



Lancing: What is the future?

Lutz Heinemann

Profil Institute for Clinical Research, San Diego, US

Profil Institut für Stoffwechselforschung, Neuss

Science & Co, Düsseldorf

A Glance into the Crystal Ball (you don't always see what you want to see)





- ◆ **Profil perform clinical-experimental and clinical studies in cooperation with numerous companies**
- ◆ **Scientific Advisory Boards / Advisory Panels**
- ◆ **Consultant**
- ◆ **No stock of any companies!**



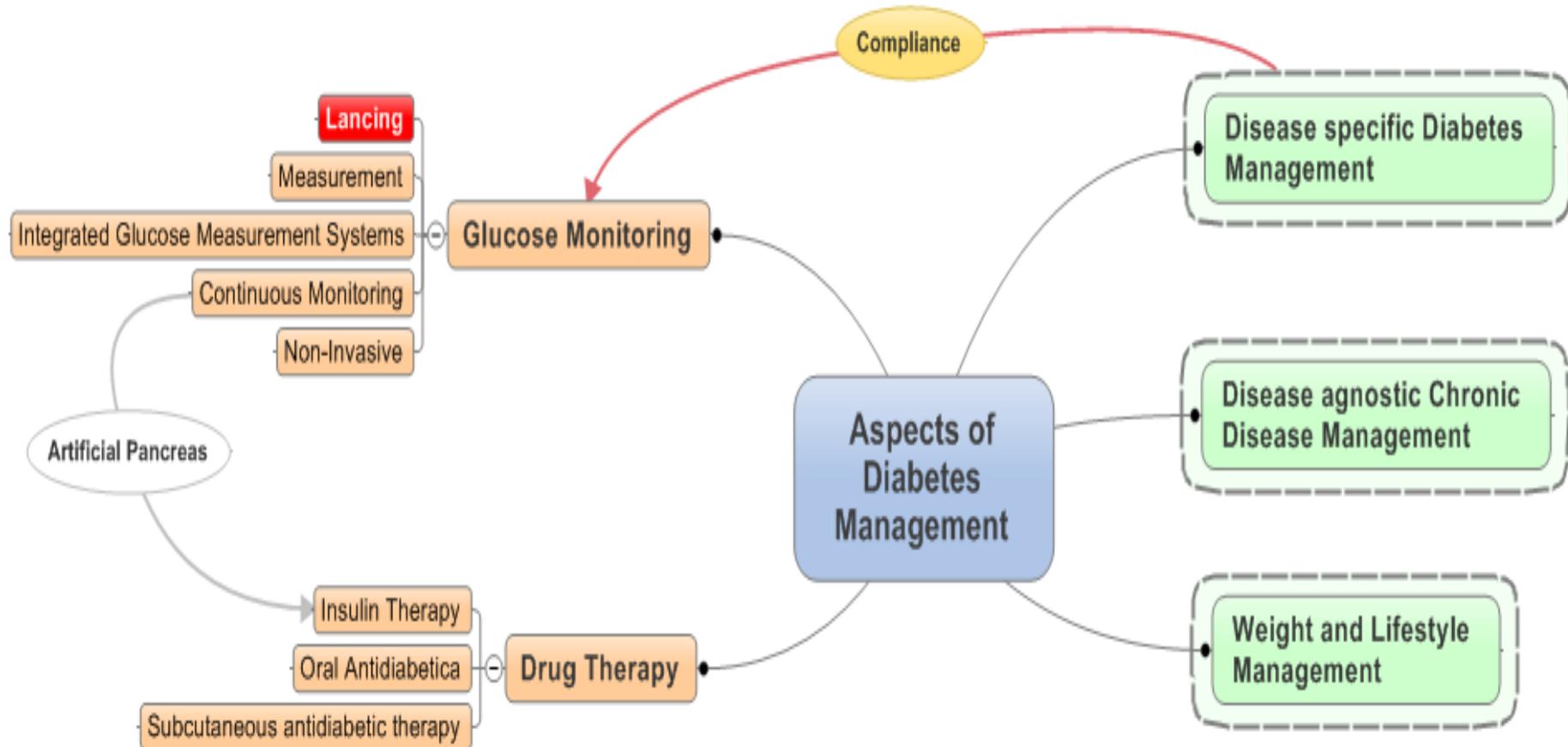
- ◆ **“One of the things I use a lot is a lancing device. Don’t we all? Yes, yes we do, but I don’t think many people give them that much thought.”**

<http://dontfeardiabetes.com/2010/06/one-touch-delica-my-first-product-review/>
(visited June 12, 2010)



- ◆ **Many discussion about this topic in blogs of patients, pros and cons of the different devices**
- ◆ **Patients are most often not involved in the selection of the lancing device!**
- ◆ **Selection of the lancet devices handed over to them by chance or simply the one that comes along with the BG meter**
- ◆ **Replacing a lancet at a time is consuming and laborious**

Landscape of diabetes management and the position of lancing





- ◆ **Why finger-pricking?**
- ◆ **Which size of blood drop do we need?**
- ◆ **Why do we prick finger tips?**
- ◆ **What induces pain?**
- ◆ **What do patients do in reality?**
- ◆ **How can we reduce the pain?**
- ◆ **Which lancing devices are the “best“ and why?**
- ◆ **What is needed?**
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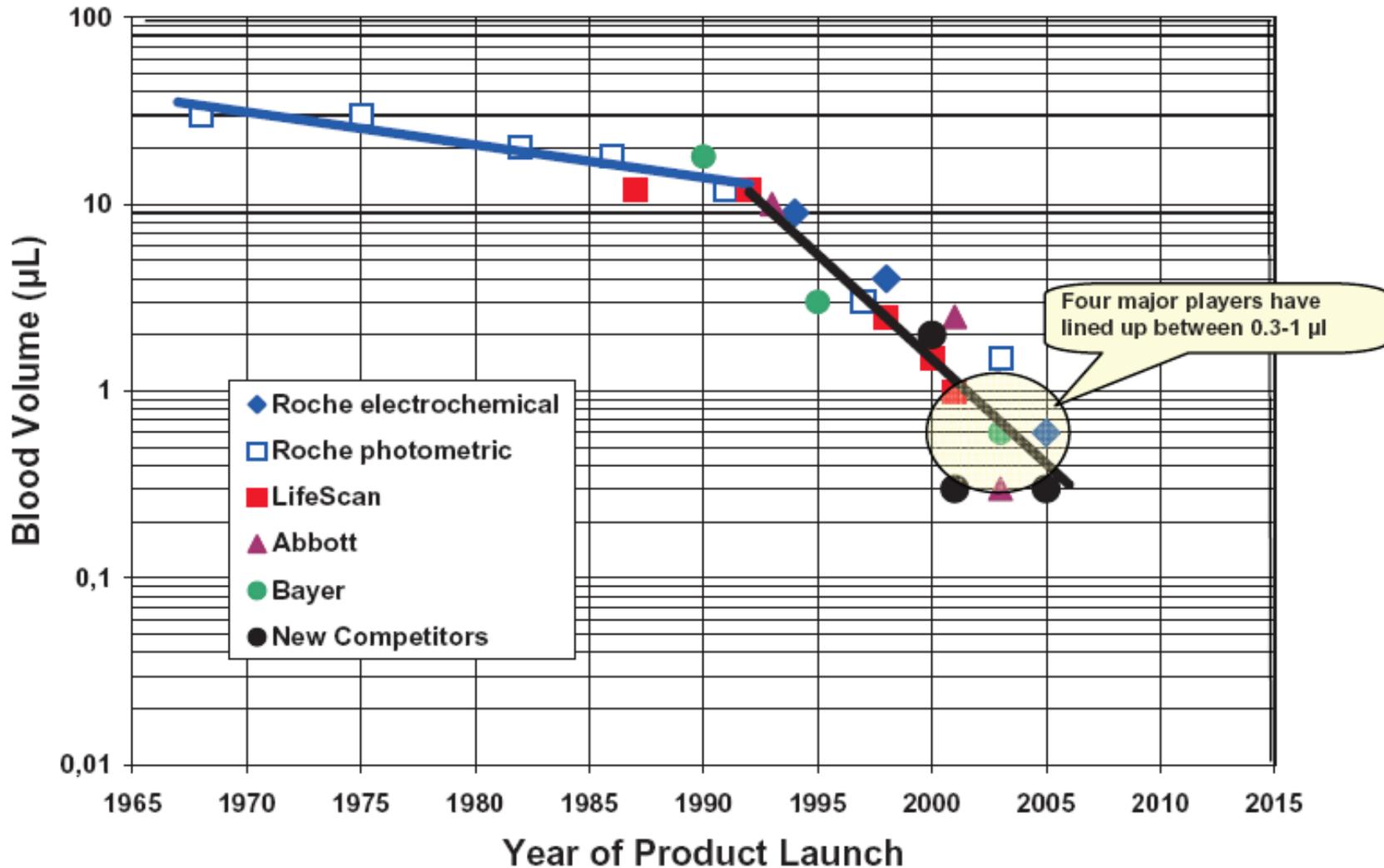


- ◆ **Intensified insulin therapy requires SMBG in capillary blood samples collected at the finger tips**
- ◆ **Finger pricking makes the SMBG an annoying procedure (more pain than insulin injection)**
- ◆ **Major reason (besides the costs) why patients do not to measure their BG frequently**
- ◆ **Small number of publications about lancets and modern lancing devices (more recently)**
- ◆ **Again an aspect that is highly relevant for patients that is ignored by academic research**
- ◆ **Considerable know-how has accumulated inside the respective companies**



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Which size of blood drop do we need?



Sample volume: 20-30 μL



- ◆ This is a large drop of blood
- ◆ This was necessary for blood glucose determination using the glucose meters in 1974.



Blood volume at the fingertip and alternative glucose test-site (forearm)



Fingertip



10 μ l

Forearm



<3 μ l

Which size of blood drop do we need?



- ◆ It is not only the size of the blood drop needed for the measurement per se that is relevant
- ◆ Blood drops must be of “appropriate” size to allow patients to see it and to guide the tip of the test strip to it
- ◆ Blood drop must have a certain size to allow sucking up of the required volume with certainty
- ◆ Reproducible generation of a small blood drop (<math><1.0\ \mu\text{L}</math>) is practically difficult
- ◆ Realistically 2-4 μL are needed



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Why do we prick finger tips?



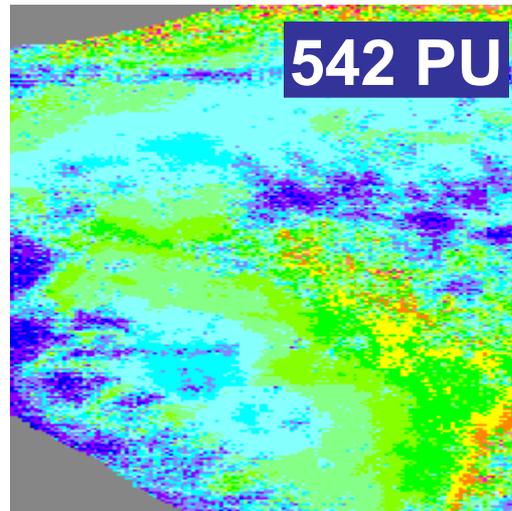
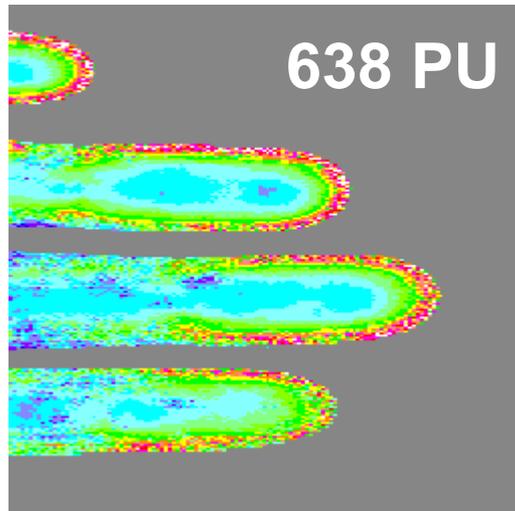
- ◆ **High blood flow at the finger tips**
- ◆ **Allows generation of blood drops with the first attempt (= high success rate)**
- ◆ **Patients hate to prick again!**



Laser Doppler-Flux in upper dermal layers (<2 mm) - Representative examples -



Finger

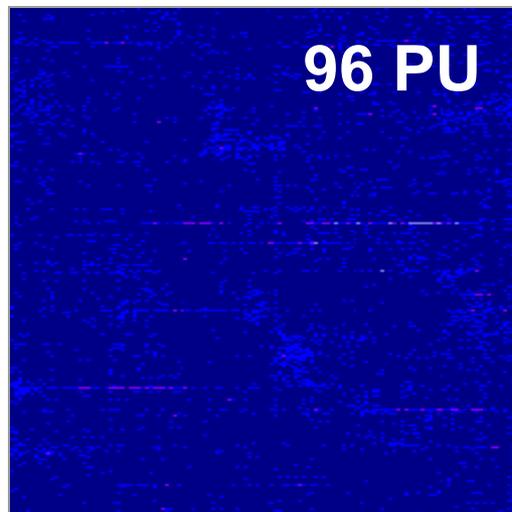
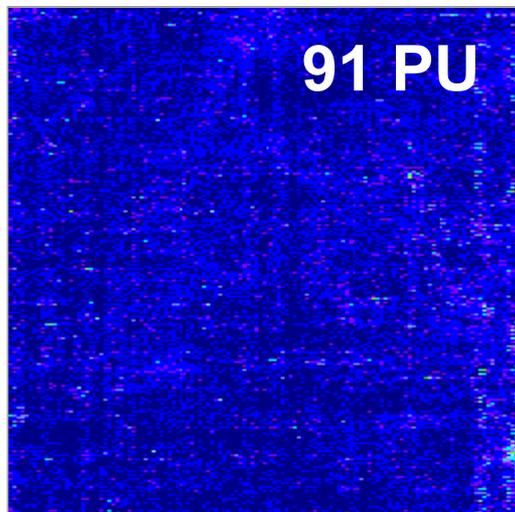


Ball of Thumb

[PU]



Forearm



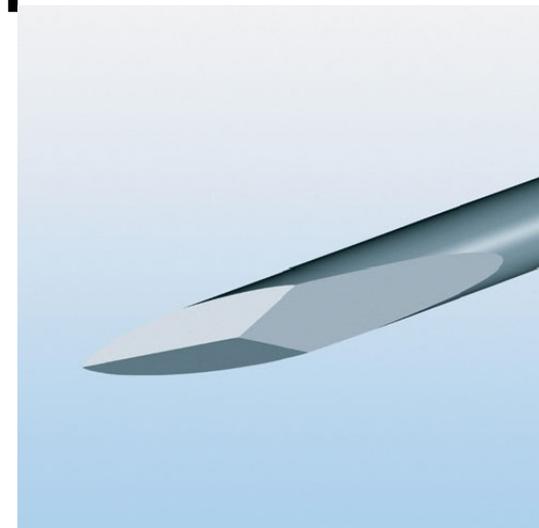
Abdomen



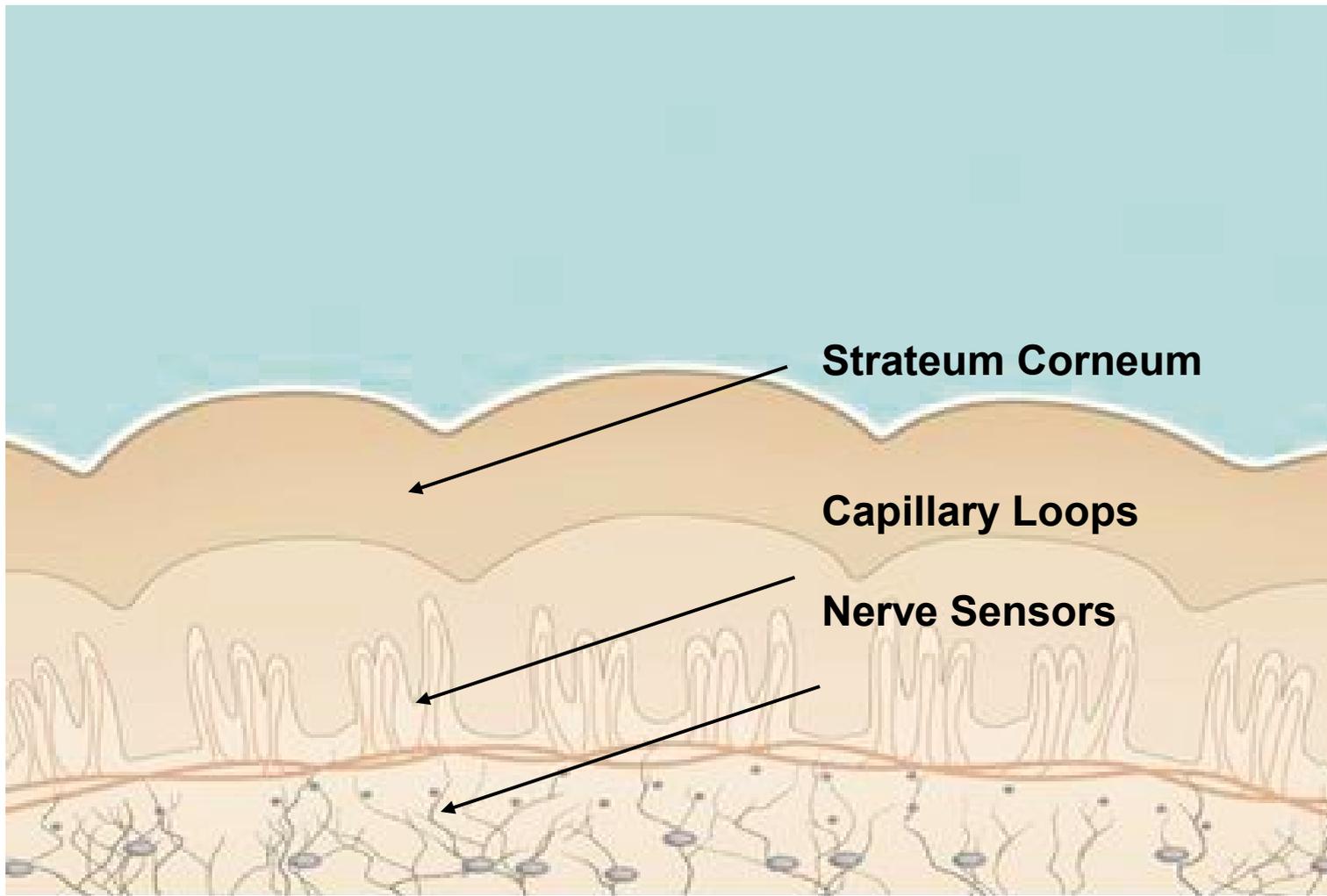
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- ◆ **Invention of modern lancets allow penetration of skin with reduced pain**
 - **Special sharpening**
 - **Polished surface with coating**
 - **Soft insertion without friction into the skin**
- ◆ **Is this sufficient?**
- ◆ **More physiologic factors are of relevance**
- ◆ **Work of Fruhstorfer and colleagues in the early 1990:**
 - **insertion depths**
 - **vibrations**

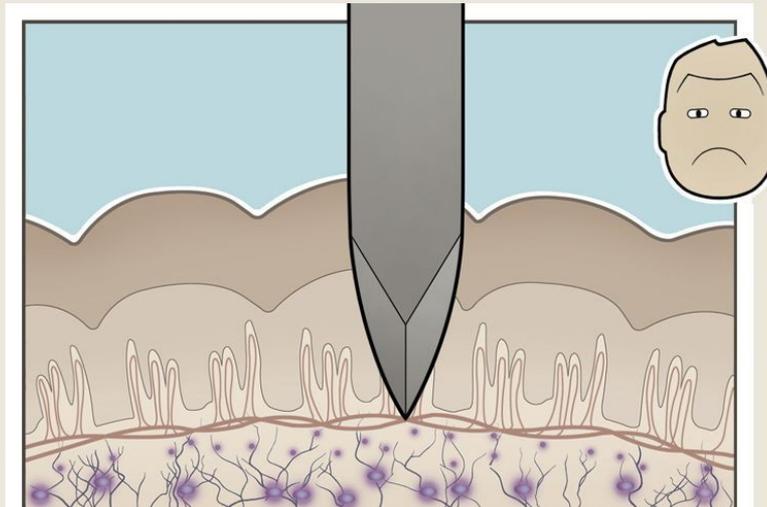
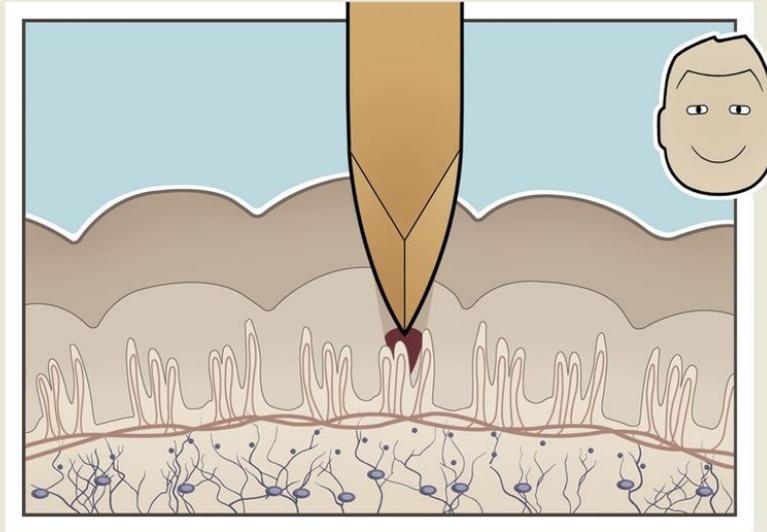


Top Layer of Skin (Epidermis)

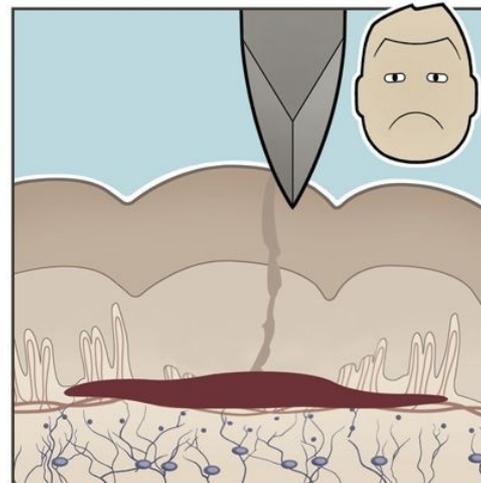
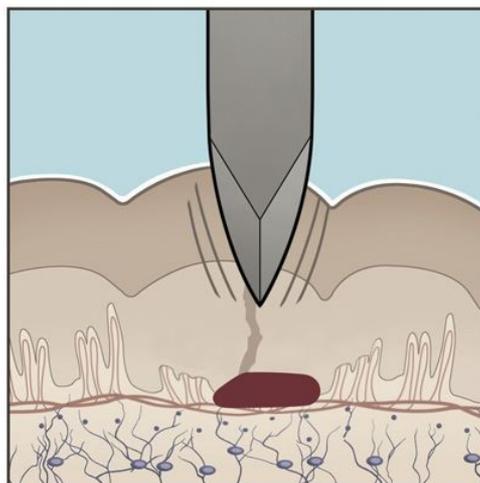
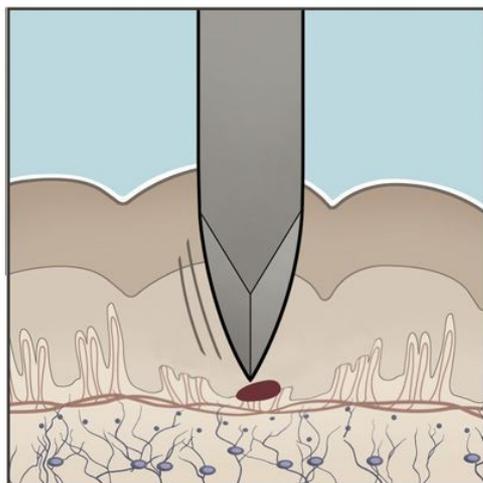
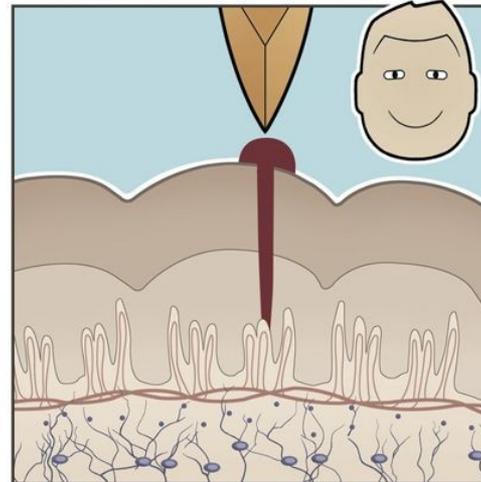
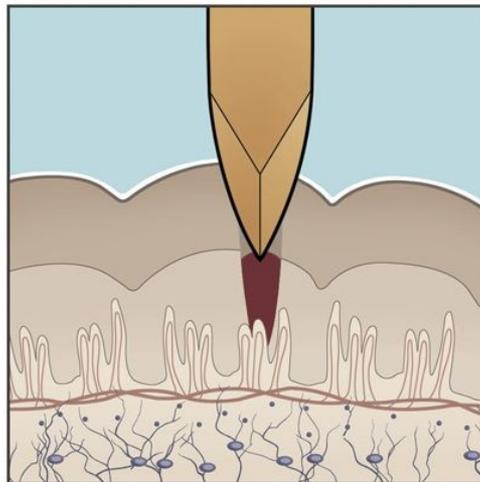
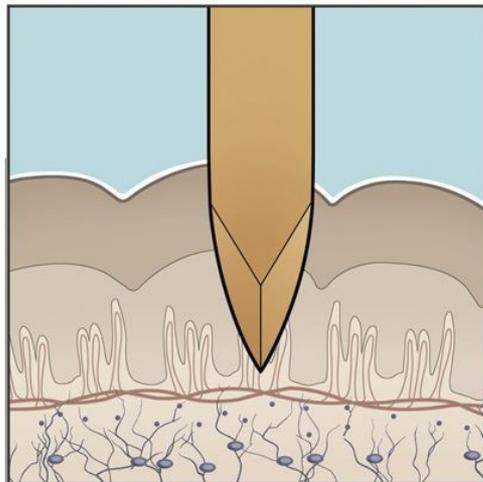




Insertion depth of the needle



Insertion and retraction of the needle

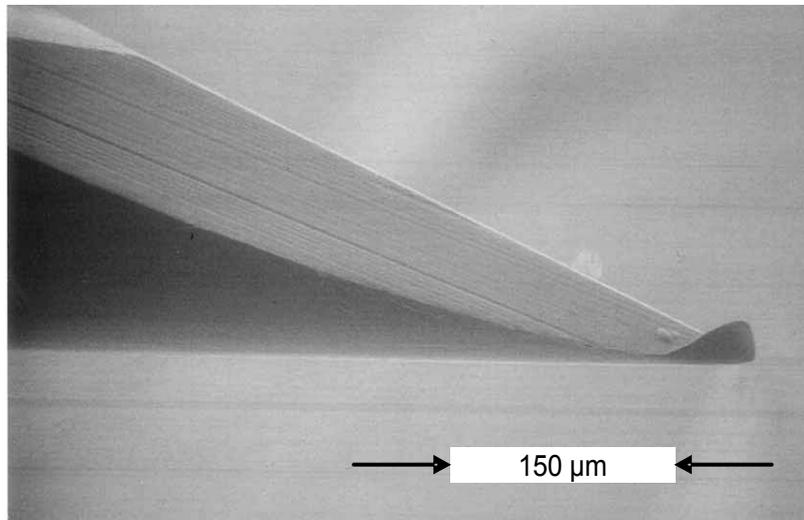
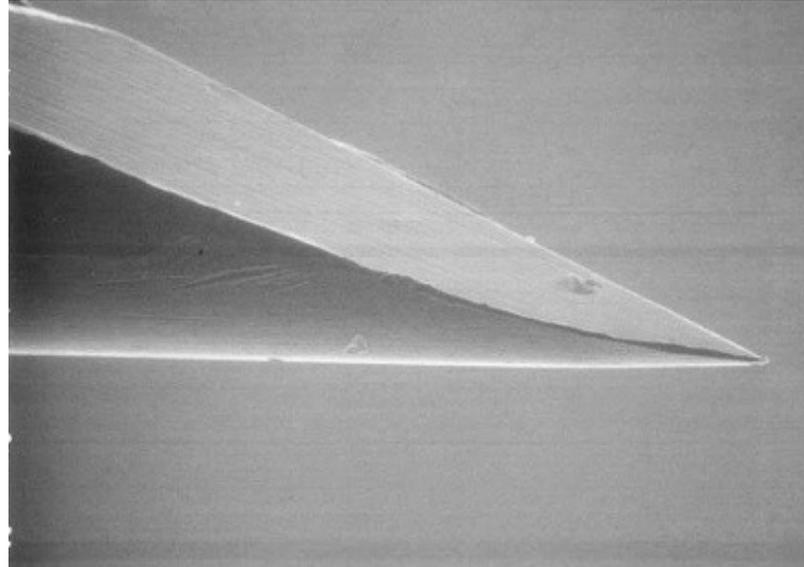




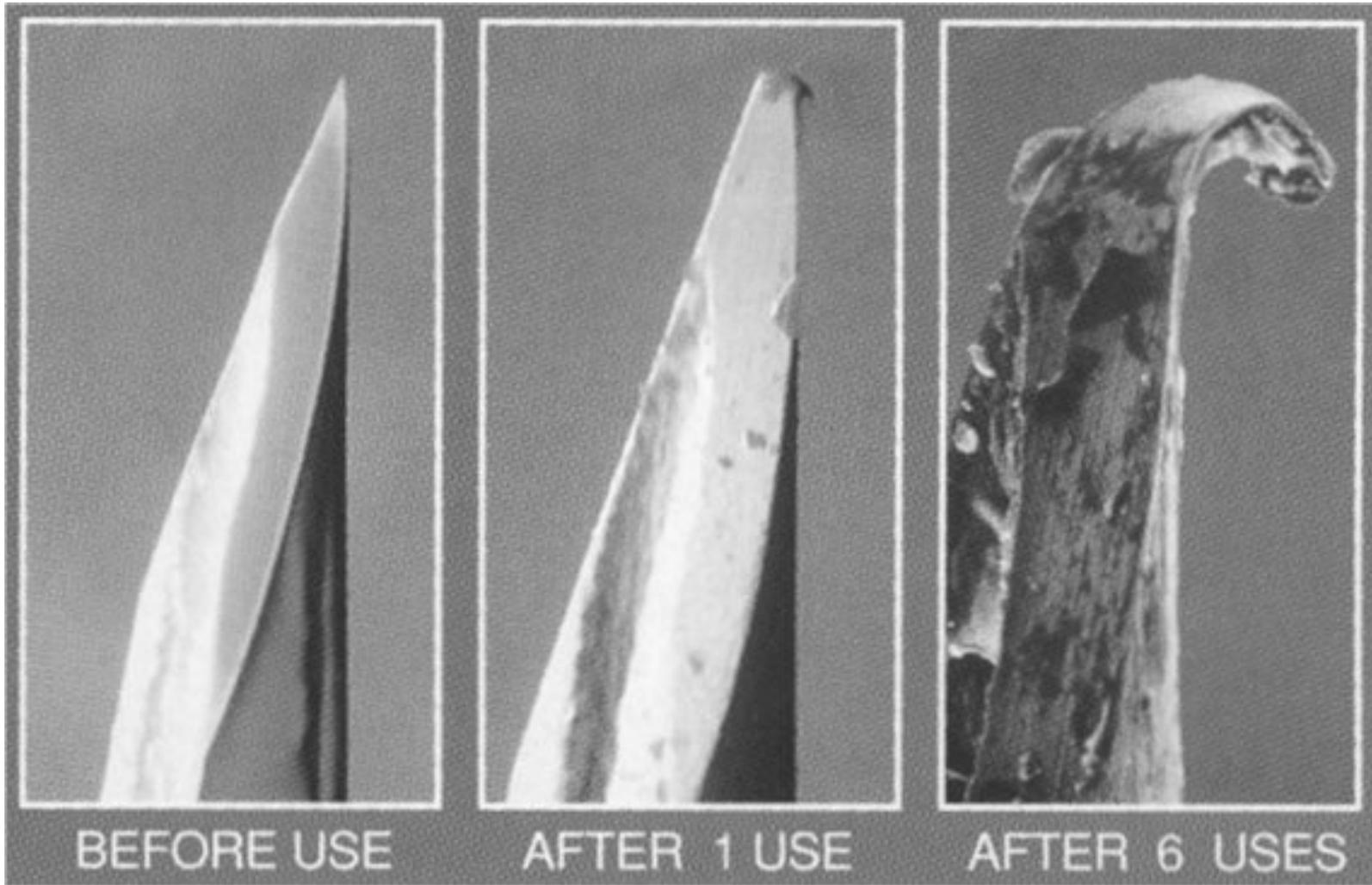
- ◆ **A number of factors are of relevance and must be carefully controlled to reduce pain:**
- ◆ **Depth of penetration**
- ◆ **Speed of penetration**
- ◆ **Shape of the needle**
- ◆ **Surface**
- ◆ **Movement**
- ◆ **Skin fixation**
- ◆ **All this must be achieved to allow lancing “without” pain**
- ◆ **One other factor!**



Native and used lancet after one skin penetration



What induces pain? Repeated usage





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What do patients do in reality?



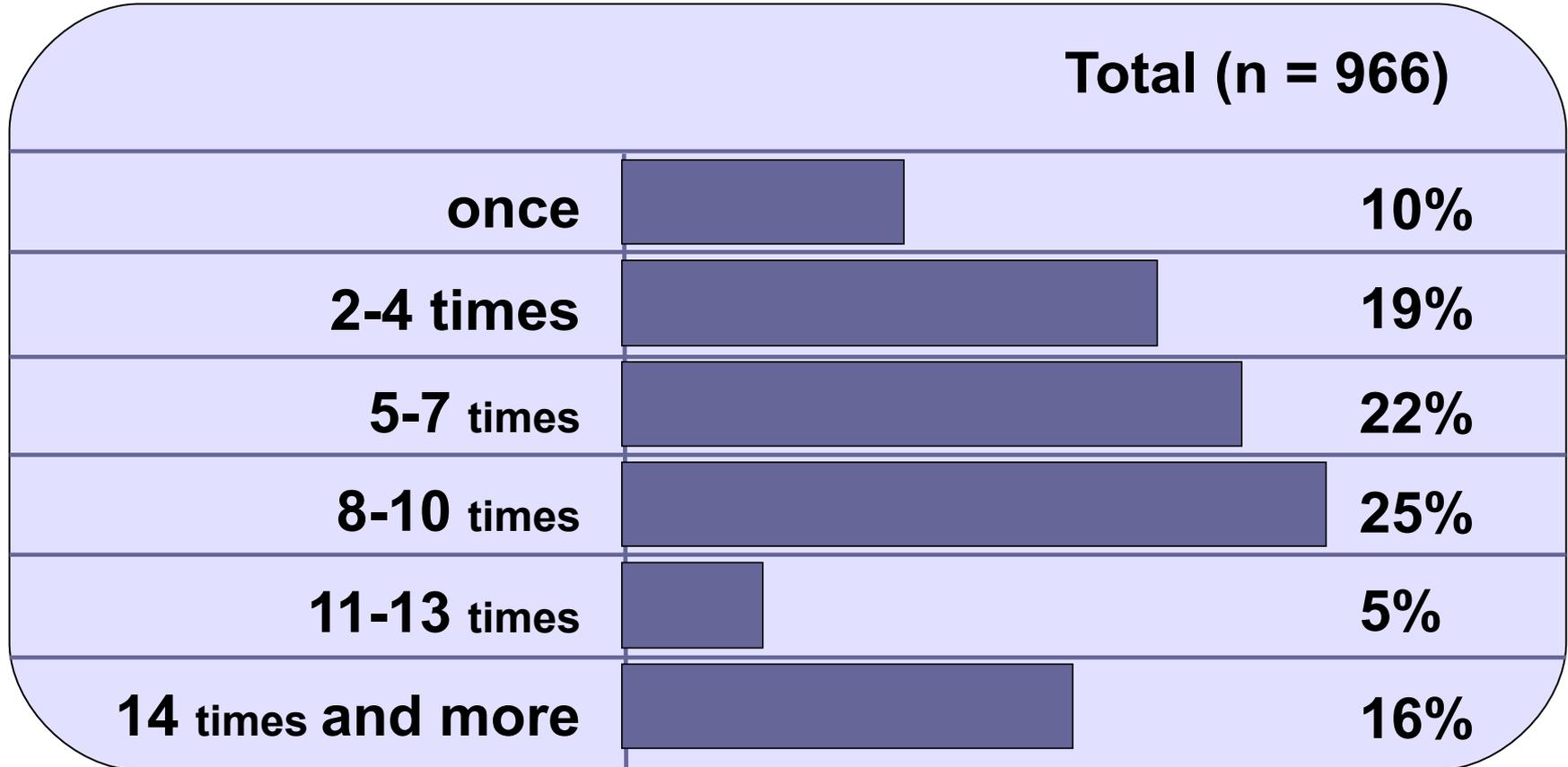
- ◆ **Survey in Germany: 2000 people with diabetes were randomly chosen to be a representative sample of patients performing SMBG according to age, sex and type of treatment**
- ◆ **Questionnaire sent out: 20.04. – 05.05.2006**
- ◆ **Nearly 1000 people responded**
- ◆ **Performed by Marktforschungsinstitut Ipsos, Hamburg**
- ◆ **Sponsor: Roche Diagnostics, Mannheim, Germany**

Koschinsky T. Blood glucose self-monitoring report 2006 reveals deficits in knowledge and action. Diabetes, Stoffwechsel und Herz 16:185-192, 2007

What do patients do in reality?



Total (n = 966)



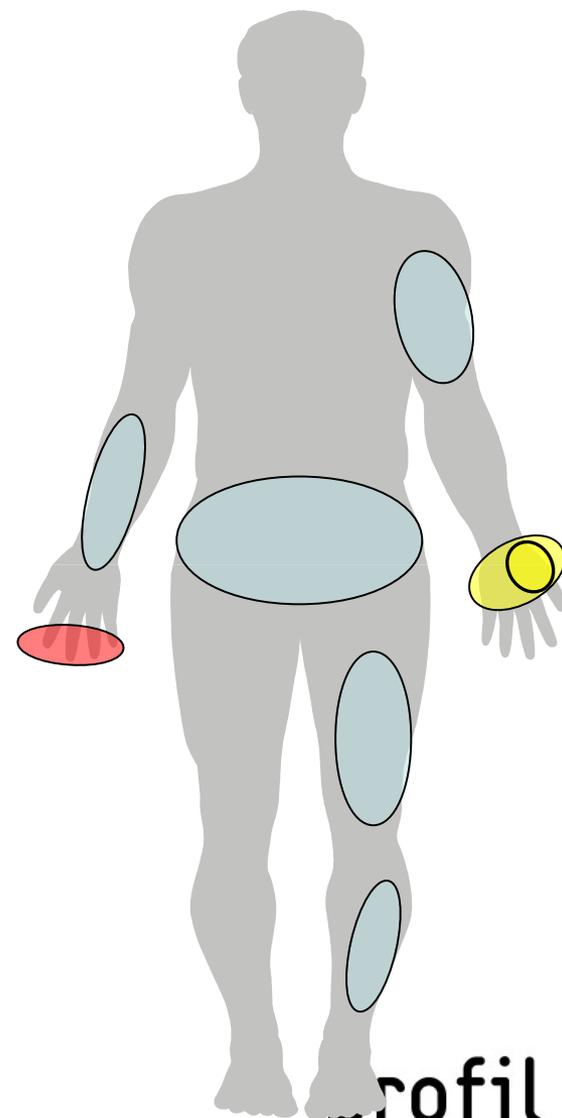


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- ◆ **How can we reduce the pain? = AST**
- ◆ Which lancing devices are the “best“ and why?
- ◆ What is needed?
- ◆ What is the future?



Alternate sites testing for blood glucose measurement

- ◆ **Capillary blood sampling from sites other than the fingertips**
- ◆ **Advantage:**
 - less densely innervated = reduced pain perception
- ◆ **Disadvantages:**
 - Poor correlation in glycemia between finger tips and AST when glycemia changes rapidly
 - pain (?)
 - blood stains in the skin/clothes
 - perform this procedure in public





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- ◆ **How can we reduce the pain? = Laser**
- ◆ Which lancing devices are the “best“ and why?
- ◆ What is needed?
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Lasette, Cell Robotics ISO tech Laser Doctor®

- ◆ **Send a laser beam to the skin to burn a little hole into the very upper layers of the skin only,**
- ◆ **Advantage:**
 - no stimulation of pain receptors
- ◆ **Disadvantages:**
 - devices is bulky and expensive
 - side effects: a certain bang, a little cloud of smoke, some smell and not generating a sufficient amount of blood each time



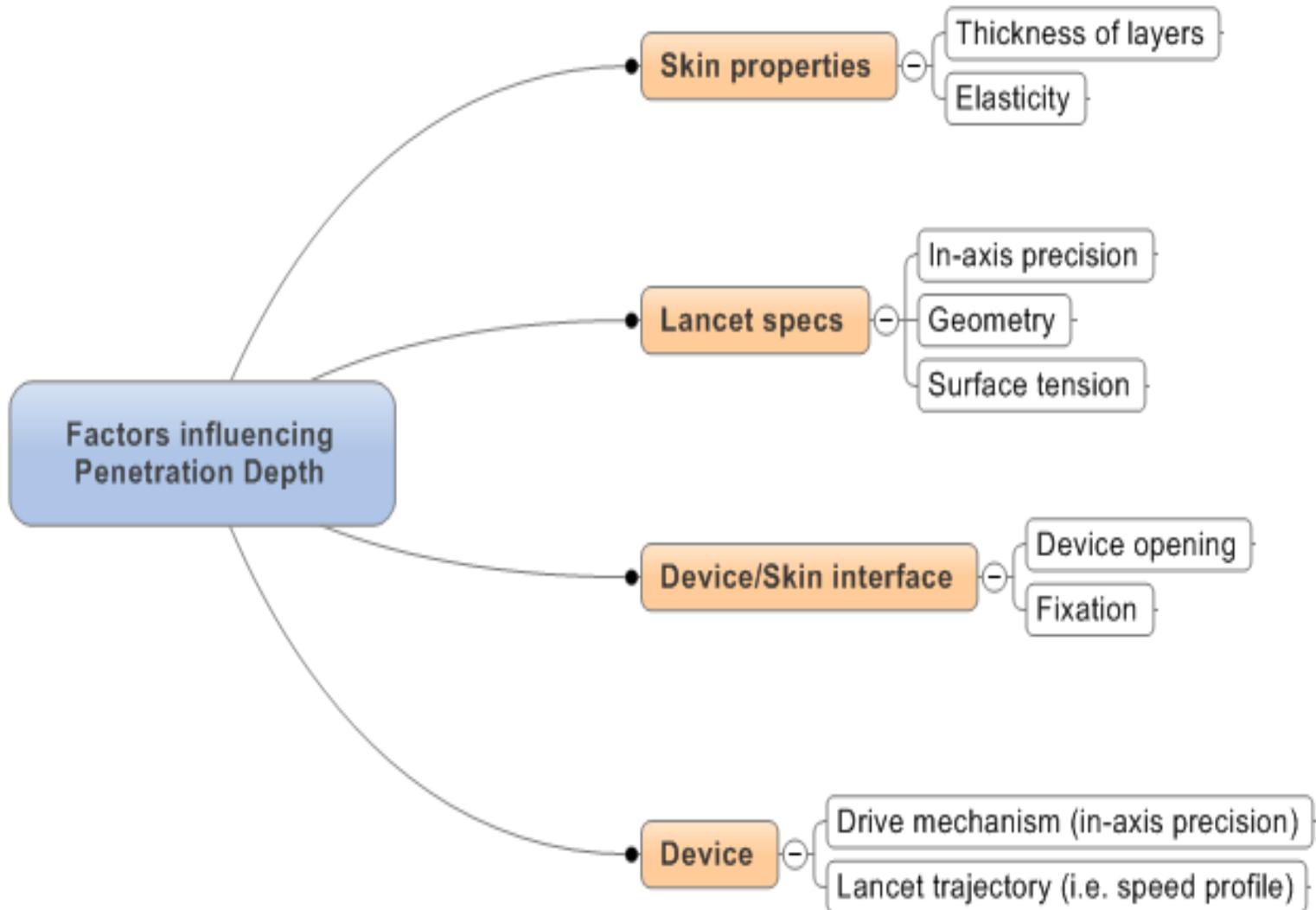


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- ◆ How can we reduce the pain? = Laser
- ◆ **Which lancing devices are the “best“ and why?**
= electronic approach
- ◆ What is needed?
- ◆ What is the future?

Key factors determining precision of penetration depth





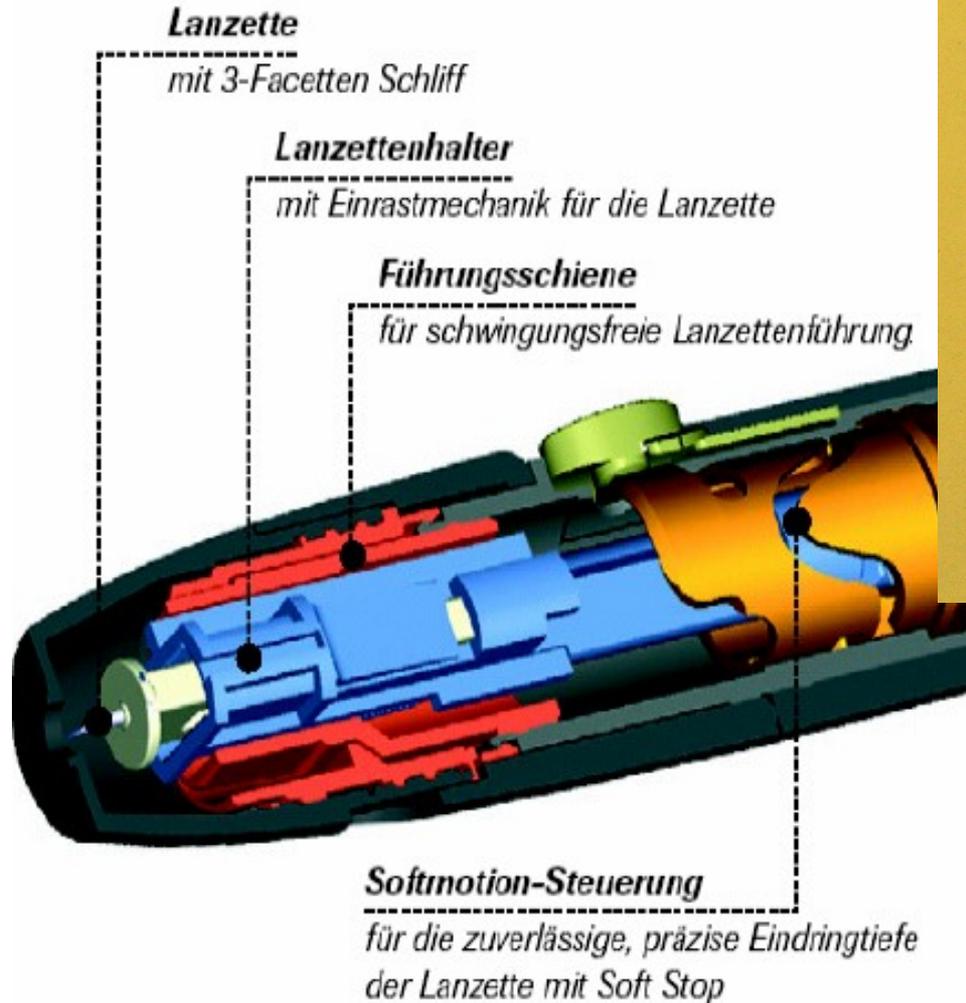
- ◆ **Perfect control of needle movement/depth of insertion**
- ◆ **Advantages:**
 - no pain!
 - new approach / new ideas
- ◆ **Disadvantages:**
 - Company is not active anymore
 - devices was expensive (\$200)
 - no publications
- ◆ **Same happened with the Renew Lancing system (not electronic)**





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- ◆ **Which lancing devices are the “best“ and why?
= mechanical approaches**
- ◆ What is needed?
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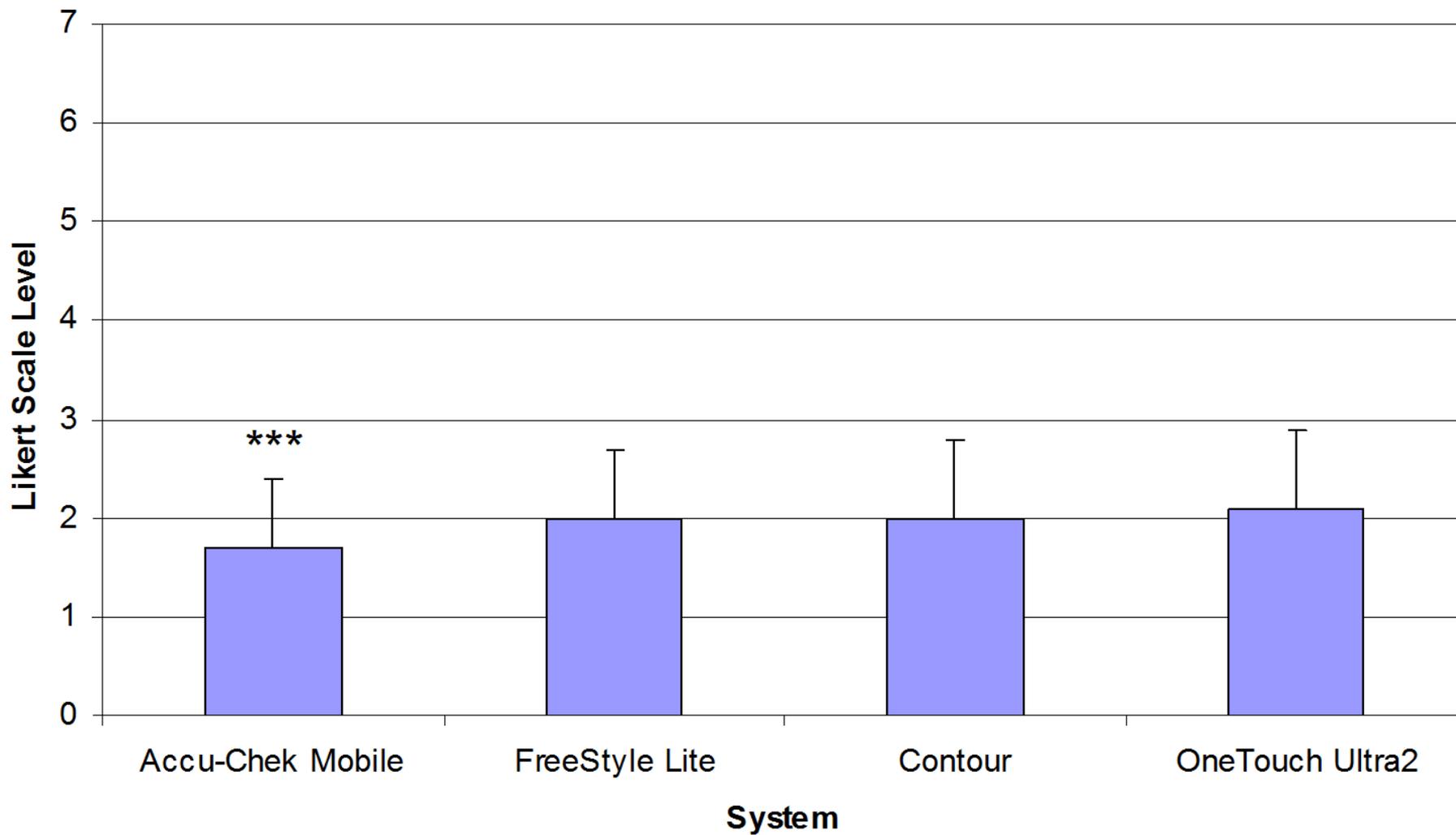
Mechanical approaches: Complex technique is required (Roche Dig.)



Mechanical approaches: Complex technique is required (LifeScan)



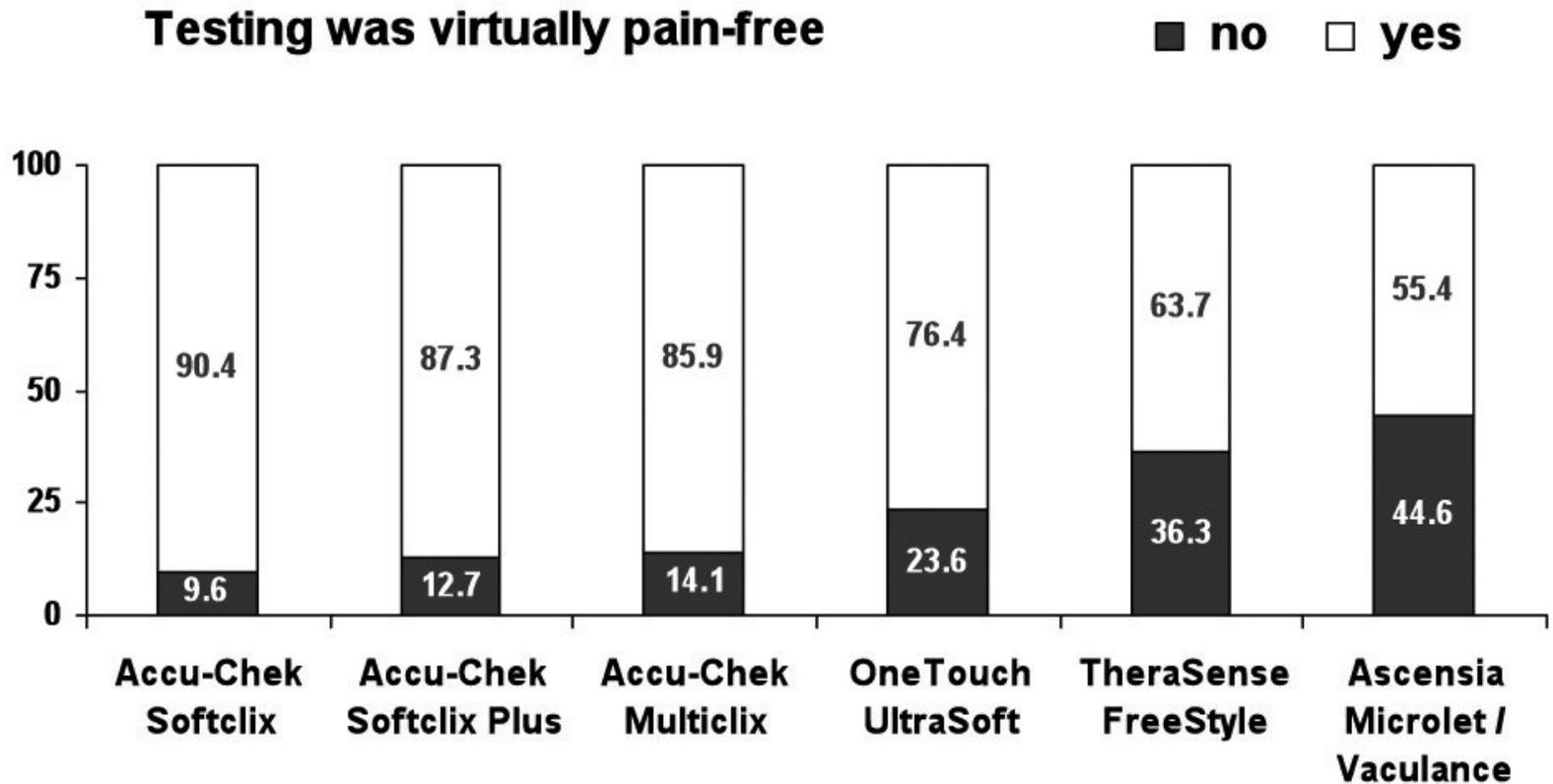
Successful reduction in pain



Adapted from:
Jendrike et al. Diabetologie u. Stoffwechsel 2010

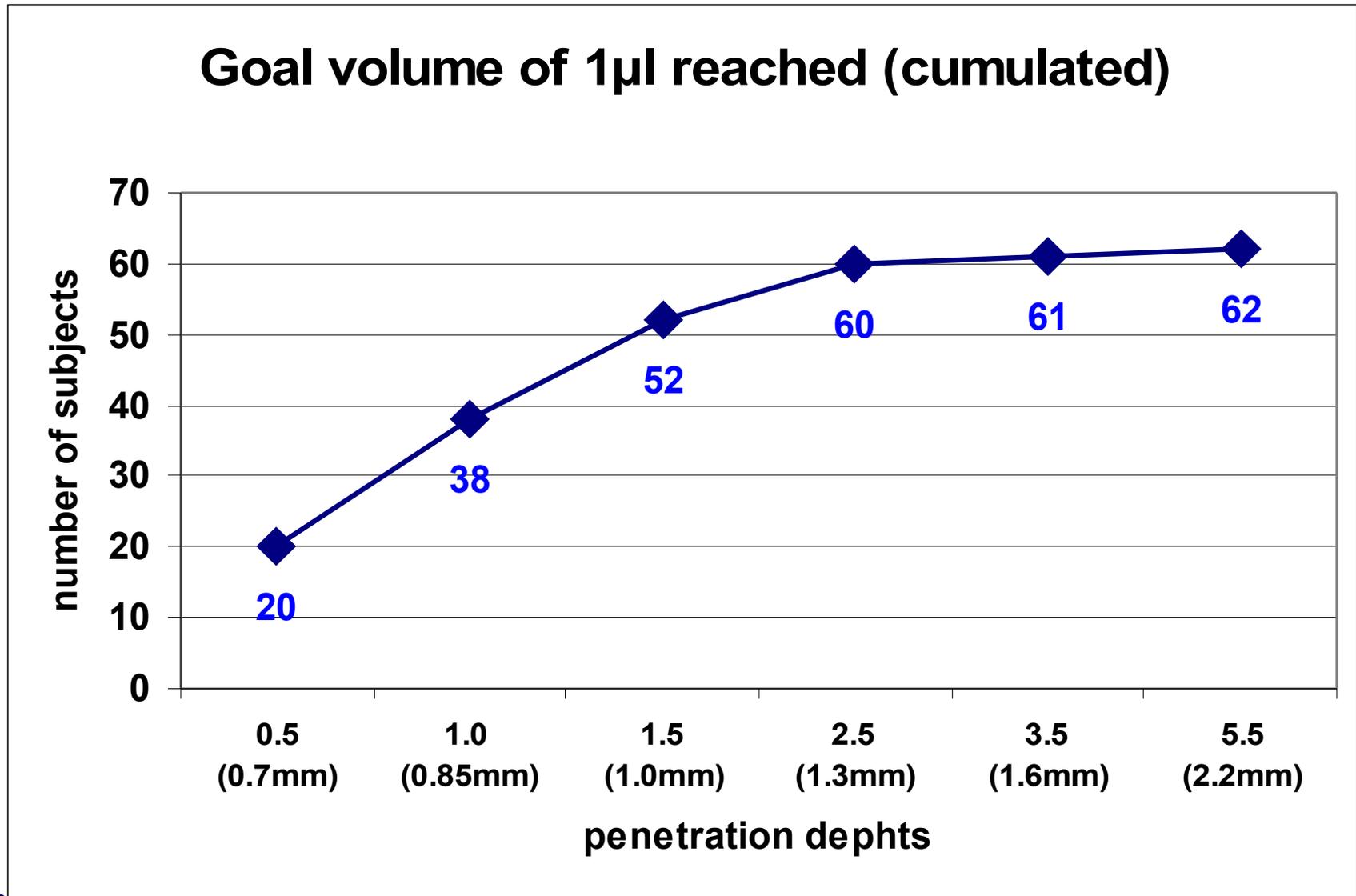
Kocher S, Tshiananga JK, Koubek R:
Comparison of lancing devices for self-
monitoring of blood glucose regarding
lancing pain. *J Diabetes Sci Technol*
3:1136-1143, 2009

B
(%) fraction of subjects



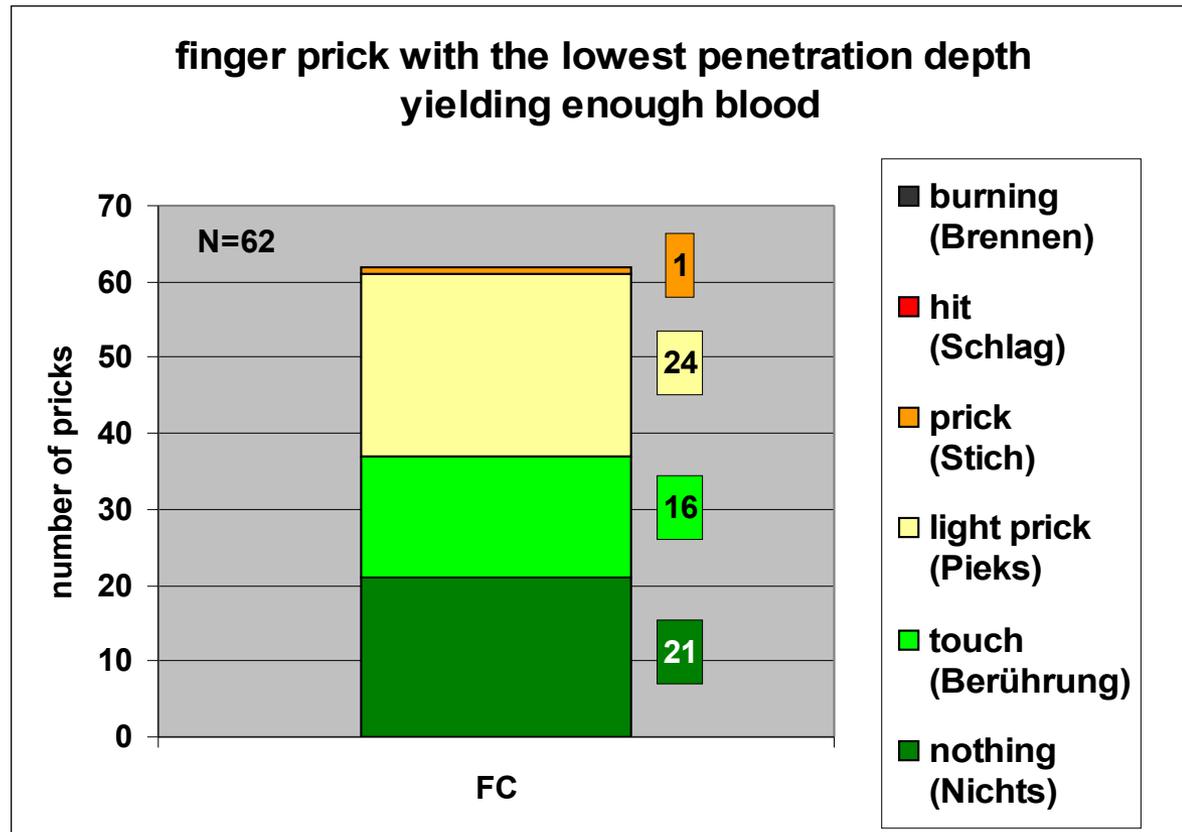
Results

In all 62 study participants $>1\mu\text{l}$ blood was obtained



Results – Pain Sensation

- 60% of the successful fingerpricks were without any pain (descriptors “nothing” or “touch”)
- 38% of patients described a “light prick”
- 2% (one patient)
a “prick”
- no participant characterized strong pain



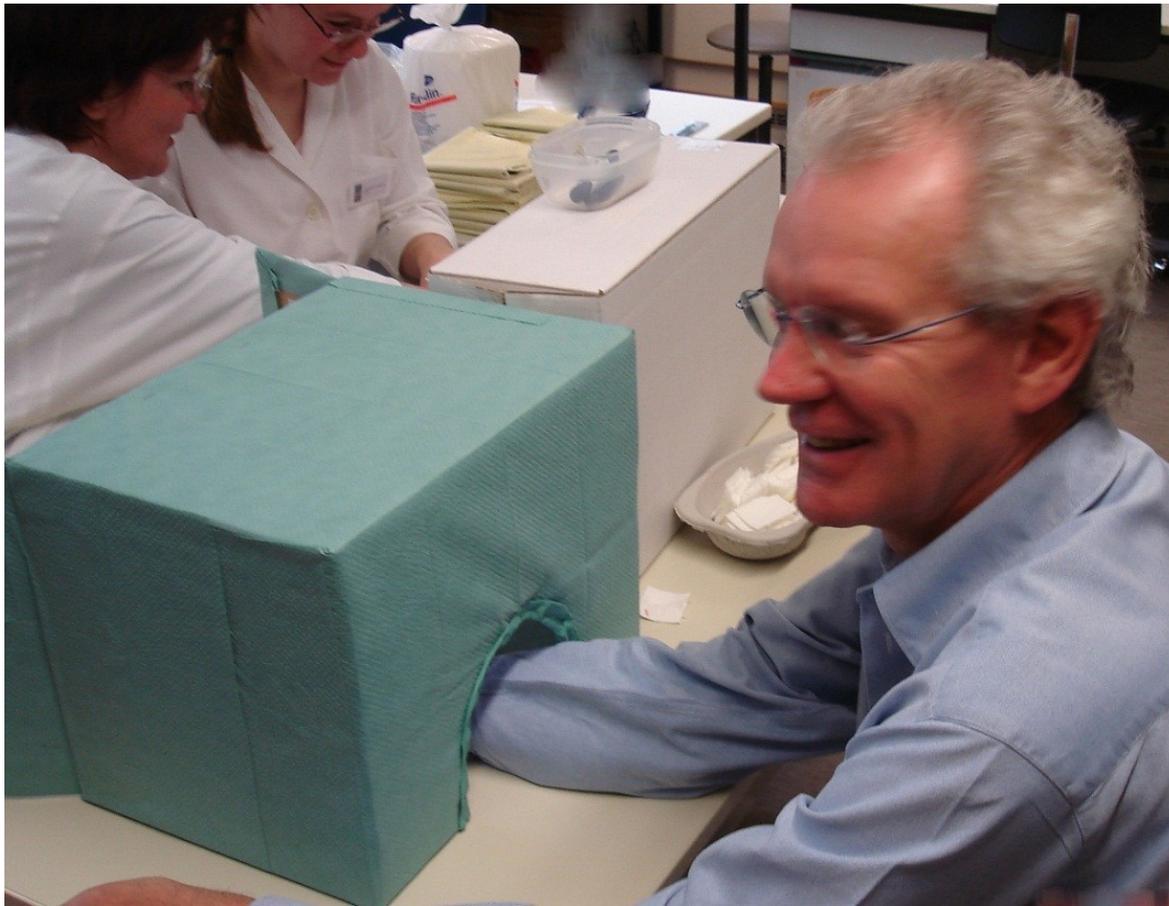


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What is needed?

- ◆ **More interest of the academic world for this topic**
- ◆ **Specific attention on lancing in the diabetes training courses for patients**





What is needed?

- ◆ **Appropriate clinical trials (devices per se and long-term studies)**
- ◆ **Head-to-head comparison**
- ◆ **Outcome pain but also “sufficient” size of blood drop**
- ◆ **Single-blind, appropriate set-up, training of technicians**
- ◆ **Independent! Most studies were performed by a manufacturer of the device, the outcome is clear...**
- ◆ **Endpoints?**
- ◆ **Register all studies at [Clintrial.gov](https://www.clinicaltrials.gov), publish them!**



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- **CGM without need for calibration and recalibration**
- **Combination of all SMBG steps in one device**
- **Further improvement of e.g. the shape of the needle**

- **Performance of a long-term clinical trial that demonstrates that a reduced pain associated with lancing is worth the investment to gain reimbursement**
- **Else?**

Combination of all steps involved in SMBG in one device (first attempts)



Combination of all steps involved in SMBG in one device (first attempts)



- ◆ **mendor discreet**
- ◆ **Portable all-in-one Blood glucose meters**
- ◆ **Integrated lancing device**
- ◆ **25 strips in one cartridge**
- ◆ **No need for carry case**
- ◆ **Easy to use and discreet**

- ◆ **www.mendor.com**



What is the future? My personal view!



- ◆ **There is a lot to gain in lancing!**
- ◆ **Great options for improvement taking all our knowledge into account**
- ◆ **It is tricky to improve the currently already available systems within cost and size boundaries**
- ◆ **Aim is: Low cost high performance system in the interest of the patients with diabetes**

Thank you very much for your attention!



Lancing: Quo Vadis?

by

Lutz Heinemann, Ph.D. 1,2

Dirk Boecker, M.D., Ph.D. 3

1Profil Institut für Stoffwechselforschung GmbH, Neuss, Germany

2Profil Institute for Clinical Research Inc, San Diego, CA, US

3Toto Consulting, LLC, Palo Alto, CA, US

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