obstructs the detection and the measurement of the alterations in the tissue's optical properties, induced after the administration of agents, which enhance the optical contrast between normal and pathologic tissue. More specifically, when an agent alters selectively the scattering characteristics of the pathologic tissue, the strong surface reflection that takes place in both pathologic (agent responsive) and normal (agent non responsive) tissue areas, occludes the diagnostic

signal that originates from the interaction of the agent with the subsurface features of the tissue. In other words, surface reflection constitutes optical noise in the diagnostic signal degrading substantially the perceived contrast between agent responsive and agent non-responsive tissue areas.

[0024] For accurate diagnoses using the aforementioned imaging devices, appropriate optics can be used to eliminate noise arising from surface reflection.

[0025] The diagnostic examination of non-directly accessible tissues located in cavities of the human body (ear, cervix, oral cavity, esophagus, colon, stomach) is performed with the aid of common clinical microscopes. In these devices, the illumination-imaging rays are near co-axial. More specifically, the line perpendicular to the exit point of light into the air, and the line perpendicular to the objective lens, form an angle of a few degrees. As a result, these microscopes operate at a specific distance from the subject (working distance), where the illuminated tissue area coincides with the field-of-view of the imaging system. These microscopes are found to be inappropriate in cases where tissue imaging through human body cavities of small diameter and at short working distances is required. These technical limitations hinder the successful clinical implementation of the method described herein. As discussed above, elimination of surface reflection results in a substantial improvement of the diagnostic information obtained from the quantitative assessment of marker-tissue interaction kinetics. If a common clinical microscope is employed as the optical imaging module, then as a result of the above-mentioned illumination-imaging geometry, multiple reflections occur in the walls of the cavity before the light reaches the tissue under analysis. Multiple reflections are more numerous in colposcopy because of the highly reflective blades of the speculum, which is inserted into the vagina to facilitate the inspection of the cervix. • If the illuminator of the imaging apparatus emits linearly polarized light, the multiple reflections randomize the polarization plane of the incident light. As discussed above, if the light impinging on the tissue is not linearly polarized, then the elimination of the contribution from the surface reflection to the image can not be effective.

[0026] Figure 1 illustrates an optical imaging apparatus that includes a light source located at the central part of its front-aperture. With this arrangement, the central ray of the emitted light cone is coaxial with the central ray of the light beam that enters the imaging apparatus. This enables illumination rays to directly reach the tissue surface under examination before multiple reflections occur with the wall of the cavity or speculum. A reflective-objective lens is used, which includes a first reflection (1RM) and a second reflection (2RM) mirror. A light source (LS) is disposed at the rear of the second reflection mirror (2RM), together with, if required, optics for light beam manipulation such as zooming and focusing (SO). The reflective-objective lens (RO), by replacing the common refractive-objective used in conventional microscopes, provides imaging capability in cavities of small diameter with the freedom of choosing the working distance. The zooming and focusing optics of the light beam can be adjusted simultaneously with the mechanism for varying the magnification of the optical imaging system so that the illumination area and the field-of-view of the imaging system vary simultaneously and proportionally. Thus, image brightness is preserved regardless of the magnification level of the lens. The imaging-illumination geometry embodied in this optical imaging apparatus, along with the light beam manipulation options, helps to eliminate the surface reflection contribution to the image and consequently helps to efficiently implement the method described herein.

Equivalents

[0027] Those skilled in the art will recognize, or be able to ascertain using no more than routine experimentation, many equivalents to the specific embodiments of the invention described herein. Such equivalents are intended to be encompassed by the following claims.

Claims

1. An optical imaging apparatus comprising

   a) a reflective objective lens (RO) incorporating a first reflection mirror (1 RM) and a second reflection mirror (2RM) wherein the second reflection mirror (2RM) is disposed in the central part of the optical front aperture of the reflective objective lens (RO); and

   b) illumination means (LS) disposed at the rear of the second reflection mirror (2RM) in a manner such that the central ray of the light cone emitted from the illumination means (LS) is coaxial with the central ray of the light beam that enters the reflective objective lens (RO) following reflection of the emitted light by a tissue (T) surface under examination.

2. The optical imaging apparatus of claim 1 wherein the illumination means comprises a light emitting diode.

3. The optical imaging apparatus of claim 1 or 2 further comprising optics (SO) for light beam manipulation.

4. The optical imaging apparatus of claim 3 wherein the optics (SO) for light beam manipulation permit zooming and focussing of the light beam.

5. A microscope or colposcope comprising the optical imaging apparatus of any of claims 1 to 4.

6. The microscope of claim 5 which is a surgical micro-

scope or a microscope used in clinical diagnostic examinations.

Patentansprüche

1. Optische Abbildungsvorrichtung, die Folgendes aufweist:

   a) eine reflektierende Objektivlinse (RO), die einen ersten Reflexionsspiegel (1 RM) und einen zweiten Reflexionsspiegel (2RM) aufnimmt, wobei der zweite Reflexionsspiegel (2RM) im zentralen Teil der optischen Vorderöffnung der reflektierenden Objektivlinse (RO) angeordnet ist; und
   b) ein Beleuchtungsmittel (LS), das an der Rückseite des zweiten Reflexionsspiegels (2RM) so angeordnet ist, dass der zentrale Strahl des von dem Beleuchtungsmittel (LS) abgegebenen Lichtkegels koaxial mit dem zentralen Strahl des Lichtstrahls ist, der in die reflektierende Objektivlinse (RO) nach Reflexion des abgegebenen Lichts von einer untersuchten Fläche eines Gewebes (T) eintritt.

2. Optische Abbildungsvorrichtung nach Anspruch 1, wobei das Beleuchtungsmittel eine Lichtemitterdiode aufweist.

3. Optische Abbildungsvorrichtung nach Anspruch 1 oder 2, die des Weiteren eine Optik (SO) zur Lichtstrahlverarbeitung aufweist.

4. Optische Abbildungsvorrichtung nach Anspruch 3, wobei die Optik (SO) zur Lichtstrahlverarbeitung eine Ausschnittsvergrößerung und Scharfstellung des Lichtstrahls erlaubt.

5. Mikroskop oder Kolposkop, mit der optischen Abbildungsvorrichtung nach einem der Ansprüche 1 bis 4.

6. Mikroskop nach Anspruch 5, das ein Operationsmikroskop oder ein Mikroskop, das in klinischen Diagnoseuntersuchungen verwendet wird, ist.

Revendications

1. Appareil d'imagerie optique, comprenant :

   a) une lentille d'objectif réflectrice (RO) incorporant un premier miroir de réflexion (1RM) et un deuxième miroir de réflexion (2RM), où le deuxième miroir de réflexion (2RM) est disposé dans la partie centrale de l'ouverture frontale optique de la lentille d'objectif réflectrice (RO) ; et
   b) un moyen d'éclairage (LS) disposé à l'arrière du deuxième miroir de réflexion (2RM) de telle sorte que le rayon central du cône de lumière émis par le moyen d'éclairage (LS) est coaxial avec le rayon central du faisceau de lumière qui entre dans la lentille d'objectif réflectrice (RO) à la suite de la réflexion de la lumière émise par une surface de tissu (T) sous examen.

2. Appareil d'imagerie optique selon la revendication 1, dans lequel le moyen d'éclairage comprend une diode d'émission de lumière.

3. Appareil d'imagerie optique selon la revendication 1 ou 2, comprenant en outre des optiques (SO) pour la manipulation du faisceau de lumière.

4. Appareil d'imagerie optique selon la revendication 3, dans lequel les optiques (SO) pour la manipulation du faisceau de lumière permettent le zoom et la focalisation du faisceau de lumière.

5. Microscope ou colposcope comprenant l'appareil d'imagerie optique selon l'une quelconque des revendications 1 à 4.

6. Microscope selon la revendication 5, qui est un microscope chirurgical ou un microscope utilisé pour des examens de diagnostic cliniques.

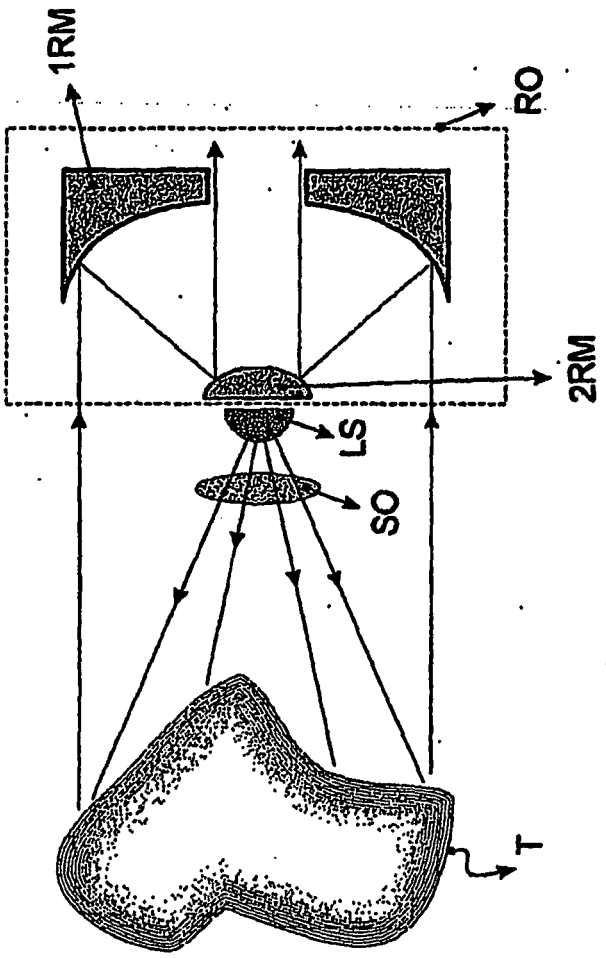

Figure 1

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	用于表征和绘制组织病变的方法和系统		
公开(公告)号	EP2057936B1	公开(公告)日	2014-05-07
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当前申请(专利权)人(译)	FORTH PHOTONICS LIMITED		
[标]发明人	BALAS KONSTANTINOS PELECOUDAS DEMETRIOS		
发明人	BALAS, KONSTANTINOS PELECOUDAS, DEMETRIOS		
IPC分类号	A61B1/303 A61B5/00 G01N21/64 A61B1/00 A61B1/267 A61B1/273 A61B1/307 A61B1/31 A61B10/00 G01N21/27 G01N21/65 G01N21/75 G01N33/15 G01N33/48		
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其他公开文献	EP2057936A1		
外部链接	Espacenet		

摘要(译)

一种光学成像设备，包括反射物镜，其包括第一反射镜，第二反射镜和设置在第二反射镜后部的照明装置，使得从照明装置发射的光锥的中心光线是同轴的在检查后的组织表面反射发射的光之后，光束的中心光线进入反射物镜。光学成像设备可以结合到显微镜或阴道镜中。

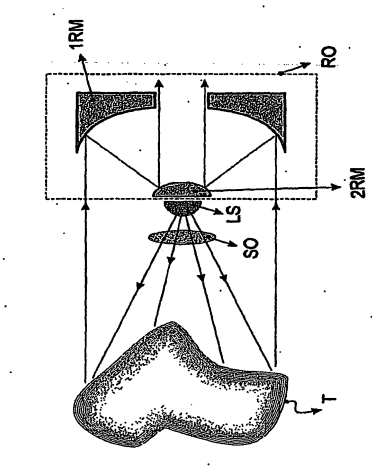

Figure 1