DOCUMENT
Informed Consent Form

OFFICIAL TITLE OF THE STUDY

Effect of Phosphoric Acid Etching Duration on the Performance of Direct Resin-Based Composite Restorations in Permanent Anterior Teeth: A Randomized Controlled Single-Center Trial

NCT NUMBER

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DATE OF THE DOCUMENT

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University Center for Dental Medicine Basel UZB
Mattenstrasse 40
CH-4058 Basel

Request to participate in dental research

Study title: **Effect of Phosphoric Acid Etching Duration on the Performance of Direct Resin-Based Composite Restorations in Permanent Anterior Teeth: A Randomized Controlled Single-Center Trial**

Layman's title: How does the etching time with phosphoric acid influence the Behavior of tooth-colored resin fillings in anterior teeth? A clinical Study

Dear Sir or Madam

We would like to inform you about a study on tooth-colored resin fillings for front teeth and ask you whether you would like to take part in the examination. tions. It is important for dentists to be aware of the effects of new interventional techniques. methods order to further improve dental care.

We call such research a **clinical trial**[1]. In this study we want to to find out whether the exposure time of a phosphoric acid gel has an influence on the quality of plastic fillings on front teeth. Specifically, we would like to know whether longer or shorter This gel has a longer application time and leads to less discoloration at the margins of the filling. This gel is used as standard in the production of resin fillings. Until now, each However, it is not clear how long the optimum exposure time should be. Therefore compare In this study, we used two different application times for the gel. You need one of these anterior filling. We would therefore like to ask you whether you would like to take part in this study.

Your participation is voluntary. The following **patient information** is intended to help you decide help you with your planning. You can discuss any questions you may have about participating in the study with the investigator. the test dentist. This is what we call the dentists who are responsible for a study and who are responsible for you in the context of this study. If you participate please sign the **declaration of consent** at the end. With your un By signing below, you confirm that you have read and understood the patient information. If you do not understand something, please ask the examining dentist. 33

[1] The law uses the term "clinical trial" for this purpose.

The patient information and declaration of consent consist of four parts:

Part 1	**The most important facts in brief**
Part 2	**This is what it's all about in detail: Information on the study**
Part 3	**Data protection and insurance cover**
Part 4	**Declaration of consent**

If you read **Part 1**, you will get an overview of the study.
In Part 2, we explain the entire process and background of the study in detail.
Part 3 contains information on data and insurance protection.
With your signature at the end of the document, **part 4**, you confirm that you have understood everything. and to participate.

This study was initiated by the University Center for Dental Medicine Basel UZB. This Institution is called the sponsor. The sponsor is responsible for, manages and finances a study program. the.

In the context of this study is responsible for you:

Name	PD Dr. med. dent. Florin Eggmann
Address	UZB, Mattenstr. 40, 4058 Basel
Telephone	061 267 26 80
	079 374 13 81 (available 24 hours a day)
e-mail	florin.eggmann@unibas.ch

Part 1:
The most important facts in brief

1 Why are we this study?

You have an anterior tooth that is missing due to caries, a defective filling or a damaged tooth. a tooth-colored plastic filling is required for the desired change in shape. That's why we ask Please indicate here whether you would like to participate in this study.

When restoring a tooth with a resin filling, the tooth must be pre-treated. be applied. Pre-treatment ensures that the filling adheres well to the tooth. The pretreatment The standard is to treat the tooth by applying a special gel for a short time. time on the tooth. This gel contains phosphoric acid. It is currently unclear how optimum exposure time of the phosphoric acid gel.

In this clinical study, we are investigating how the duration of exposure to the phosphorus- acid gel the susceptibility of the fillings to marginal discoloration. Further investigated In this study, we examine the overall behavior of anterior fillings over time. This examination of the filling quality is based on a comprehensive assessment of the fillings and the filled teeth. In **chapter 4** you will learn more about the scientific Background to the study.

2. what do you have to do when you take part?

Your participation in this study will last 5 years. We will visit you for 6 study visits invite you. 5 of these 6 appointments are part of your general dental treatment and also take place independently of your participation in the study. The other 1 appointment is a additional appointment and is only part of the study. Placement of the filling including documentation takes approx. 45-90 minutes. The first control appointment lasts 20-60 minutes. The four control appointments mine take about 30 minutes. The number of appointments **is shown in** the **illustration in Chapter 5**.

If you decide to take part, you will be randomly assigned to one of 2 groups. They belong to either the test group or the control group. They are not wis- to which group you belong. In the test group, you will be given the interventi- The phosphoric acid gel is treated using a method that involves a very short exposure time (10 seconds). In the control group, the phosphoric acid gel works longer on your tooth (up to max. 30 seconds).

Chapter 5 provides more information on the study process and procedure.

3. what are the benefits and risks with participation?

Benefit

You have no direct benefit from participating in the clinical trial. However, it is
It is possible that your participation will help future patients. The Nut-
The main advantage of the study is that the knowledge gained from the study
methods for the fabrication of tooth-colored resin fillings.
People who want to have their teeth colored in the future will benefit from improved treatment methods.
need a filling.

Risk

All materials used are approved and certified in Switzerland. The interventi-
The method of shortening the exposure time of the phosphoric acid gel has been proven in laboratory studies.
comprehensively examined.

Side effects may occur regardless of whether you use the intervention method or not.
the shortened exposure time of the phosphoric acid gel or the treatment method
of the control group, which involves a longer exposure time. We know
Perhaps not all the risks and side effects of the intervention method of shortening
the exposure time of the phosphoric acid gel. The following risks and side effects have been
are known in the treatment with tooth-colored resin fillings:

- Hypersensitivity or pain after placement of the filling.
- Chipping, fractures of the filling material and/or the adjacent tooth sub-
  stance.
- Partial or complete loss of the adhesive bond between the filling and the tooth, resulting in
  partial or complete loss of the filling.
- Air pockets in the filling material or underneath the filling
- Minor, superficial injury to the gums.
- Ingestion of material.
- Allergic reactions to components of the filling materials (e.g. methacrylate-
  plastics), the local anesthetic or the auxiliary parts used during the treatment.
  be set.

Chapter 6 contains further information on risks and burdens.

Part 2:
This is what it's all about in detail: Information on the study

4 The scientific background of the study

4.1 Background: Why are we this study?

Adults often have front teeth that require a front tooth filling.
Such an anterior filling may be necessary due to caries (a "hole in the tooth").
tooth", a defective filling that needs to be replaced, or because of a desired
Change in shape of an anterior tooth. If you need an anterior filling, you get
typically a tooth-colored resin filling. When placing such an artificial
filling, the tooth is routinely prepared with a gel containing phosphoric acid.
deals.

This procedure has been established for many years. There is already research in humans on
Use of phosphoric acid gels when placing resin fillings. When using
However, when using today's most common bonding agents ("dental adhesive"), it is
It is unclear how long the optimal exposure time of the phosphoric acid gel is. Previous studies that
in the laboratory have shown that the adhesive bond of the restorative material
on the enamel (the outer layer of the tooth) with a shortened exposure time is the same.
is as good as with a longer exposure time. In the so-called dentine, which is also called the dentin
and is located underneath the enamel, the shortened exposure time of possible
advantages for the adhesive bond. However, clinical studies are currently lacking
to this. It is therefore currently unclear how a shorter exposure time of the phosphoric acid gel
the susceptibility of the fillings to marginal discoloration.

In this study, we are therefore investigating whether the intervention method of a shortened onset
The longer exposure time of the phosphoric acid gel just as effective as a longer exposure time.

All substances and materials in the study are registered in Switzerland.
certified and approved. They are routinely used worldwide for tooth-colored fillings.
used.

In this study, we are also investigating how anterior fillings as a whole
over time. This examination of the filling quality is based on a comprehensive
Send assessment of fillings and filled teeth. 150

4. 2 Structure of the study: How do we proceed?

In our study, participants are randomly divided into groups. This is important, to obtain reliable results from the study. This is called randomization. Each group receives a different treatment. There are 2 groups in our study:

- **Group 1** (experimental group): In this group, the phosphoric acid gel is applied simultaneously to the enamel and dentin. The application time of the gel on both the enamel and the dentin is a total of 10 seconds.
- **Group 2** (control group): In this group, the phosphoric acid gel is first to the enamel and only shortly afterwards to the dentin. The The gel is applied to the enamel for 15-30 seconds and to the tooth surface for 10-15 seconds. seconds on the dentin.

The study is a so-called blinded study. In this case, "blinded" means that neither the participants nor the investigators know in which group the participants were divided into. The practitioners who had the one- However, they are not blinded, as they do not know which intervention is being used. tion method. The participants therefore do not know which group they belong to. And the sub The examiners who evaluate the results have no knowledge of them. This approach is intended to ensure that the results remain as objective as possible. Randomization and blinding allow us to reliably assess how well the intervention method is really effective.

4. 3 Regulations on scientific research involving human subjects

We are conducting this study in accordance with the laws in Switzerland (Humanfor- Protection Act, data protection laws). In addition, we observe all internationally recognized guidelines. The responsible ethics committee has reviewed and approved the study.

Our study is a national study. The study is only being conducted at one location, the UZB, in Switzerland.

A description of this study can also be found on the website of the Federal Office for Health at www.kofam.ch under the SNCTP registration number ..... or the BASEC-Number.....

5. course of the study

5. 1 What do you have to do if you in the study?

Participation in the study is voluntary and lasts 5 years. You must adhere to the procedure plan (→ Chapter 5.2) and also to all specifications that your dentist has issued. dentist does.

You must inform your test dentist,

- if your state of health changes, e.g. if you get worse, or if you have new complaints; this also applies if you discontinue the study prematurely. (→ Chapters 5.3 and 5.4);
    - if you get toothache on the treated tooth or if this tooth tooth becomes hypersensitive;
    - If a dentist performs a treatment on the treated study patient, he/she must tooth would like to perform;
    - when you notice the loss of adhesion of the filling;
    - if the filling is partially or completely lost (breaks off or becomes loose) detaches from the tooth);
    - if you become pregnant or are breastfeeding.

You must also note the following:

- You may not undergo dental whitening during your participation. have your teeth whitened. (Note: The desire for dental teeth whitening is generally not a criterion for exclusion. However, the tooth whitening at least two weeks before the resin filling is placed. be).

5. 2 What happens during the appointments?

In the course of your participation, you will come to us 6 times for a study visit. 5 of these appointments are part of your general treatment and are also paid independently of your Study participation. The other 1 appointment is an additional appointment and includes for the research study only. An appointment lasts about 30-45 minutes on average. The The sequence of dates is shown in the illustration below.

We do the following for all appointments:

- We will answer your questions.
- We will ask you questions about your state of health.
- We examine your teeth and gums.
- We use dry ice to check whether the tooth is sensitive to cold.
- We take photos of the front teeth.

At the first appointment, we will check whether you meet the requirements for participation in the study. fulfill. In addition, we will explain the exact process of the study. If you wish, you can take a few days after this appointment, to in peace about your participation.

If you decide to take part voluntarily, you will be given the following information at the second appointment fillings are used. We examine these fillings at the following appointments very precisely. In doing so, we evaluate them according to defined criteria in order to find out whether ver- colorations occur at the edges of the fillings and how well the materials used function.

No data from your medical records will be used or analyzed for this study.

The following schedule shows all the necessary dates:

Schedule: general and additional examinations

Study visit/Ter-min	**The current term**	**1**	**2**	**3**	**4**	**5**	**6**
Approxima te duration (hours)	0.5	0.75-1.5	0.3-1	0.5	0.5	0.5	0.5
Query on health stood	✓	✓	+	✓	✓	✓	✓
Assessmen t of tooth sensitivity	✓	✓	+	✓	✓	✓	✓
Cold test tooth	✓	✓	+	✓	✓	✓	✓
Placing dental filling		✓					
Post-polishing dental filling			(+)				
Evaluation dental filling			+	✓	✓	✓	✓
Photos tooth		✓	+	✓	✓	✓	✓

The schedule on the previous page shows all dates. The **general examinations**
courses are with a **tick (✓)**. The **additional study-specific un**
examinations are **with a plus sign** (**+**). Only these studies represent
therefore represent an additional expense for you.

We arrange the appointments together with you. You receive a precise overview
about the dates. We kindly ask you to inform us quickly if you still need to make an appointment.
date important reasons.

5. 3 When does participation in the study end?

For you, participation lasts 5 years and ends after the 6th date. You can choose your part

You can also stop taking the program earlier at any time (→ Chapter 5.4). You do not have to explain why
you no longer wish to participate. If you would like to end your participation earlier yourself
If you have any questions, please speak to your investigator.

If you end your participation prematurely, this has no influence on your further dental treatment.

medical care and treatment (→ Chapter 5.4 for alternative treatment options).
nes). In this case, we will carry out a final examination for your safety.

If you discontinue the study earlier please contact your investigator // your investigator's dentist
continue to inform you if your state of health changes, e.g. if you feel unwell.
you feel worse or if you have new complaints. If your participation is premature
ends, we will retain the data collected up to that point (e.g. information on the status of the payer).
and the filling and photographs of the tooth with the filling) are still available for the study.
evaluate. Your study data and samples will remain encrypted (→ Chapter 9).

We may also have to ask you to end the study early. This is
for exampleif you want to use a material that is used for the fabrication of tooth-colored
plastic filling in the study.

5. 4 What happens if you do not wish to participate?

Even if you are not part in this study, we will treat and care for you dentally.
medical treatment in accordance with current standards. If you do not take part in the study
If you would like to take part in a clinical trial, your dentist will advise you on alternative options.
treatment options.

5. 5 Pregnancy

Except in emergencies, pregnant and breastfeeding women are generally not allowed to eat.
of fillings.

For women who may become pregnant: At the time of the filling placement, you may
not be pregnant. We will therefore provide you with a pregnancy test,

to be able to rule out pregnancy. In addition, at the time of the filling placement.

If pregnancy or breastfeeding occurs during the follow-up period participation in the study is still possible. In this case, the dates can be for the follow-up examinations, which only include a short dental check-up, after consultation with the dentist.

The dosage can be adjusted in consultation with you and according to your doctor's recommendation.

You will discuss these questions with your examining dentist.

6 Risks, burdens and side effects

6.1 What risks and stresses can occur?

There are risks and burdens involved in participating in this study, as with any medical study. treatment. Some risks are already known, others are still unknown. These Uncertainty is not unusual in the context of studies. In **chapter 6.2** you will find a List of the most common and most serious risks. Many side effects are (dental) medical treatable. During the study, we will inform you about all new findings on risks and treatment options. and side effects.

With a new intervention method, it is possible that there are risks that we have not yet identified. know.

To date, there have been no studies in the dental literature on the effects of The shorter exposure time of phosphoric acid gel has a positive effect. However, the dental adhesion promoters that we use, also for application without prior use of Phosphoric acid approved. Especially for fillings in the cervical area and fillings in Many dentists use these bonding agents without phos- phosphoric acid gel. This indicates that the shortened exposure time of the phosphoric acid gel is highly unlikely to pose any serious risks.

In addition, there are risks associated with the medical examinations that we are investigating in this study. do. You will already be familiar with some of the tests. In **chapter 6.3** you will find a List of these risks of the investigations.

6. 2 The most frequent and most serious risks posed by the in tervention method

Here you will find information about the most common and most serious side effects, that we already know.

We use the following descriptions for this:

very often	We find the side effect in more than 10 people out of 100 (more than 10%).
frequently	We find the side effect in 1 to 10 people out of 100 (1%-10%).
occasionally	We find the side effect in 1 to 10 people out of 1,000 (0.1%-1%).
rare	We find the side effect in 1 to 10 people out of 10,000 (0.01%-0.1%).
very rare	We find the side effect in less than 1 person in 10,000 (less than 0.01%).

Common side effects are:

- Hypersensitivity or pain after placement of the filling.
    - Consequences: Depending on the degree of severity, the course of the disease will be described in additional
      The patient is observed at regular intervals or an intervention required. If required a painkiller that you tolerate well. If strong
      If pain occurs, the filling is replaced or an additional root canal treatment.

Occasional side effects are:

- Chipping, fractures of the filling material and/or the adjacent tooth substance.
    - Consequences: The filling must repaired or replaced.
- Partial or complete loss of the adhesive bond between filling and tooth, resulting in partial or complete loss of the filling.
    - Consequences: The filling must be repaired or replaced.
- Air pockets in the filling material or underneath the filling
    - Consequences: Depending on the location and size of the air pocket, the filling repaired or replaced.
- Minor, superficial injury to the gums
    - Consequences: Such injuries usually do not require treatment and on their own within about 1-2 weeks. If required
      You can use a wound ointment that you can apply to the gums and/or a Mouthwash solution that supports healing.

Rare side effects are:

- Ingestion of material.
    - Consequences: Ingestion does not usually lead to any problems, as no side effects are to be expected due to the small quantities.

Very rare side effects are:

- Allergic reactions to components of the filling materials (e.g. Methacrylate plastics), the local anesthetic or the auxiliary parts used in the treatment. can be used.

- Consequences: Patients with known or suspected allergies to
  These substances are excluded from treatment with such materials.
  closed. Nevertheless, despite these precautionary measures, in rare cases
  severe allergic reactions, such as anaphylactic shock, can occur.
  shock, which require immediate emergency treatment.

6. 3 Risks and burdens from examinations in the stu-
the

We carry out various dental examinations for this study (→ Chapter
5.2). These examinations are tried and tested procedures. Nevertheless, they can involve risks and
They can have a negative impact, i.e. they can unpleasant. In this study there are the following
Risks and burdens:

- Brief pain stimulus due to the cold test on the tooth
- Additional examination date

7 Financing and compensation

This study is initiated by the sponsor UZB and is jointly organized by the UZB and the
paid by the company Ivoclar Vivadent AG. The filling materials and selected instruments for
Ivoclar Vivadent AG will provide you with the necessary tools for placing and polishing the fillings free of charge.
made available.

The researchers involved have no direct financial benefit from the implementation of the project.
conduct of this study.

You have to cover the cost of the plastic filling placed during the study yourself.
to cover the costs. This is done according to the usual fee model for dental treatment in the
Switzerland. Payment can be made directly out of your own pocket, via the insurance company or through social security.
Depending on the individual circumstances.

For the first follow-up examination after placement of the filling, which is used to assess the stu-
is necessary and is not of the regular check-up appointments, the patient receives a
You will receive a fee of CHF 90.00 per hour. Shorter appointments will be charged accordingly.
proportionately remunerated.

In addition, the travel costs for the first follow-up appointment after the placement
of up to CHF 50.00 for 2nd class public transport.

You will not be any additional financial incentives. Your participation in the
The study should be conducted out of genuine interest in research and not for financial compensation.
be carried out.

8. results from the study

There are results that concern you These results will be communicated to you by your dentist.
Your test dentist with. There are also incidental findings. Incidental findings are "concomitant results",
that are not intended. These can changes to the oral mucosa, for example. We
inform you if these random results are relevant to your health.

For example, we will inform you if we happen to discover an illness of which you are aware.
we do not yet know and which we can treat. // We will also inform you when we have a

Find the risk of a disease that can be prevented by taking preventive measures.
can. If you *do not* wish to be informed, please discuss this with your dentist.
your examining dentist. Some incidental findings are always reported, for example,
if other persons are endangered or if it must be reported by law.

There are also the overall results of the study, which are based on the data from all participants.
come. This includes, for example, knowing more about the behavior of the front
dental fillings over time (→ Chapter 4.1). These results will affect you and your
health directly. At the end of the study, your investigator dentist will give you
but would be happy to send you a summary of the overall results of the study if you wish.
the results. In addition, the results are presented in layman's terms after the end of the study.
Language published (link or reference, expected from 2031). 389

Part 3:
Data protection and insurance cover

9. Protection of data

We protect your data (e.g. information on the condition of your teeth and other dental data). information from your medical history). For the protection of data, the Switzerland has strict legal regulations.

The Swiss Data Protection Act gives you the right to information, rectification and Receipt of your data that is collected, processed and forwarded as part of the study. These rights may be exercised in exceptional cases due to other legal or regulatory requirements. requirements cannot always be guaranteed. If you have any questions, please contact please contact your test .

9.1 Encryption of data

Each study generates data from the investigations (e.g. information on the condition of the teeth and the filling). This data is documented. This is usually done electronically in large tables, the so-called "data collection sheets". All data is documented in encrypted form. "Encrypted" means that personal information that you directly identifiable are stored *separately* from the test results. the. For this purpose, there is a list (key list) that each person is assigned a unique code. identified. For example, your name, date of birth or place of residence are *not* directly listed in the database. data collection form. This key list remains at the institute for a period of 20 years. UZB and is then destroyed. No one else receives this key list. Special exceptions are regulated in chapter 9.5.

If we pass on data for the purpose of this study - to other professionals or organizations - we will not be able to use it. organizations that carry out further investigations - then the data is always encrypted. and your personal data is protected. This also applies if the data is transferred abroad. be passed on.

9. 2 Safe handling of data during the study

The sponsor UZB is responsible for the secure handling of your data from this Study. He is responsible for ensuring that the applicable laws, e.g. data protection laws, must complied with. This also applies if (encrypted) data is used for investigations in other countries. where data protection laws less favorable. This is how the sponsor protects your data in this study:

In this study, your data is recorded and transmitted electronically. The data is stored in in an encrypted form on an ISO-certified server in the Netherlands (data filling quality) and a backup copy of this data on an ISO-certified storage medium. on a server in Ireland. The image data (photographs that exclusively show the teeth, gums and the oral mucosa) are located in a password-protected folder. Only the study team has access to it. They are stored in Microsoft OneDrive, a secure cloud storage service. The image data is not only stored in a stored in a single location, but on several servers in different Microsoft repositories. centers around the world - including in North America, South America, Europe, Asia and Australia. Nevertheless, there is always a certain residual risk that strangers may be on access your personal data (e.g. risk of "hacking").

Sometimes it is important that your family doctor collects data on your medical history. the investigator dentist. This also applies to other doctors who You treat. By giving your consent at the end of the document, you authorize this.

9. 3 Secure handling of data after the end of the study

The sponsor remains responsible for the safe handling of the study after the end of the study. Your data. The law stipulates that all study documents, e.g. the data collection The data, including the data sheets, stored for at least 20 years.

At the end of this long period, study data remains encrypted. Health-relevant data of your medical history, including from this study, are and remain important for your treatment. always accessible.

Once a study has been completed, the results are usually published in scientific journals. The results are published. The results are also reviewed by other experts. Your encrypted data must be forwarded to these specialists. The However, data may not used for new research purposes. Therefore it would require your separate consent (→ Chapter 9.4).

9. 4 Further use and disclosure of your data in other, future studies

Your data from this study is very important for future research. Data which used for this experiment can possibly be used for other experiments. used and/or passed on (also abroad).

Please read the additional declaration of consent at the end of the document carefully by. Please sign the consent form if you wish to carry out further research with your data. in the future. Even if you do not agree, you can still in the study.

9.5 Inspection rights during inspections

The implementation of this study can be verified. The review is carried out by authorities such as the responsible ethics committee. The sponsor must also carry out such reviews. to the quality of this study and the results.

For this purpose, a small number of specially trained people are given insight into your personal data and your medical history. The data is therefore *not* required for this review. encrypted. The people who see your unencrypted data are subject to confidentiality. obligation.

As a study participant, you have the right to view your data at any time.

10. insurance cover

In the event of damage attributable to an approved and medically standardized medicinal product / medical device or are also attributable to the use of a standard therapy would have occurred, the same liability rules apply as in the case of treatment outside of a study. In such a case, the liability insurance of the UZB the costs / compensation.

Part 4:
Declarations of consent

This consent consists of two independent declarations of consent:

- Informed consent for participation in this study *Effect of Phosphoric Acid Etching Duration on the Performance of Direct Res-in-Based Composite Restorations in Permanent Anterior Teeth: A Randomized Controlled Single-Center Trial*
- Declaration of consent for the further use and disclosure of data from this Study in coded form for further research.

Please read this form carefully. Please ask us if there is anything you do not or if there is anything else you would like to know. To participate, your written Consent required.

Declaration of consent to participate in the study

BASEC number	
Title of the study	Effect of Phosphoric Acid Etching Duration on the Performance of Direct Res-in-Based Composite Restorations in Permanent Anterior Teeth: A Randomized Controlled Single-Center Trial
Layman-understandable title	How does the etching time with phosphoric acid influence the behavior of tooth-colored resin fillings in anterior teeth? A clinical study
Responsible institution (Sponsor with address)	University Center for Dental Medicine Basel UZB Mattenstrasse 40 CH-4058 Basel
Place of implementation	University Center for Dental Medicine Basel UZB Mattenstrasse 40 CH-4058 Basel
Examining dentist at the place of study	PD Dr. med. dent. Florin Eggmann
: Surname and first name in block capitals: Date of birth:	

- I have received verbal and written information about the study, namely by the test dentist who signs below.
- The investigator has explained to me the purpose, procedure and risks of the study and the treatment method.
- I am taking in the study voluntarily.

- The examining dentist has explained to me which standard treatments are possible. there are outside the study.
- I had enough time to this decision. I keep the written in formation and receive a copy of my written declaration of consent.
- I can end my participation at any time. I don't have to explain why. Also if I stop participating, I will continue to receive my medical treatment. The data up to this point will be analyzed as part of the study. valued.

- If I resign, the data remains encrypted.
- If it better for my health, the examining dentist can give me the following information doctor the study at any time.
- I understand that my data will only be forwarded in encrypted form for this study. are sent abroad. The sponsor shall ensure that the data protection is complied with in accordance with Swiss standards.
- In case of results // In case of results and/or incidental findings that directly affect my health I will be informed of any changes that affect my health. If I do not wish to be informed, I discuss this with my test .
- My general practitioner may use data from my medical history that is required for the study. that are important the investigator. This also applies to another doctors who treat me.
- The responsible experts of the sponsor, the Ethics Committee and the Drug *Swissmedic* may view my unencrypted data for inspection. All these persons are subject to a duty of confidentiality.
- The liability insurance of the institution UZB insures possible damages.

Place, date	Surname and first name of in block capitals Signature of participant

Confirmation of the examining : I hereby confirm that I have completed the-
The nature, significance and scope of the study is explained to this participant
have. I confirm that I have fulfilled all obligations in connection with this study.
accordance with Swiss law. Should I learn of any aspects in the course of the study,
which influence the participant's willingness to take part in the study.
I will her/him of this immediately.

Place, date	Surname and first name of the test in block capitals Signature of the examining dentist

Declaration of consent for further use and/or disclosure of data in encrypted form

This consent does not concern you in the sense of personal participation in a study. (→ Chapter 9.4 of the patient information).

"Further use" means that your data will be stored beyond the time of your participation in the study. and can be used in encrypted form for further research. The can mean, for example, that examination results from you that were obtained during dental check-ups were statistically analyzed together with a large number of other values. or new tests are carried out with it.

"Disclosure" means that your data is passed on to other research persons or research institutes. institutions in encrypted form for further research projects. fen. These other research persons or research institutions can also be included in the training program. country. It is the sponsor's responsibility to ensure that this country has an adequate level of data protection comparable to that in Switzerland.

BASEC number:	
Title of the study	Effect of Phosphoric Acid Etching Duration on the Performance of Direct Resin-Based Composite Restorations in Permanent Anterior Teeth: A Randomized Controlled Single-Center Trial
Layman-understandable title	How does the etching time with phosphoric acid influence the behavior of tooth-colored resin fillings in anterior teeth? A clinical study
Participant: Surname and first name in block capitals: Date of birth:	

I authorize the use of my coded data and from this study for the (dental) me- and passed on (also abroad) for further use in medical research may.

- I understand that the data is encrypted and the key is stored securely. is maintained.

- If I resign, the data remains encrypted.

Place, date	Surname and first name of in block capitals Signature of participant

Confirmation of the test : I confirm that I am authorized to participate in the test.
the nature, significance and scope of the further use and/or further processing of the data.
of samples and/or (genetic) data.

Place, date	Surname and first name of the test dentist in block capitals Signature of the examining dentist