of the stent is carried out by way of a movably mounted spray mandrel, which is inserted into the sleeve provided with the stent.

The coating methods and apparatuses of the prior art have the disadvantage that the differentiated application of the coatings to the luminal and abluminal sides of the stent is not possible or difficult. In addition, separately applied luminal or abluminal coatings frequently have lower stability, so that they can become detached from the implant in an uncontrolled manner.

A first aspect of the invention relates to the provision of a device for coating a stent, comprising a holder for the stent, a spraying unit with a spray mandrel and an air nozzle. The spray mandrel, the air nozzle and the holder are designed and disposed relative to each other such that the spray mandrel projects from one side into the stent during coating and the air nozzle projects into the stent from the opposing side.

A further aspect of the invention relates to the provision of a method for coating a stent, comprising the following steps:

a) providing the aforementioned device for coating the stent;
b) coating the luminal side of the stent by introducing a spray jet via the spray mandrel and an air flow via the air nozzle such that the spray jet is deflected radially outwardly by the air flow in the counterflow region;
c) displacing a position of the counterflow region relative to the stent by at least one of the measures selected from moving the stent, moving the spray mandrel, moving the air nozzle, regulating the spray jet and regulating the air flow.

The invention is based on the realization that luminal and/or abluminal coatings can be achieved in a very simple and reliable manner using a spraying method in which a counterflow is generated by means of an air nozzle. For this purpose, the device comprises a spraying unit comprising a spray mandrel, the outside diameter of which is smaller than the inside diameter of the stent. Moreover, an air nozzle is present, the outside diameter of which likewise is smaller than the inside diameter of the stent. During the coating process, the stent is accommodated by a holder such that the lateral openings of the stent are

accessible and the lateral walls are not shielded. The spray mandrel is then inserted into the stent from one side and the air nozzle from the opposing side. During the coating process, a spray jet is generated by the spray mandrel and an air flow is directed at this spray jet by the air nozzle. In the region where the spray jet and air flow meet (which here is referred to as the counterflow region), the spray jet is deflected radially outwardly and thus coats the luminal surface of the stent in this region. Using different measures, it is now possible to vary the counterflow region relative to the position of the stent, whereby locally differentiated luminal coating of the stent is possible. These measures include moving the stent, the spray mandrel or the air nozzle and regulating the spray jet and air flow. The coating method according to the invention results in a form-fitting, mechanically very stable coating.

The device is preferably designed such that the position of the stent relative to the spray mandrel and the air nozzle can be varied during coating. The holder is notably designed such that, during coating, the stent can be moved in the direction of the spray mandrel or in the direction of the air nozzle. In other words, according to this variant the stent is moved along an axis formed by the spray mandrel and air nozzle by means of the holder during the coating process. The adjustments of the position and flow rate in the counterflow region can be determined in this region particularly easily by experiments and simplify the implementation of the method in the industrial manufacturing process.

It is further preferred for the spraying unit to comprise a spray nozzle, which is directed at an abluminal side of the stent. According to an associated variant of the method, in step a) a device for coating the stent is provided, in which the spraying unit comprises such a spray nozzle, which is directed at an abluminal side of the stent. The abluminal coating can be carried out simultaneously with the aforementioned luminal coating (ii), before that (i) or (iii) thereafter. For simultaneously coating the abluminal side of the stent, a spray jet of the spray nozzle is directed at the counterflow region while steps b) and c) are carried out. Abluminal coating, however, can also be carried out before or after the luminal coating process, wherein a spray jet is directed at the outside of the stent. The quantity of coating material inadvertently reaching the luminal surface can optionally be reduced by an air

flow from the air nozzle, or by a counterflow region, which is generated by means of an air nozzle and a spray mandrel that is operated without active agent.

In keeping with the aforementioned descriptions, according to this variant the spraying unit of the device according to the invention comprises an additional spray nozzle, which is directed at the outside of the stent. Over the course of the abluminal coating step, the flow that is radially directed outwardly in the counterflow region can largely prevent coating material for the abluminal coating step from entering the interior of the stent. As an alternative or in addition, overpressure is generated in the interior of the stent by means of the spray mandrel or the air nozzle, this overpressure being intended to prevent penetration of the spray jet generated by the spray nozzle or to discharge penetrating material laterally.

During the abluminal coating step, the spray jet generated by the spray mandrel does not have to contain any carrier material or active agent, unless minor mixing is desirable for abluminal coating. The compositions of the coatings on the luminal and abluminal sides of the stent are generally different from each other, which is to say they comprise differing carrier materials and/or differing active agents. For example, growth-inhibiting active agents are preferably deposited on the abluminal upper face of the stent, while healing-promoting substances are applied to the luminal surface. The luminal and abluminal sides are preferably coated with differing active agents. In particular, atorvastatin is applied luminally and sirolimus is applied abluminally.

The active agents can notably be embedded in a carrier matrix. The carrier matrix can be biocorrodible and preferably comprises PLLA.

A further aspect of the invention relates to a stent, which is produced according to the aforementioned method.

FIG. 1 is a schematic illustration of the device according to the invention for coating the luminal side of the stent;

FIG. 2 is a schematic illustration of the device according to the invention for coating the abluminal side of the stent;

FIG. 3 is a schematic illustration of a transversally cut implant cross-section having a luminal and an abluminal layer thickness after sequentially combining separate inside and outside coatings;

FIG. 4 is a layer thickness evaluation for the outside coatings of implant cross-sections in four transversal cutting planes for analysis of the longitudinal layer thickness consistency; and

FIG. 5 is a layer thickness evaluation for the inside coatings of implant cross-sections in four transversal cutting planes for analysis of the longitudinal layer thickness consistency.

FIG. 1 schematically shows the principle of coating the luminal side of a stent 10 using the device according to the invention. For this purpose, the device comprises a holder 12, which is used to accommodate the stent 10 during the coating process. The holder 12 is designed to perform a translatory movement by means of actuators, which are not shown in detail here.

The device further comprises a spraying unit 20 comprising a spray mandrel 22. A spray jet 24 consisting of the coating material and a suitable carrier is generated by means of the spraying unit 20. The spray jet 24 is conducted into the interior of the stent 10 via the spray mandrel 22.

An air nozzle 30, which generates an air flow 32, is located on the opposite side of the stent.

The spray jet 24 and the air flow 32 meet in a counterflow region 40 and the spray jet 24 – which is now mixed with the air flow 32 – is accordingly directed radially outwardly and there impinges on the luminal surface of the stent 10 to be coated. A portion of this radially

CLAIMS

1. A device for coating a stent, comprising a holder for the stent, a spraying unit with a spray mandrel and an air nozzle, wherein the spray mandrel, the air nozzle and the holder are designed and disposed relative to each other such that the spray mandrel projects into the sent from one side during coating and the air nozzle projects into the stent from the opposing side.

2. The device according to claim 1, wherein the device is designed such that the position of the stent in relation to the spray mandrel and the air nozzle can be varied during coating.

3. The device according to claim 2, wherein the holder is designed such that, during coating, the stent can be moved in the direction of the spray mandrel or in the direction of the air nozzle.

4. A device according to any one of claims 1 to 3, wherein the spraying unit comprises a spray nozzle, which is directed at an abluminal side of the stent.

5. A method for coating a stent, comprising the following steps:
   a) providing a device for coating the stent according to either claim 1 or 3;
   b) coating the luminal side of the stent by introducing a spray jet via the spray mandrel and an air flow via the air nozzle such that the spray jet is deflected radially outwardly by the air flow in the counterflow region; and
   c) displacing a position of the counterflow region relative to the stent by at least one of the measures selected from moving the stent, moving the spray mandrel, moving the air nozzle, regulating the spray jet, and regulating the air flow.

6. The method according to claim 5, wherein in step a) a device for coating the stent according to claim 4 is provided and, for coating the abluminal side of the stent, a spray jet of the spray nozzle is directed at the counterflow region (i) while carrying out steps b) and c), and/or (ii) subsequently to steps b) and c) and/or (iii) before steps b) and c) a spray jet is directed at the outside of the stent, wherein in the interior of the stent an air flow is generated by means of the air nozzle or a spray jet is generated by means of the spray mandrel, or both are generated simultaneously.

7. The method according to claim 6, wherein the luminal and abluminal sides are coated with differing active agents.

8. The method according to claim 7, wherein a healing-promoting active agent is applied to the luminal side.

9. The method according to claim 8, wherein the healing-promoting active agent is atorvastatin.

10. The method according to claim 7, wherein a proliferation-inhibiting active agent is applied to the abluminal side.

11. The method according to claim 10, wherein the proliferation-inhibiting active agent is sirolimus or a derivative thereof.

12. A method according to any one of claims 7 to 11, wherein the active agents are embedded in a carrier matrix.

13. The method according to claim 12, wherein the carrier matrix is biocorrodible.

14. The method according to claim 13, wherein the carrier matrix comprises PLLA.

15. A stent, produced according to a method according to any one of claims 5 to 14.

of the stent is carried out by way of a movably mounted spray mandrel, which is inserted into the sleeve provided with the stent.

The coating methods and apparatuses of the prior art have the disadvantage that the differentiated application of the coatings to the luminal and abluminal sides of the stent is not possible or difficult. In addition, separately applied luminal or abluminal coatings frequently have lower stability, so that they can become detached from the implant in an uncontrolled manner.

The invention is defined in the independent claims. Some optional features of the invention are defined in the dependent claims.

In one arrangement, there is a device for coating a stent, comprising a holder for the stent, a spraying unit with a spray mandrel and an air nozzle. The spray mandrel, the air nozzle and the holder are arranged for disposal relative to each other for the spray mandrel to project from one side into the stent during coating and for the air nozzle to project into the stent from the opposing side.

In another arrangement, there is a method for coating a stent, comprising the following steps:

a) coating the luminal side of the stent using the aforementioned device by introducing a spray jet via the spray mandrel and an air flow via the air nozzle such that the spray jet is deflected radially outwardly by the air flow in the counterflow region;
b) displacing a position of a counterflow region relative to the stent by at least one of the measures selected from moving the stent, moving the spray mandrel, moving the air nozzle, regulating the spray jet and regulating the air flow.

The inventors have realized that luminal and/or abluminal coatings can be achieved in a very simple and reliable manner using a spraying method in which a counterflow is generated by means of an air nozzle. For this purpose, the device comprises a spraying unit comprising a spray mandrel, the outside diameter of which may be smaller than the inside diameter of the stent. Moreover, an air nozzle is present, the outside diameter of which likewise may be smaller than the inside diameter of the stent. During the coating process, the stent may be accommodated by a holder such that the lateral openings of the stent are

accessible and the lateral walls are not shielded. The spray mandrel may then be inserted into the stent from one side and the air nozzle from the opposing side. During the coating process, a spray jet may be generated by the spray mandrel and an air flow may be directed at this spray jet by the air nozzle. In the region where the spray jet and air flow meet (which here is referred to as the counterflow region), the spray jet may be deflected radially outwardly and thus coats the luminal surface of the stent in this region. Using different measures, it is now possible to vary the counterflow region relative to the position of the stent, whereby locally differentiated luminal coating of the stent is possible. These measures include moving the stent, the spray mandrel or the air nozzle and regulating the spray jet and air flow. The coating method may result in a form-fitting, mechanically very stable coating.

The device is preferably designed such that the position of the stent relative to the spray mandrel and the air nozzle can be varied during coating. The holder may notably be designed such that, during coating, the stent can be moved in the direction of the spray mandrel or in the direction of the air nozzle. In other words, according to this variant the stent can be moved along an axis formed by the spray mandrel and air nozzle by means of the holder during the coating process. The adjustments of the position and flow rate in the counterflow region can be determined in this region particularly easily by experiments and simplify the implementation of the method in the industrial manufacturing process.

It is further preferred for the spraying unit to comprise a spray nozzle, which is directed at an abluminal side of the stent. According to an associated variant of the method, a device for coating the stent is provided, in which the spraying unit comprises such a spray nozzle, which may be directed at an abluminal side of the stent. The abluminal coating can be carried out simultaneously with the aforementioned luminal coating (ii), before that (i) or (iii) thereafter. For simultaneously coating the abluminal side of the stent, a spray jet of the spray nozzle is directed at the counterflow region while steps a) and b) are carried out. Abluminal coating, however, can also be carried out before or after the luminal coating process, wherein a spray jet is directed at the outside of the stent. The quantity of coating material inadvertently reaching the luminal surface can optionally be reduced by an air

flow from the air nozzle, or by a counterflow region, which may be generated by means of an air nozzle and a spray mandrel that is operated without active agent.

In keeping with the aforementioned descriptions, according to this variant the spraying unit of the device comprises an additional spray nozzle, which may be directed at the outside of the stent. Over the course of the abluminal coating step, the flow that is radially directed outwardly in the counterflow region can largely prevent coating material for the abluminal coating step from entering the interior of the stent. As an alternative or in addition, overpressure may be generated in the interior of the stent by means of the spray mandrel or the air nozzle, this overpressure being intended to prevent penetration of the spray jet generated by the spray nozzle or to discharge penetrating material laterally.

During the abluminal coating step, the spray jet generated by the spray mandrel does not have to contain any carrier material or active agent, unless minor mixing is desirable for abluminal coating. The compositions of the coatings on the luminal and abluminal sides of the stent can be generally different from each other, which is to say they may comprise differing carrier materials and/or differing active agents. For example, growth-inhibiting active agents are preferably deposited on the abluminal upper face of the stent, while healing-promoting substances may be applied to the luminal surface. The luminal and abluminal sides are preferably coated with differing active agents. In particular, atorvastatin may be applied luminally and sirolimus may be applied abluminally.

The active agents can notably be embedded in a carrier matrix. The carrier matrix can be biocorrodible and preferably comprises PLLA.

A further aspect relates to a stent, which is produced according to the aforementioned method.

FIG. 1 is a schematic illustration of the device for coating the luminal side of the stent;

FIG. 2 is a schematic illustration of the device for coating the abluminal side of the stent;

FIG. 3 is a schematic illustration of a transversally cut implant cross-section having a luminal and an abluminal layer thickness after sequentially combining separate inside and outside coatings;

FIG. 4 is a layer thickness evaluation for the outside coatings of implant cross-sections in four transversal cutting planes for analysis of the longitudinal layer thickness consistency; and

FIG. 5 is a layer thickness evaluation for the inside coatings of implant cross-sections in four transversal cutting planes for analysis of the longitudinal layer thickness consistency.

FIG. 1 schematically shows the principle of coating the luminal side of a stent 10 using the device. For this purpose, the device comprises a holder 12, which is used to accommodate the stent 10 during the coating process. The holder 12 is designed to perform a translatory movement by means of actuators, which are not shown in detail here.

The device further comprises a spraying unit 20 comprising a spray mandrel 22. A spray jet 24 consisting of the coating material and a suitable carrier is generated by means of the spraying unit 20. The spray jet 24 is conducted into the interior of the stent 10 via the spray mandrel 22.

An air nozzle 30, which generates an air flow 32, is located on the opposite side of the stent.

The spray jet 24 and the air flow 32 meet in a counterflow region 40 and the spray jet 24 – which is now mixed with the air flow 32 – is accordingly directed radially outwardly and there impinges on the luminal surface of the stent 10 to be coated. A portion of this radially

CLAIMS

1. A device for coating a stent, comprising a holder for the stent, a spraying unit with a spray mandrel and an air nozzle, wherein the spray mandrel, the air nozzle and the holder are arranged for disposal relative to each other for the spray mandrel to project into the stent from one side during coating and for the air nozzle to project into the stent from the opposing side.

2. The device according to claim 1, wherein the device is arranged for the position of the stent in relation to the spray mandrel and the air nozzle to be varied during coating.

3. The device according to claim 2, wherein the holder is arranged such that, during coating, the stent can be moved in the direction of the spray mandrel or in the direction of the air nozzle.

4. A device according to any one of claims 1 to 3, wherein the spraying unit comprises a spray nozzle, arranged for direction at an abluminal side of the stent.

5. A method for coating a stent, comprising the following steps:

   a) coating the luminal side of the stent using a device according to claim 1 or claim 3 by introducing a spray jet via the spray mandrel and an air flow via the air nozzle such that the spray jet is deflected radially outwardly by the air flow in a counterflow region; and

   b) displacing a position of the counterflow region relative to the stent by at least one of the measures selected from moving the stent, moving the spray mandrel, moving the air nozzle, regulating the spray jet, and regulating the air flow.

6. The method according to claim 5, wherein in the device for coating the stent is a device according to claim 4 and, for coating the abluminal side of the stent, a spray jet of the spray nozzle is directed at the counterflow region (i) while carrying out steps a) and b), and/or (ii) subsequently to steps a) and b) and/or (iii) before steps a) and b) a spray jet is directed at the outside of the stent, wherein in the interior of the stent an air flow is generated by means of the air nozzle or a spray jet is generated by means of the spray mandrel, or both are generated simultaneously.

7. The method according to claim 6, wherein the luminal and abluminal sides are coated with differing active agents.

8. The method according to claim 7, wherein a healing-promoting active agent is applied to the luminal side.

9. The method according to claim 8, wherein the healing-promoting active agent is atorvastatin.

10. The method according to claim 7, wherein a proliferation-inhibiting active agent is applied to the abluminal side.

11. The method according to claim 10, wherein the proliferation-inhibiting active agent is sirolimus or a derivative thereof.

12. A method according to any one of claims 7 to 11, wherein the active agents are embedded in a carrier matrix.

13. The method according to claim 12, wherein the carrier matrix is biocorrodible.

14. The method according to claim 13, wherein the carrier matrix comprises PLLA.

15. A stent, produced according to a method according to any one of claims 5 to 14.