1. Fields of application

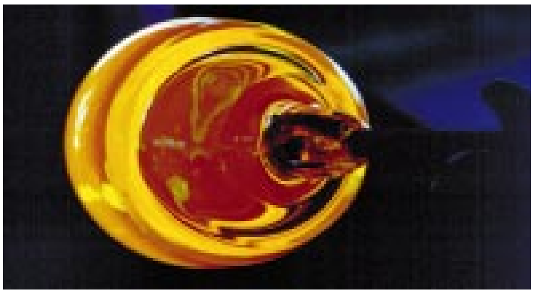
The main point of ZX-27 Attractive Glass Abutment System is that if somebody has still teeth but does not want prosthesis and implants yet he can get fixed prosthesis. ZX-27 substitutes the missing abutment teeth, glass abutment fits on the gingiva on definite edentulous regions. It can be used also in case of uni- and bilateral gap at the end of the set of teeth, frontal tooth gaps and the combination theseof, too. ZX-27 can be used successfully when it is combined with implants, as well.

2. Development progress

The support of non-supported, open-ended bridges has been engaging the attention of dental research workers for a long time already. ZX-27 Attractive Glass Abutment System has long history. Hereinafter we can see why the tried materials were not successful.
In case of metals the cast piece shall be finished, polished, as a result of these operations it is not precise enough to be resultful, the pieces will not rest on the gingiva precisely along its full length. The situation is similar in case of plastics, the problem is with finishing. Even the plastic materials are porous which may result in food deposit, then inflammation. Moreover the majority of commercial plastic materials is not hard enough, is too flexible and do not stand really the thermal effects either.
In case of glass ceramic and ceramic the shrinkage after adaptation to the gingiva results in inaccuracy, moreover these materials are not really self-cleaning.
The general glasses were not successful either, we will describe the reasons later.

3. About glasses in general

Glass is inorganic fusion, its basic materials are lime, soda and quartz. Very hard transparent product is produced when these materials are fused. The intermolecular bonds do not elongate but break. Therefore the glass is hard but fragile. In addition to the above glass



may consist of other components, too, and this results in wide range of features. The glass used for dental purpose shall conform to several aspects simultaneously, namely: fusibility, workability, solidity, chemical resistance. Such material can not be found among gener-

al glasses, the most important problem is with fusibility and chemical resistance. General glass can not be tempered properly under dental mechanic laboratory conditions. During heating it may crack or invisible hair-cracks may occur which may result in break. Similar processes are going on upon cooling down.
The other problem is with chemical resistance. Saliva gets in touch with glass and enters into chemical reaction after longer time. As a result of these processes toxicants like e.g. lead and barium get from the general glasses to saliva. These materials have harmful effects on human organism.

4. ZX27 glass

Requirements towards the glass to be used:
– workability
– proper solidity apt for use
– effect of chemical resistance on human organism

Workability
When choosing the structural material it is an important aspect that the technology to be used shall be simple, i.e. the glass abutment shall be formed and built in the bridge in the traditional dental laboratory relatively easily, without considerable investment within short time. From this point of view **ZX-27** glass can be said to be specially ideal. It has properly low softening point, after its heating the glass surface resting on gingiva can be formed according to the mould easily.

Solidity apt for use
The glass formed as a support of bridge is exposed to great pressure and shearing power effect during chewing. The stress-relieved **ZX-27** glass stands these effects. The elastic coefficient of **ZX-27** glass falls within the range of 500–800 MPa, its compression strength is great as compared to commercial plastics, 120–150 Kp/mm^2. Its thermal and current conductivity is bad, we do not have to fear that it acts as galvanic element and accelerates the corrosion of other metal elements built in the mouth.

Chemical resistance
Resistance of glasses to aqueous solutions is to be understood under chemical resistance, therefore we examine glasses from the point of view of solubility in water, acid, alkali. Chemical resistance depends on the composition of glass, the concentration of active solution and the duration of effect. The following had to be considered when the composition of **ZX-27** glass was planned.
The resistance of glass to water and acids is deteriorated by alkali oxides – Na_2O K_2O – considerably, less by earth alkali oxides but they also reduce resistance.
The volume of boron, phosphorus and earth alkali oxides deteriorates alkali resistance,

too, in addition to alkali oxide content.
The chemical resistance of **ZX-27** glass is appropriate yet we shall consider a certain complex reaction between glass and the solution contacting with it, including saliva as well. Basically this complex reaction can be divided into two processes being in interaction with each other. As a result of one of the processes hydrogen ions get from the solution to the surface of the glass and get inside that by slow diffusion. Meanwhile alkali of the same volume as of hydrogen ions, primarily sodium ion gets in the solution. The other reaction results in gradual, slow decomposition of the polymeric structure of glass as a consequence of which all components of glass get in solution. In unfavourable case we shall consider the dissolution of toxicants being harmful to organism. After testing several experimental glasses **ZX-27** glass conformed to the above mentioned aspects the best.

Main features:
a. Melting temperature: 1560 – 1600 ^{o}C
b. Compression strength: 120 – 150 Mpa/kp/mm^2
c. Acid resistance: hydrolytic class 1.
d. Solubility in alkali: hydrolytic class 2.

In addition to its main components **ZX-27** glass contains some zinc and magnesium, too, but it does not contain barium or lead being harmful to health, which can usually be found in glasses.
The feature of **ZX-27** that it can be formed well under laboratory conditions, too, is due to its high boron-trioxide content. The high alkali content being essential otherwise could be reduced this way. Owing to low Na content corrosion does not result in considerable local pH increase near gingiva.
The above ensures that the structural elements made of **ZX-27** glass can be used for dental purpose.

5. Treatment

Heat treatment and diamond tools are applied. The heat source is flame developed by the mixture of PB gas and oxygen. When the glass cooled down we cut it to proper size by diamond tools, and polish off its so called belly. We pay attention to the fact that we must not touch by any tools that part of bridge which will be visible later. Then we prepare the bridge frame in standard way.

Gingiva changes of people having glass abutment bridge
Cytological, histological, element analysis examinations

Written by: **Prof. Dr. Tibor Kerényi**
Professor, SOTE, Head of Pathologic Department of
„Központi Honvéd Kórház" (Central Military Hospital)

We have made cytological, histological examinations, DNS analysis related to the oral mucosa of patients having glass abutment bridges apt for the substitution of unilateral or bilateral gap of teeth at the end of dentiton, and have performed scanning electronmicroscopic tests and energy-dispersive radiological element analysis regarding removed glass abutments. The examinations were made partly on the request of the medical attendant of patient, partly on own initiatives. The aim was to clear the effects of the glass abutment, being in mouth durably and resting on gingiva on relatively small surface, on oral mucosa on the one hand, and to show the possible corrosive effect of mouth milieu on glass abutments. The danger of stable mechanic irritation, the metaplasia of oral mucosa which may be precancerosis state. The superficial corrosion on glass abutment or the dissolution of the components of glass may doubt the suitability of the abutment for use and may result, respectively, in the toxic damage of oral mucosa contacting with the abutment. As essential criterium of the approval and the introduction of a new prosthetic solution valid for long period is among others that changes which mean unforeseeable risk to the patients must not occur either in the recipient organism or the built in material (Fazekas, 1996). The following examinations give satisfying reply from pathologic point of view, in several aspects, to these misgivings.

Material and method

We have tested smears from the deposit of mouth wash (physiological saline solution) as well as from the surface of the cleaning thread pulled-through under the glass abutments. In case of a part of patients examined this way we have exposed some gingiva sections under the glass abutment to histological test. The bridges were built in the nine patients – who appeared for examination – 14 days or 6 years (in average 2 years) ago before sampling. The age of patients was between 32 and 62 years (in average 49,88 years), both men and women were examined (the rate of men and women was 5: 4).
We stained the **cytological specimens** got from the deposit of mouth wash and by the cleaning thread by haematoxilin eosin (HE), Giemsa and Gram method, and performed PAS test. As a control we used the cytological specimens – got similarly to the above way – of patient having traditional bridge for more than ten years.

From among the above mentioned nine persons four contacted us for **histological sampling**. We used the oral mucosa of gingiva of six patients having traditional prosthesis and the gingiva sections of five persons with gaps of teeth not having prosthesis (archive) as a control for gingiva sections under the abutment, cut under local anaesthesia. The oral mucosa defects produced by the cut under the abutment healed in both cases well and without complication.
We tested the sections of 3–5 micron thickness of the blocks of gingiva fixed by 8 % formalin, embedded in paraffin by HE, resorcin-fuchsin-van Gieson staining, and examined furthermore by Berlin blue and Feulgen-Schiff tests. Thus, in addition to recognising the

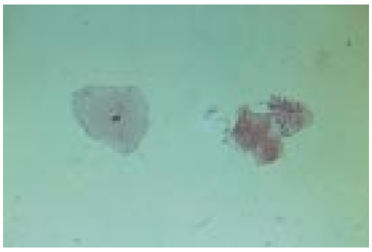
general tissue structural changes it was possible to test also the composition of subcutaneous tissue, traumatisation after mechanic load as well as DNS content of cells.

DNS analysis was performed on Feulgen-Schiff specimen by computer quantitative histologic image processing program (DNASK). The image resolution was 512x512 pixel, with 256 shades of grey. The program can determine 13 morpho-and densitometric parameters of cell and cell nucleus.

We exposed new, unused glass abutments, those removed for different reasons after use for eight (2 pcs) and twelve (3 pcs) months, primarily their gingival surface to **scanning-electronmicroscopic examinations**. The fine structure test was performed on specimens steamed by golden, the element composition tests (EDX) based on **energy-dispersive X-ray analysis** were performed on nat and carbonised specimens. We cemented all samples to aluminium blocks by electrically conductive colloidal silver and tested by Opton DSM 940 scanning electronmicroscope, microanalysis was performed by Link AN 10/55 S device. The superficial structures were tested at object-detector distance of 12 mm, EDX analysis at object-detector distance of 20 mm, 15–30 kV accelerating voltage.

Results

Mostly superficial, over-matured cells were found in the cytologic smears got from the **mouth wash**. In addition to the majority of matured, non-keratinized cells we have found some keratinized, otherwise typical cells (picture 1/a) in 17 smears of patients having glass abutment from among the 67 cytological specimens of the examined 9 patients. These three persons had one or two glass abutment supported bridges built in 2–4 years ago. Keratinization was insignificant in the specimen of the other six patients having glass abutment, similarly to the smears sedimented from the mouth wash of two control persons having traditional bridges.



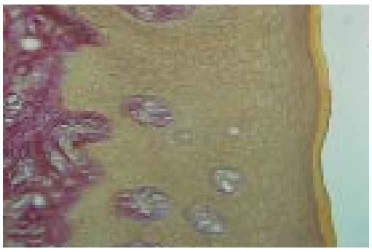
picture 1/a

picture 1/b

In addition to cells a great number of haemophilus influensae, Hyphomycetes, candida albicans (picture 1/b) and primarily in the smears containing much mixed flora – great volume of inflammed cells (neutrophilic granulocyte) could be found in the cytological smear of all controlled persons. The intensity of inflammation did not influence the level of maturity of epithelial cells, the tendency of keratinization, its type.

In case of all patients having glass abutment we have found a great number of cells apt for test in the smears got by **dental cleaning thread**. The cytological picture of these specimens differed from the picture seen in the sediment in respect of the number of inflammed cells and bacteria which was greater in case of the former. More aggressive sampling did not increase the rate of keratinized or transitional cells in the smears.

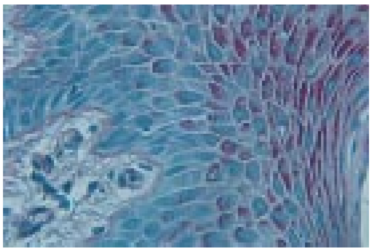
Stratified epithelium of typical structure, showing keratinization was found under the glass abutment, on the surface of gingiva (pictures 2/a, 2/b). Histologically the keratinization conformed to parakeratosis and hyperkeratosis. Decomposing form could not be found among the epithelial cells, the epithelial layers - advancing to the surface - showed normal


picture 2/a

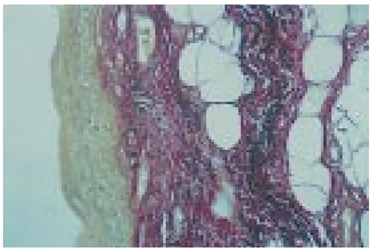

picture 2/b

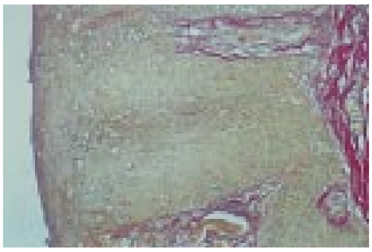
maturity tendency (picture 2/a). The used fixing agent fixes the glycogen of tissues improperly, despite this the cytoplasm of cells contained glycogen in great volume (pictures 3/a, 3/b). The contour of epithelium and connective tissue was sharp, papillation flattened out slightly, vascularisatio could hardly be seen in the connective tissue but the volume of collagen increased (picture 2/a). It was remarkable that the elastic fibres disappeared mostly from gingiva sections under the abutment though, it could not be established reliably in all cases because of the superficial resection. Within the epithelium the basal layer extended in spots only, the spinocellular layer enlarged more and relatively better (pictures 2/a, 2/b).


picture 3/a


picture 3/b

Keratinization tendency on gingiva sections without prosthesis under the removable prosthesis serving for control, could also be recognised though the horny layer seemed to be narrower than that under the glass abutment (picture 4). However, the narrower horny layer could in almost all cases be explained - provably - by the soaking of epithelium. On the basis of the volume of desquamated horn-sheets, primarily when chewing was by gingiva, the rate of keratinization was higher than was observed under the glass abutments and the traditional prosthesis. The spinocellular cells were focally hyperplastic here, too (picture 5). The contour of epithelial and connective tissue was sharp in every examined case.


picture 4


picture 5

By Berlin blue test we did not observe haemosiderin deposit referring to earlier traumatization, haemorrhage neither under the abutment nor in the control specimens.

According to the image analysis – performed for DNS determination – on the basal cells of epithelial layer normal Gauss diagram was received in case of all the three tested groups (patients having glass abutment, removable prosthesis, or chewing by gingiva). The apex of the diagram was in normal diploid DNS range. The number of tetraploid cell nucleus was below 4 %, aneuploid polyploidy did not happen at all.

By **scanning electronmicroscope** the surface was smooth at the marginal region of the gingival side of the new abutment. Crater-like cavities of 1–3 micron and conchiform faults of rounded surface of 5–40 micron were observed on the sulcus in the middle of the new abutment. We did not observe scratch, mechanic damage, deformity which may be considered from the point of view of the irritation of oral mucosa.

The element composition, measured at five different places (two marginal and three sulcus points of a surface of 350 micron diameter), was practically the same. Since carbon and other elements of smaller atomic weight can not be detected by **EDX method**, BeOs constituting 12–18 % of used glass can not be identified on the element distribution diagrams. The volume of silicon, aluminium, sodium and potassium was the same at the measured places.

The surface and the chemical composition of glass abutments being in mouth for eight months and one year, respectively, were identical with those of the new abutment. Special differences, which do not have connection with the time of wear, could be observed in the volume of conchiform faults of smooth surface only.

Consultation

According to general pathologic knowledge the chronic, mechanic, thermal, chemical and osmotic irritation of non-keratinized flat epithelium results in its keratinization, leukoplakia (hyperkeratosis, parakeratosis) and if it is accompanied by dysplasia, preneoplasy state may be developed (Riede, Schaefer 1993). Our examinations referred just to clear the effects of chronic irritation caused by the abutment on oral mucosa.

The staining procedures used for cytological and histological specimens, made possible to detect the maturity of cells, possible metaplasia, mitotic activity, bacteria and fungi in the mouth.

On the basis of the cytological and histological examinations it can be established that the oral mucosa under the glass abutment showed slight but typical keratinization tendency to which hyperkeratosis and parakeratosis refer and not the dysplasia of pretumorous leukoplakia.

Similarly to the oral mucosa of patients having traditional bridges, removable prosthesis, chewing by gingiva, tested as a control, the signs of histologically harmless adaptive keratosis were observed under the glass abutment, too. The rate of keratinization is far below the datum experienced in the field of leukoplakia appearing on the effect of hot food, strong spice, while the cells remained typical at the same time. Structural or cytological changes referring to epithelium irritation could not be observed. The maintained glycogen content refers to the maturity of epithelium and its troublefree adaptation to mechanic stress. We did not observe the penetration of neutrofil granulocyte into the epithelial cells anywhere. The connective tissue rich in collagen under the epithelium was also free of any neutrofil granulocyte. Neither free nor intracellular haemosiderin could be observed in the latter which means that the intensity of traumatisation did not cause histotripsy and intercellular haemorrhage as a result of the former. Berlin blue test should show with certainty the place of haemorrhage in the periosteum and the connective tissue milieu after half a year and such histotripsy.

Comparing the cytological picture with histological changes it can be established that the changes of epithelial cells in the mouth wash and gained by teeth cleaning thread can be harmonised well with the picture got from the histological specimens. The mixed bacterium and fungus flora found in cytological smears and the acute inflammation of changing intensity do not reflect mucositis under the abutment but general mouth hygienic problem. The characteristic of tissular and cytological picture did not change in respect of the gingiva sections under the glass bridges built in one and six years before. Owing to the small number of cases, possibly accidentally, the keratinization tendency of the oral mucosa of gingiva could be observed mostly in case of the bridges of 2–4 years old. The partial flattening of the papillated character of the epithelium, the reduction of the volume of elastic fibres are adaptation consequences which are resulted on the effect of the chronic but not traumatising mechanic stimuli of collagen fibres accumulating under the epithelium

The dominance of diploid cells on DNS histogram showed the oral mucosa loaded by control and glass abutment even more peaceful than at the standard histological tests. The flattening of Gauss diagram can be explained by the fact that only a slice of nucleuses of in average 8 micron got in the sections of max. 5 micron thickness. Though, the tested person was almost fifty years old, the rate of tetraploid nucleuses did not increase in the basal layer of oral mucosa. (E.g. the majority of cells in the liver of persons of 50 years old is tetra and octoploid already.) This can be explained by the well-known quick turnover and good regeneration ability of oral mucosa. The quick and troublefree healing of the wound of people, volunteering for histological sampling, proved the maintained regeneration ability of oral mucosa stressed continuously by glass abutment and the epithelium saving feature of glass abutment at the same time. The abutment kept its place during sampling and healing.
The decay in layers (............) described as specific feature of the biological degradation of glass - got in organism - could not be observed on the glass abutments for one year, even its chemical composition remained the same.

It can be established as a conclusion that the cytological and the histological changes of oral mucosa under the glass abutments do not differ qualitatively from what was experienced in case of the traditional bridges, prosthesis and patients not having prosthesis, chewing by gingiva. The cytological and the histological tests as well as DNS analysis confirmed, too, what was established by the earlier macro examination and radiological controls according to which pathologic changes were not observed under the support abutment or in its milieu (Junior Ádám Szentpéteri). According to Scabbubg electronmicroscopic and EDX examinations the surface of glass abutment does not irritate mechanically and chemically, its material is resistant to the dissolving effect of saliva, its composition is stable, unchanged after one year, too. On the basis of the results the use of glass abutment can not be objected from pathologic point of view. Further examinations shall be made for reliable statistic analysis and the consequences of stable use shall also be cleared.

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Riede, U.N., Wieetler, O.D., Müller, H: Formale Tumorigenese.
In Allgemeine und spezielle Pathológie. p375. Eds: Riede, U.N., Scahefer, H.E. Georg Thieme Verlag, Stuttgart – New York 1993

Jun. Á. Szentpéteri: Patent Requirements

Budapest, February 15, 1997

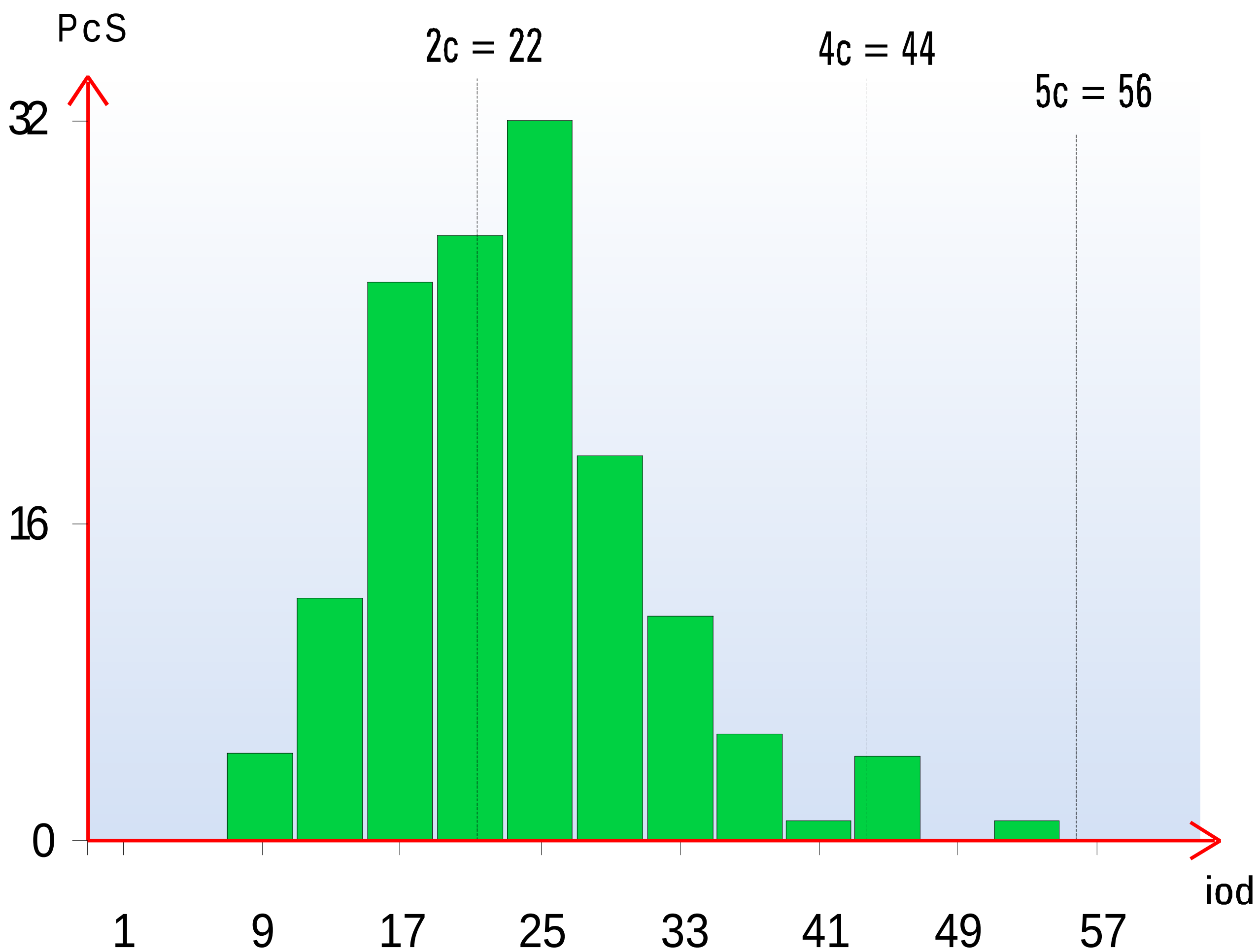
DNS investigation

Patient name: Proba
Histology
PNO code

MH. KH.
Kerenyi dr.
Cserba

Number of Object cells	:	137
Obj CV	:	31.90
Reference cells	:	a
Number of Reference cells	:	13
Mean IOD	:	22,46
Ref CV	:	26,33

CI :	1.09	G1 :	0.00
OI by ASK:	1.09	S:	0.00
2cDI:	0.47	G2 :	0.00



S E M M E L W E I S   O R V O S T U D O M Á N Y I   E G Y E T E M

II. SZ. PATHOLÓGIAI
INTÉZET

Németh László

DentAvantgArt Labor
Sopron
Madách u. 5.
9400

Budapest, 1997. 09. 17.

Tisztelt Németh Úr,

elvégeztük a nálunk lévõ és eddig meg nem vizsgált két üvegpillér (8 hónapos és egy éves minták) elemanalízisét. Az Önhöz korábban eljuttatott leletekkel mindenben megegyezõ eredményeket kaptunk.

Az üvegpillért viselõk, hagyományos híddal rendelkezõk és fogatlan ínnyel rágók szövettani vizsgálatára beágyazott gingiva preparátumainak továbbmetszésével nyert anyagban is a korábbiakkal megegyezõ elváltozásokat találtuk.

Így fönntartom véleményemet mind az üvegpillér nyállal szemben mutatott rezisztenciáját illetõen, mind pedig a gingivahám üvegpillér alatti és protézis nélkül rágókban megfigyelt fokozott elszarusodási hajlamának adaptív jellege mellett.

Tisztelettel

Dr. Kerényi Tibor
egyetemi tanár

Eötvös Lóránd Tudományegyetem
(Eötvös Lóránd University of Sciences)
General and Inorganic Chemistry Department

Professional report related to the use of borosilicate glass of ZX-27 fantasy name in special dental bridges

It is advisable to prepare the supporting abutment, increasing the life of non-supported, open-ended dental bridges, which is fixed to the bridge at one of its ends and fitting to gingiva on the other end, from such material which has proper mechanic features considering great load and does not get material, harmful to health, to organism, and can be worked in dental laboratories of standard equipment.

Silicate glass of properly chosen composition may meet all the three requirements.

The pressure and the bending strength of silicate glasses is enough that the supporting abutment made of them can stand – without damage – the pressing and the shearing effects during chewing. Their hardness and resistance to wear are far above the requirements because the supporting abutment is not exposed to intensive erosion as teeth.

Further favourable feature of silicate glasses is that they conduct heat and electricity badly. The works of art made of glass do not participate in those electrochemical processes which would increase the corrosion of metal elements in the mouth.

From technological point of view it is advantageous that the premanufactured glass rods can be cut to the required size easily. In addition to this it is also an important requirement that the glass rods can be formed according to the mould. Glass of relatively low softening point is required because of this which could be obtained most simply by increasing the alkali-oxide concentration of glass. However, the chemical resistance of glasses with high alkali content decreases considerably. Owing to change of ions alkali ions emit from the glasses contacting with aqueous solutions (saliva) and hydrogen-(oxonium) ions take their place in the glass. Though, the change of ions is a very slow process at body temperature, upon its effect the concentration of hydroxide ions, the pH of the solution may yet increase in the solution contacting with glass, which may damage gingiva. The alkali content higher than usual is favourable to another glass corrosion process, the so called rotting, too. In the course of this process – though, very slowly - all components of glass get also in the solution. Therefore it is an important requirement that the glass to be built in mouth shall not contain any heavy metal ions harmful to health. Therefore the reduction of softening point by the adding of heavy metal ion (lead, barium) can not be solved because the latter is harmful to health.

After trying several experimental glasses the following glass with the following measured composition limits conformed to the above aspects the best:

According to the data of the manufacturer the glass is fused at a temperature of 1500-1600 ^{o}C. Its working temperature is 1400 ^{o}C. The linear coefficient of thermal expansion is 4–4.2x10^{-6} K^{-1}. The compression strength is 120-150 MPa. According to acid resistance it belongs to hydrolytic class I, as regards its alkali resistance it belongs to hydrolytic class II. It was established that in addition to the mentioned components it contains – as contamination – some zinc (ZnO 0.01 mass %) and magnesium (MgO 0.006 mass %), too, but it does not contain lead or barium being harmful to health. Thus none of the glass components, getting in the solution through glass corrosion, can be considered as toxic. Owing to its low alkali content we do not have to consider significant local pH increase in the solution in gingiva milieu. The relatively low softening point – desirable from dental technologic point of view – .is due to the boron-trioxide content of glass. The borate getting in small volume in the solution through very slow corrosion processes probably does not result in health problem similarly to silicates.

On the basis of the above I consider the borosilicate glass of the above mentioned composition suitable for the subject task, i.e. for use as a supporting abutment in dental bridges.

Budapest, December 16, 1996

dr. Gusztáv Bouquet
Assistant Lecturer

In vitro heamolysis test to determine haemolytic activity of materials being in contact with bone and soft tissues

Haemolysis test examines the haemolytic activity of the given material on the freshly taken red blood cells of a test rabbit (hereinafter referred to as rabbit RBC) during an incubation period of 90 minutes in physiological sodium chloride solution of 37 ^{o}C while in the last 60 minutes of this period rabbit RBC is also present. The obtained total haemolytic activity involves two components: haemolysis caused by components that may be dissolved from the material and the haemolysis generating effect of the solid surface.

Materials used:

1. Fresh rabbit RBC with potassium oxalate anticoagulant,
2. Water bath of 37 ^{o}C,
3. Cell centrifuge with plastic centrifuge tubes of proper size,
4. Spectrophotometer,
5. Plastic pipettes and syringes.

Method:

By adding the physiological sodium chloride solution to the fresh RBC suspension a dilution is performed so that 0.2 ml suspension haemolysed with 10 ml distilled water and measured with the spectrophotometer at a wave length of 545 nm an extinction of 0.8 +/- 0.5 will be produced.

Sample:

5 g of the material to be tested shall be cut into pieces of 0.5 cm and pre-incubated in the water bath of 37 ^{o}C in 10 ml physiological sodium chloride solution then 0.2 ml of rabbit RBC suspension diluted as described above shall be added for further incubation of 60 minutes.

Negative control:
0.2 ml diluted rabbit RBC suspension shall be added to 10 ml physiological sodium chloride solution pre-incubated at 37 ^{o}C then it shall be incubated together at 37 ^{o}C for 60 minutes.

Positive control:
0.2 ml RBC suspension shall be haemolysed with 10 ml distilled water.
After the incubation period is over all the centrifuge tubes containing samples and control material shall be centrifuged for 5 minutes with 750 xg then the supernatant shall be removed and extinction measured at 545 nm.

In vitro haemolysis test to determine the toxicity of ZX-27 Attractive Glass abutment for the purpose of approval by ORKI

Name of the product: **ZX-27 Attractive Glass Abutment**

Name of manufacturer: **DentAvantgArt** (Sopron, Madách u. 5.)

Company requesting the clinical test: DentAvantgArt (Sopron, Madách u. 5.)

Institute performing the test: DOTE Stomatological Clinic
4012 Debrecen,
Nagyerdei Blvd. 98.

Test performed:
3-3 parallel determinations of each sample were performed, 6 samples have been prepared as described above from the material to be tested.

Positive control:
Full haemolysis: 0.2 ml rabbit RBC + 10 ml distilled water.
Extinctions measured at 545 nm: 0.640
0.650
0.630
average: 0.640 +/-0.010

Negative control:
Spontaneous haemolysis: 0.2 ml RBC + 10 ml physiological sodium chloride.
Extinctions measured at 545 nm: 0.060
0.050
0.055
average: 0.055 +/-0.005

Calculation of result:
Total haemolytic activity in percentage:

$$haemolysis\% = \frac{ext._{545}\ sample - ext._{545}\ neg.control}{ext._{545}\ pos.control - ext._{545}\ neg.control} \times 100$$

Bibliography:
J.W. Stanford: Recommended standard practices for biological evaluation of dental materials.
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<u>Sample (ZX-27):</u>

Haemolysis evoking effect of 33.3 weight % material to be tested:

Extinction values measured at 545 nm:	0.090
	0.070
	0.080
	0.070
	0.095
	<u>0.075</u>
average:	0.080 +/- 0.01

<u>Evaluation:</u>

$$\frac{(0.080-0.055)\times 100}{0.640-0{,}055}$$

<u>Total haemolysis percentage:</u> <u>4.27 +/-0.83</u>

The tested material (ZX-27) with a concentration of 33.3 weight% created on the rabbit RBC a total haemolysis of 4.27 +/- 0.83 % during in vitro haemolysis test.

In the above test method total haemolytic activity below 30 % is considered as low (FDI Technical Reports No.9. Int. Dent. J. 30: 150-152, 1980).

In accordance with the above, the total haemolitic activity of 4.27 +/-0.83% for the tested materials falling in the low range. There is close coincidence between the total haemolytic activity and in vivo acute toxicity therefore the tested ZX-27 Attractive Glass abutment is considered as non-toxic.

Test was performed by:

Prof. Dr. Gusztáv Keszthelyi
Director of DOTE
Stomatologic Clinic
DOTE, Stomatologic Clinic

Éva Ölveti
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Opinion on *using ZX-27 borosilicate glass for the purpose of denture* for approval by ORKI

The company requesting the opinion: DentAvantgArt (Sopron, Madách u. 5.)

According to the tests performed at the General and Inorganic Chemistry Department of ELTE ZX-27 borosilicate glass does not contain harmful lead and barium. None of the glass components getting into the solution in a very small quantity due to rather slow glass corrosion is expected to cause health problem.
Similarly to the above, the in vitro haemolysis test performed by us confirmed the same and produced reassuring result.
ZX 27 indicated total haemolytic activity of less than five percent. The relevant bibliography (FDI Technical Reports No. 9, 1980) considers total haemolytic values below 30 % as low. In vivo acute toxicity and haemolytic activity are in close coincidence.
On the basis of the above placing ZX 27 borosilicate glass into the oral cavity cannot be considered distressing from toxicological aspect. So much the more because certain dental and filling materials also contain similar compounds with similar solubility features.
From toxicological aspect ZX 27 borosilicate glass is suitable for being placed into oral cavity as a part of prosthesis.

Debrecen, 16 April, 1997.

Dr. Gusztáv Keszthelyi
Professor
Director of the Clinic

PROSTHESIS SUPPORTED BY ZX-27 ATTRACTIVE GLASS ABUTMENT SYSTEM AND COMPARATIVE STRENGTH TEST OF NON-SUPPORTED, OPEN-ENDED BRIDGE, PERFORMED BY FINITE ELEMENT METHOD, FOR ORKI LICENCE

Denomination of Product: ZX-27 Attractive Glass abutment

Name of Manufacturer: DentAvantgArt (Sopron, Madách u. 5.)

Company applying for test: DentAvantgArt (Sopron, Madách u. 5.)

Bridges removable according to the therapeutic proposal approved in the methodological letter, or fixed or supported, respectively, on implants (implant-retained-, supported fixed prosthesis) are recommended to be prepared for the substitution of gaps of teeth at the end of dentiton.
In many cases the use of removable prosthesis is rendered difficult by the aversion of patients to this type of prosthesis while the building in of implants is impeded by biological, financial reasons as well as the fear of patient from surgical intervention.
In these cases DentAvantgArt – applying for test – recommends e.g. non-supported, open-ended bridge where the second bridge member is supported on the gingiva by a so called glass abutment, ZX-27 Attractive Glass abutment patented by DentAvantgArt.
In addition to empirical opinion the applicability or the unsuitability of this solution is advisable to be proved by several measured results (e.g. toxicological, histological, longitudinal clinical, etc.). We have tested stress distribution, by finite element method, in prosthesis, anchor, mandible and gingiva system, made available to us by the clients.
Stress analysis is a more and more popular method used in dental research – primarily in connection with implants – recently.
With the help of this method the stress, the transformation, the dislocation in the tested system can be analysed on 2D and 3D models.
Aim: comparative strength test of the statics of „glass-abutment" bridge and non-supported, open-ended bridge anchored on 43,44 teeth, supporting 45,46 non-supported, open-ended bridge members as well as their effect, respectively, on the existing teeth and oral mucosa.

1. FEATURES OF MODEL-MAKING

Until recently the stress distribution of tested systems was analysed by the authors primarily on 2D models in the dental publications while in the newer dental reports the subject of test is 3D model. Partly because of the capacity of PC-s, partly because of the possibly slight effect of certain geometric features, these models contain simplifications.
In the 2D and 3D models built up by us we used the parameters referred to in literature.
These models are apt e.g. to measure stresses, dislocation in heterogeneous systems, to show out certain tendencies. Naturally, those alterations and changes, e.g. in biological systems (like in our present case, too), whose parameters are not known properly yet (e.g. reaction of oral mucosa - bone support, changes of state in parodontium, kinetics of the dislocation of teeth, etc.) can not be modelled at present. As a result of the above primar-

ily the determination of certain parameters, the specification of marginal conditions and not more detailed geometric modelling may help to make such type of measurements more precise.

2. 2D TESTS

2.1. FINITE ELEMENT MODEL

The model 2D was prepared by producing artificial plane pressure. When modelling, we have prepared models made of 7 or 8 different materials, as per Table 1. (The chosen material features are printed bold.)

Figure 2.1. shows finite element networks demonstrating non-supported, open-ended bridge as well as glass abutment support. Assuming symmetrical conditions the model contains a „half mandible" milieu. The non-supported, open-ended model contains 4469 nodes and 4862 elements while the glass abutment supported model contains 4482 elements and 4916 nodes. The „depth" size of both models is 7 mm.

The finite element networks demonstrate two undamaged teeth, furthermore 2 ground teeth as well as two different bridges placed on them

The crown on the ground teeth has got 1 mm porcelain and 1 mm metal layers while the thickness of the metal layer in the milieu of gingiva is 0.5 mm, the ceramic layer has 0.25 mm thickness. The width of the first artificial tooth in the crown is the same as that of the other modelled teeth, while the second artificial tooth is longer by 4 mm.

The thickness of gingiva is 2 mm, the thickness of cortical bone is 3 mm each. The thickness of parodontium along the root of tooth is 0.25 mm, that of cortical bone is 0.5 mm. The total thickness of mandible is 27 mm.

The marginal conditions can also be followed with attention on figure 2.1. The right edge of mandible is fixed while in its medium plan all nodes are fixed vertically for the consideration of bending stress.

The loading model can also be seen in figure 2.1. Yellow arrows show the nodal forces which conform vertically to resultant force of 100 N.

Finite element calculations were performed by COSMOS/M finite element system in „BME Gépszerkezettani Intézet" (Mechanical Construction Institute of Budapest Technical University).

2.2. RESULTS

The resultant dislocation can be seen in the two tested cases in figure 2.2. The red colour of colour scale indicates the greatest dislocation. The type of dislocation is determined by the bending stress. The values of maximum dislocation is contained by Table 2.

The longitudinal (in horizontal direction in the figures) direct stresses can be seen in figure 2.3. The tensile and the pressed sides can be separated well according to bending. (The maximum stress results can be seen marked by Sx in Table 2.).

Figure 2.4. demonstrates vertical direct stresses (marked by Sy in Table 2.). The tensile and the pressure stress in the two ground teeth can be identified well in case of both models.

Mises equivalent stress can be seen in figure 2.5. (mark „Mises" in Table 2.). Maximum equivalent stress can be seen in metal and porcelain layers.

Point 5. contains the numerical comparison of the two models.

3. 3D TEST: VERTICAL FORCE

3.1. THE FINITE ELEMENT MODEL

The present 3D model – utilising vertical plane symmetry – is a „half model". All material features are bold, as per Table 1.
Figure 3.1. shows finite element networks in the two examined cases. The geometry of the ground tooth, that can be seen in vertical position, is identical with the geometry of model 2D.

In horizontal section the tooth has elliptic cross-section. E.g. width size in dental neck milieu is 5 mm, while perpendicularly to that it is of 7 mm. This ratio is followed by the geometry of tooth in all horizontal plane sections.
The gingiva thickness is 2 mm, the top and the bottom cortical bones are of 2 mm thick each while 1.5 mm thick on the lateral surface. The thickness of periodontal ligament along the root of tooth is 0.3 mm while the cortical bone is 0.3 mm thick. At model 3D the total size of mandible (the thickness of gingiva included) is also 27 mm.
The non-supported, open-ended model contains 14031 nodes and 12623 elements while the glass-abutment supported model is composed of 14031 nodes and 12684 elements.
Instead of the half mandible the finite element network models its smaller milieu, simplifying that by neglecting the arched character of mandible. The glass abutment support has also 1 mm thickness in the model. Rod elements can be found between the glass abutment and the gingiva for vertical load transmission.
The crown on the ground teeth has 1 mm porcelain and 1 mm metal film vertically while the metal film is 0.5 mm, the ceramic is 0.25 mm thick in gingiva milieu. The width of the first artificial tooth in the crown is the same as that of the other modelled teeth while the second artificial tooth is wider by 4 mm.
According to the marginal conditions the bottom corcital surface is fully supported, furthermore the marginal conditions consider vertical symmetry, too.
The total load is 100 N in vertical direction which is also distributed on the nodes of the second artificial tooth similarly to the model 2D.

3.2. RESULTS

The resultant dislocation can be seen in figure 3.2., the maximum dislocation are contained by Table 3.
The longitudinal (in horizontal direction in figures) direct stresses can be seen in figure 3.3. The tensile and the pressure sides can be separated well according to bending. (The maximum stress results can be seen, marked by Sx, in Table 3.).
The figure 3.4. shows the vertical direct stresses (marked by Sy in Table 3.). The tensile and the pressure stress in the two ground teeth can be identified well in case of both models.
Mises equivalent stress can be seen in figure 3.5. (mark „Mises" in Table 3.). Maximum equivalent stress can be seen in metal and porcelain layers.
Point 5. contains the numerical comparison of the two models.

4. TEST 3D: VERTICAL AND LATERAL FORCES

4.1. FINITE ELEMENT MODEL

Owing to lateral load full models (figure 4.1.) are required which were obtained by us by reflecting the models visible in figure 3.1. to vertical symmetry plane. The rod elements in the glass abutment support milieu transfer the vertical load, in case of lateral load they make possible slight dismovement of the glass abutment on gingiva surface.
Marginal conditions: support along the bottom cortical surface.
Owing to resultant force of 45 degree the 100 + 100 N force combination is very extreme. In practice lateral load is always of smaller value as compared to operating vertical load.

4.2. RESULTS

The tendency of equivalent stress can be seen without ceramic layer in figures 4.2. and 4.3. (Naturally the ceramic layer has also constituted a part of the model when the calculation was made but this layer was removed when the results were visualised – in order to make them visible.) The maximum stress results can be seen in Table 4.
Figure 4.2. shows the two models from view direction conforming to the earlier figures while figure 4.3. is rotated around the vertical axis of rotation by 180 degrees. The bending stress of the metal structure can be seen well in both figures.

5. SUMMARY

In our work we compared the statics of the „glass-abutment" and non-supported, open-ended bridges anchored on 43,44 teeth, supporting 45,46 non-supported, open-ended bridge members made available to us, and tested stress distribution by finite element in system formed by abutment teeth, prosthesis, mandible and gingiva (Table 4.).

1. In case of model 2D tested by us

The glass abutment support reduced equivalent stress by 43 % in both dentin and bridge frame.

2. In case of model 3D

At vertical power effect the glass abutment support reduced the equivalent stress by 54 %, at resultant power effect of 45^{o} the reduction was of 15 % and 13 %, respectively, in the dentin and the bridge frame.

Comment:

1. This test could not model e.g. the effect of pulsating forces on parodontal fibres, the mucosa-bone base, etc. These effects can be analysed primarily by clinical, longitudinal experiments.
2. The evaluation of received results is rendered difficult by the fact that such type of measures can not be found in connection with certain substitutions of gaps of teeth (e.g. metal film cast on mould, etc.)

Material feature: Elastic modulus

		(1)	(2)	(3)	(4)	(5)	(6)	(7)
1	Ceramic	68900		69000	69000		82800	**69000**
2	WIRON 99							**205000**
3	Gingiva			**19.6**				
4	Cortical	20000	13700	40000	10000	**14500**	13700	
5	Spongiosa	**2000**	1370		250	215	7930	
6	Dentin			18600	18000	21400		**18300**
7	Period. ligament.			68.9	**69**	7	70	1.18
8	Glass							**69000**

Material feature: Poisson's ratio

		(1)	(2)	(3)	(4)	(5)	(6)	(7)
1	Ceramic	0.28		0.28	0.28		0.35	**0.19**
2	WIRON 99							**0.24**
3	Gingiva			**0.3**				
4	Cortical	0.3	0.3	0.3	0.3	**0.3**	0.3	
5	Spongiosa	**0.2**	0.3		0.3	0.3	0.3	
6	Dentin			**0.31**	0.31	0.31		
7	Period. ligament			0.45	**0.45**	0.45	0.3	
8	Glass							**0.19**

Table 1

Model 2D

LOAD: 100 N (vertical force)

Dislocation results /mm/

	Non-supported, open-ended bridge	Glass abutment support
Ux	0. 055	0. 029
Uy	- 0. 146	- 0. 087

Stress results /MPa/

	Non-supported, open-ended bridge	Glass abutment support				
	Ceramic	WIRON 99	Dentin	Ceramic	WIRON 99	Dentin
MISES	42.7	40.9	24.2	24.4	23	13.5
Sx	-41.3	31.1	-11	-23.6	17.6	-6.3
Sy	-32.5	-40.8	-25	-18.4	-23	-14
Txy	-15.6	10.8	4.1	-8.9	6.2	2.3

Table 2

Model 3D

LOAD: 100 N (vertical force)

Dislocation results /mm/

	Non-supported, open-ended bridge	Glass abutment support
Ux	0.055	0.026
Uy	-0.148	-0.069

Stress results /Mpa/

	Non-supported, open-ended bridge			Glass abutment support		
	Ceramic	WIRON 99	Dentin	Ceramic	WIRON 99	Dentin
MISES	41.5	56.1	36.5	19.1	26.1	17
Sx	-49.1	47.1	-12.7	-22.5	21.7	-5.9
Sy	-33.3	-46.7	-49.7	-15.4	-21.8	-23.2
Sz	-11	19.3	-16.5	-5	8.9	-7.7
Txy	-17.9	-16.5	-7.6	-8.3	-7.5	-3.5
Txz	-6.3	-8.8	-1.5	-2.9	-4	-0.7
Tyz	-3.7	-8.6	-4.2	2.2	-3.9	-2

Table 3

Model 3D

LOAD: 100 N + 100 N (vertical and lateral forces)

Dislocation results /mm/

	Non-supported, open-ended bridge	*Glass abutment support*
Ux	0.09	0.061
Uy	-0.162	-0.089
Uz	-0.295	-0.293

Stress results /MPa/

	Non-supported, open-ended bridge	*Glass abutment support*				
	Ceramic	*WIRON 99*	*Dentin*	*Ceramic*	*WIRON 99*	*Dentin*
MISES	78.8	116	68.2	56.8	98.6	59.4
Sx	-81.1	118.8	19.4	-58	93.4	17.7
Sy	-41.3	66.1	59.3	-40.5	61.8	50.1
Sz	-13.2	33.1	18.9	9.3	24	16.1
Txy	29.6	53.7	19.5	27	46.4	-19.1
Txz	30.6	30.4	7.8	30.1	30	7.6
Tyz	-16.4	28.5	-32.7	-15.7	-25.5	-32.5

Table 3

SUMMARISING RESULTS
MISES EQUIVALENT STRESS (%)

LOAD: 100 N (vertical force)

Model 2D	Non-supported, open-ended bridge	Glass-abutment support
Bridge frame (WIRON 99)	100%	57%
Dentin	100%	57%

LOAD: 100 N (vertical force)

Model 3D	Non-supported, open-ended bridge	Glass-abutment support
Bridge frame (WIRON 99)	100%	46%
Dentin	100%	46%

LOAD: 100 N + 100 N (vertical and lateral force)

Model 3D	Non-supported, open-ended bridge	Glass-abutment support
Bridge frame (WIRON 99)	100%	85%
Dentin	100%	87%

Table 4

Comment: In case of vertical and lateral load the glass abutment support of concave surface has more favourable features in practice (i.e. smaller equivalent stress) than in the calculation modelling the present flat glass-abutment surface as well as flat gingiva surface. The concave surface can transmit smaller part of lateral stress to the convex gingiva surface, reducing this way the lateral bending stress of the crown.

Literature

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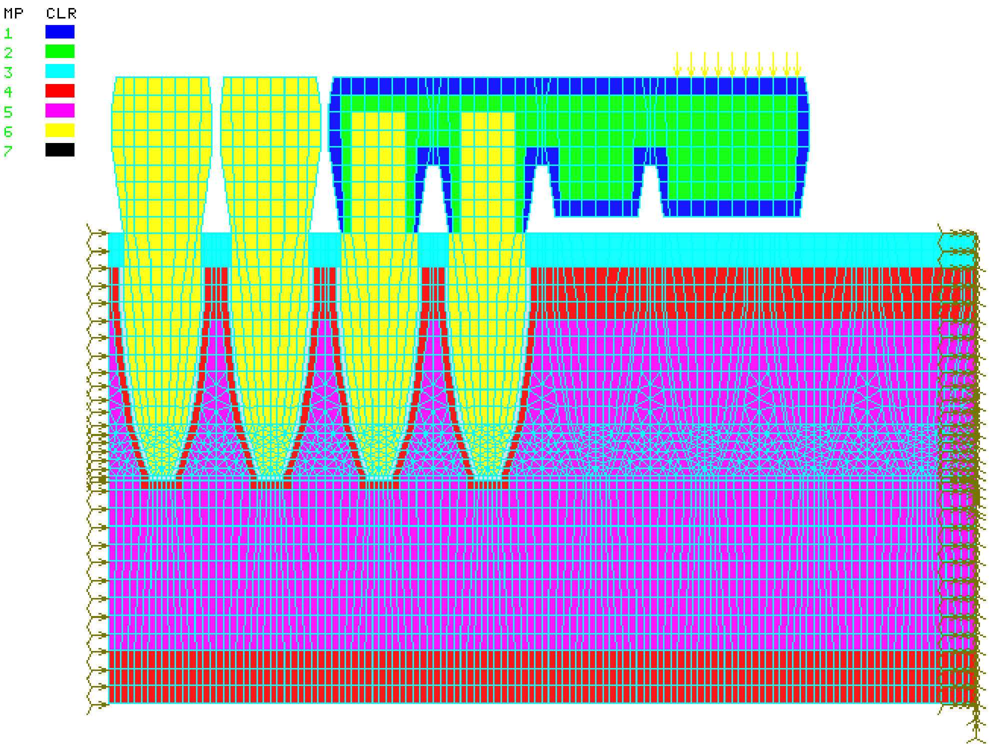
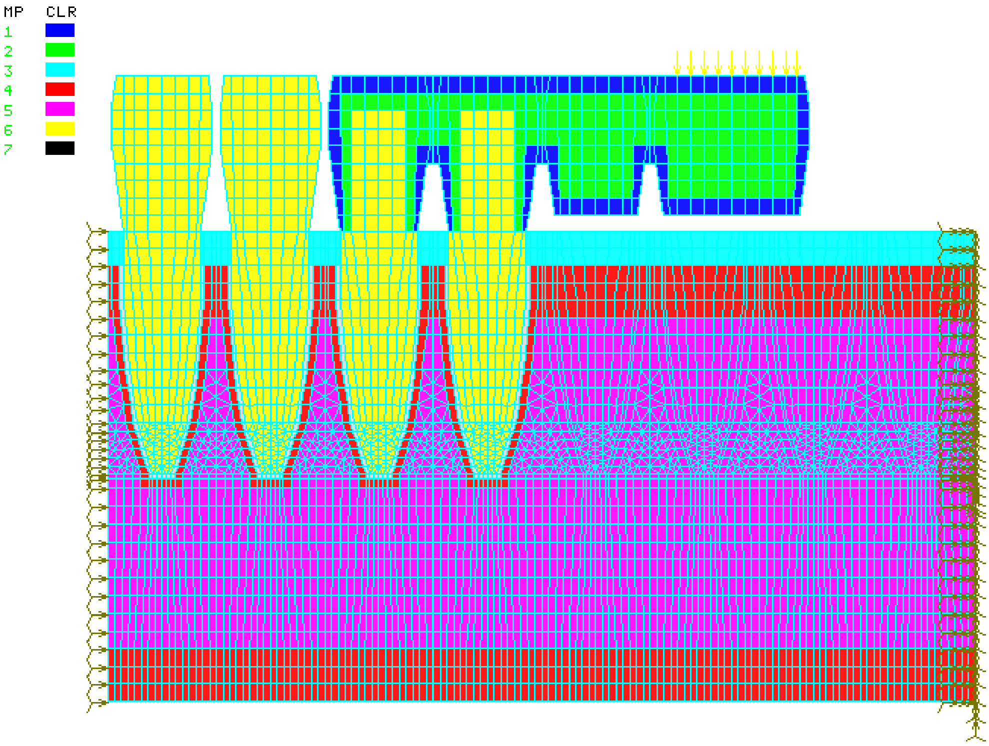
Finite element networks

Load: 100 N (vertical force)



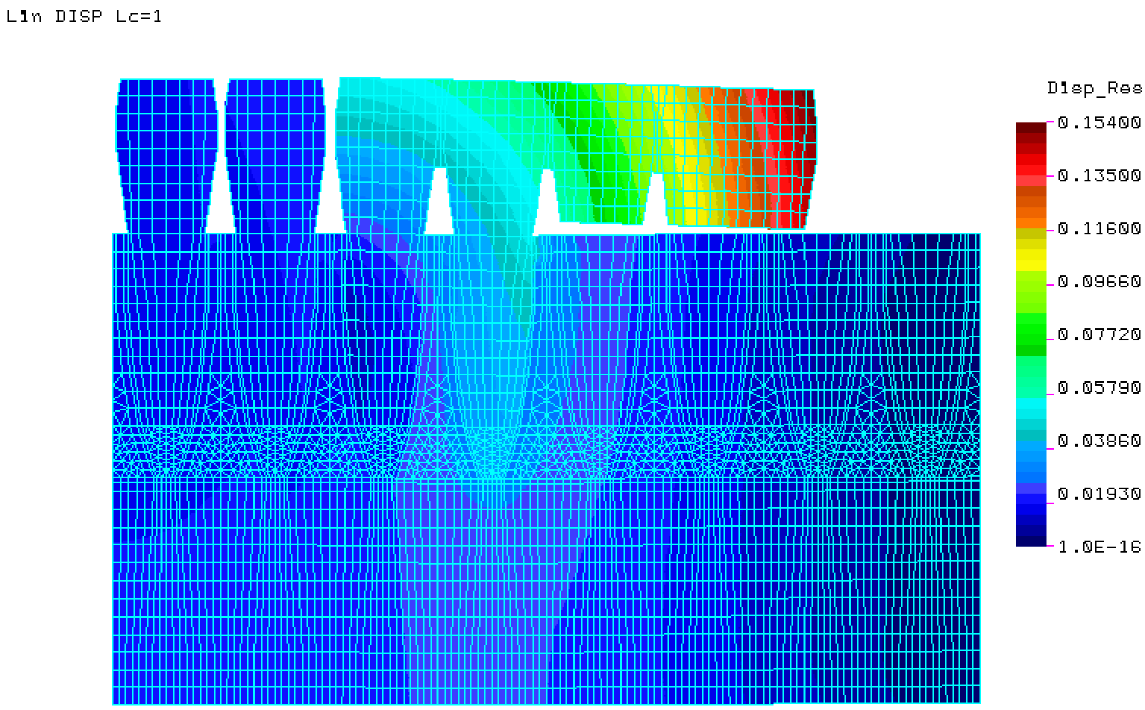
Non-supported, open-ended bridge



Glass-abutment support

Resultant dislocation

Load: 100 N (vertical force)



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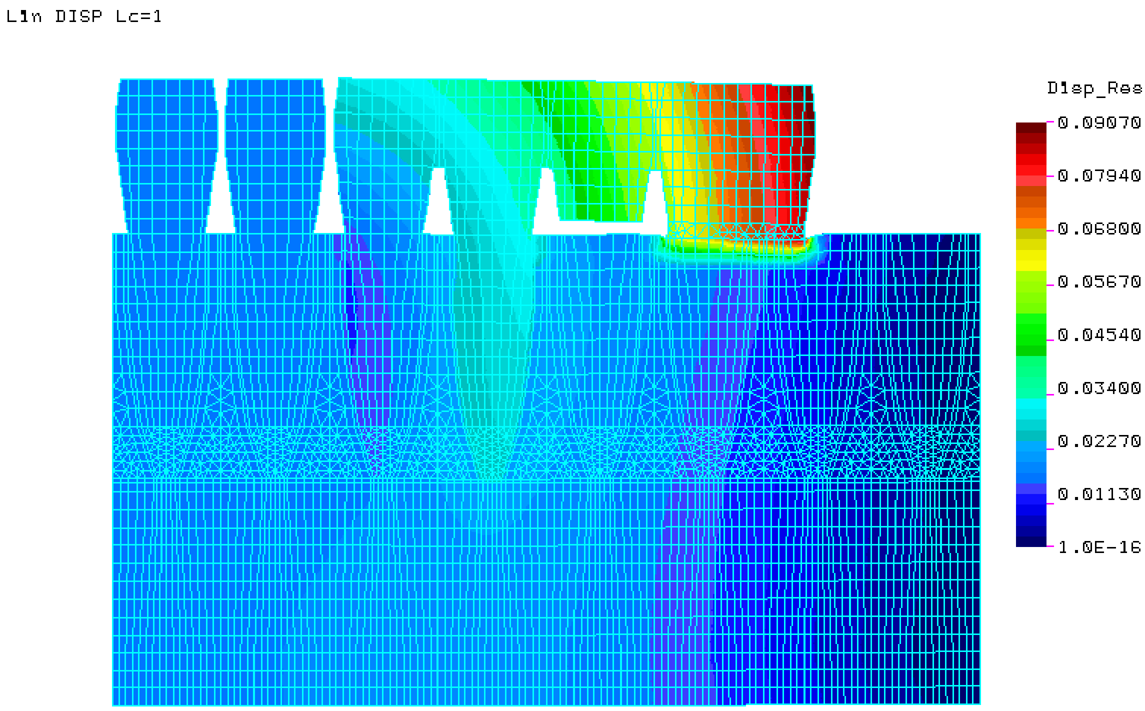
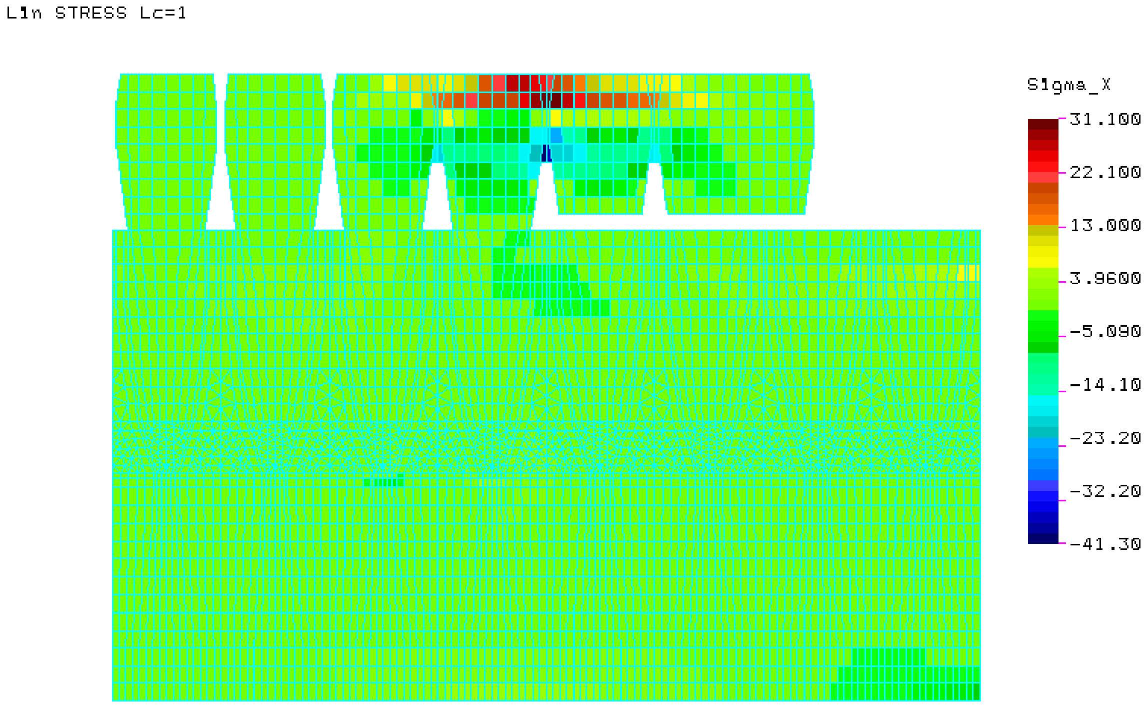


Glass-abutment support

Longitudinal direct stress

Load: 100 N (vertical force)



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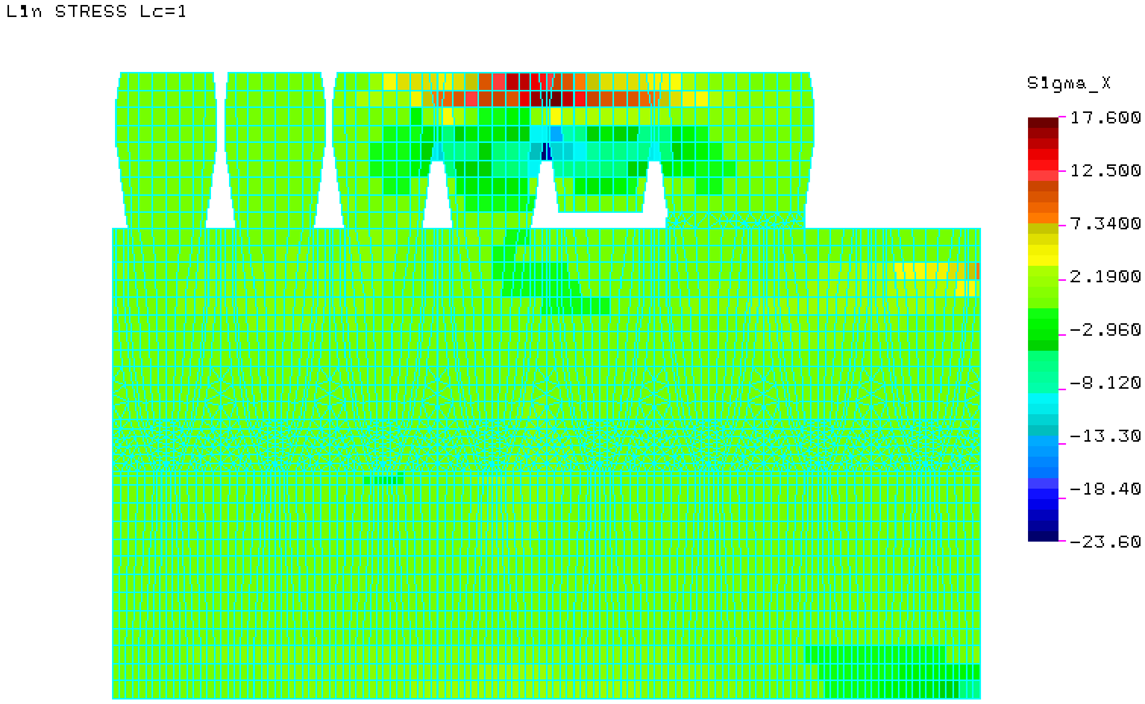
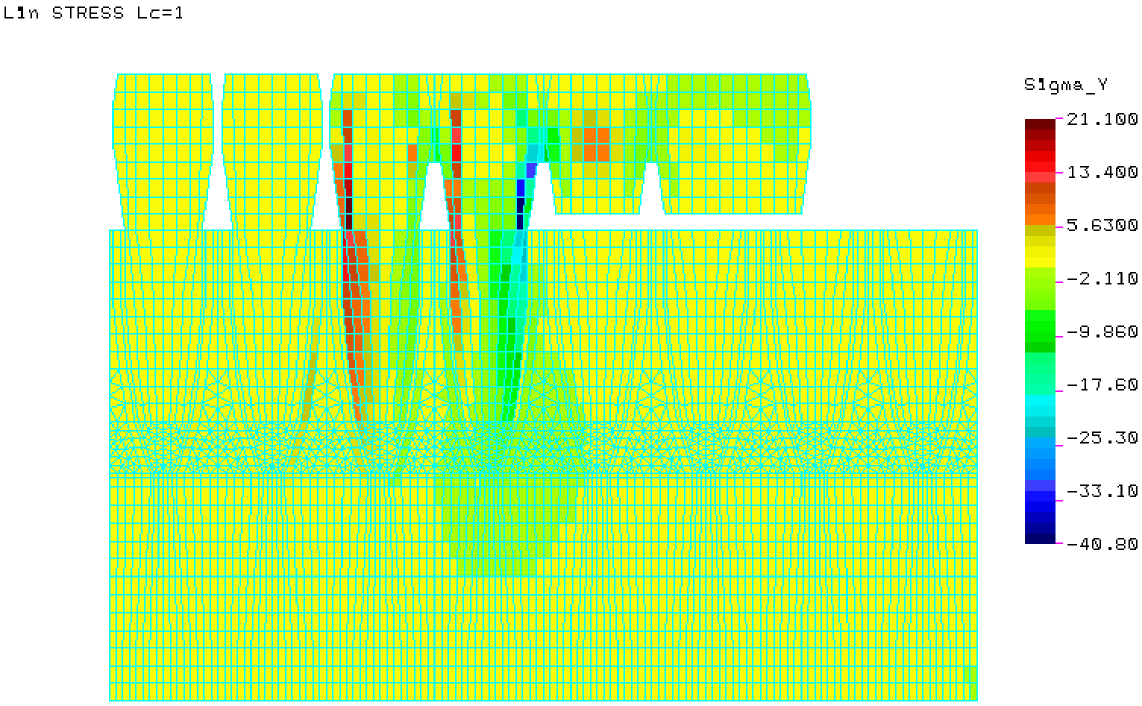


Glass-abutment support

Vertical direct stress

Load: 100 N (vertical force)



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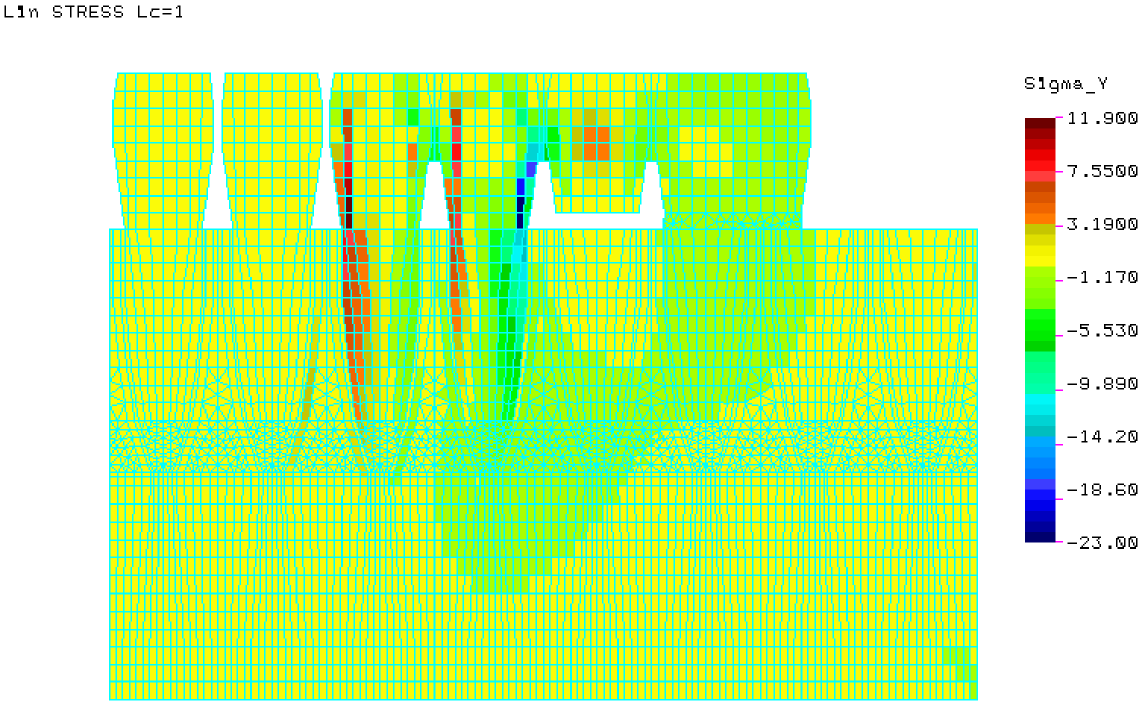
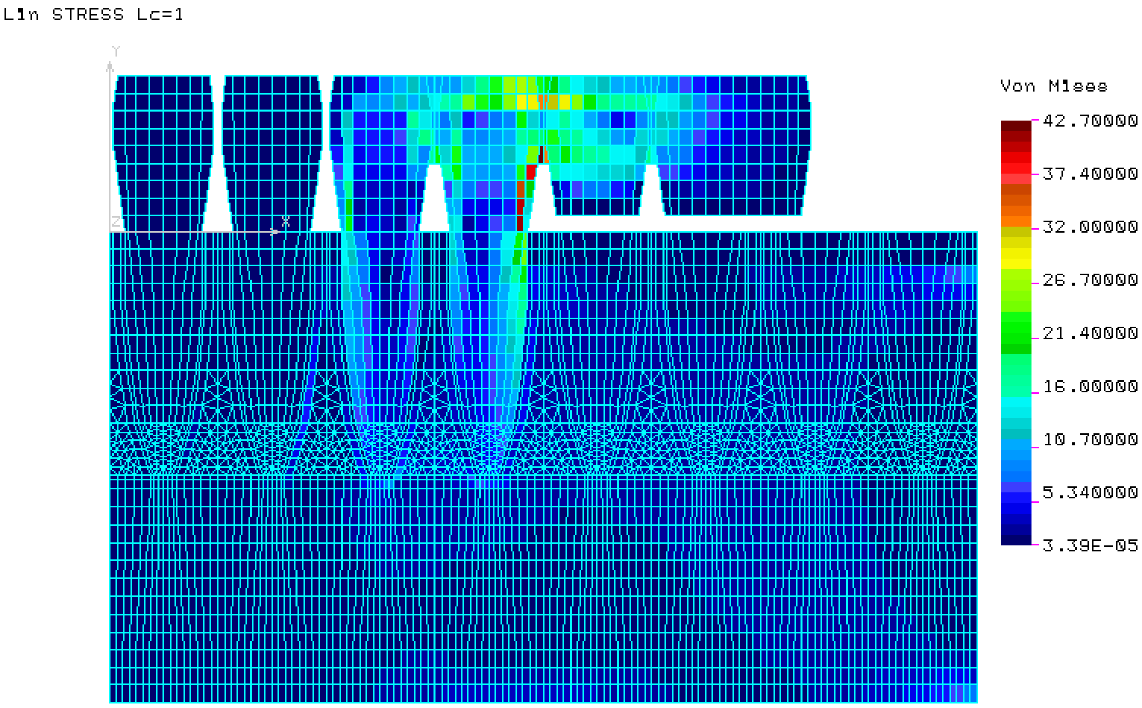


Glass-abutment support

Equivalent stress

Load: 100 N (vertical force)



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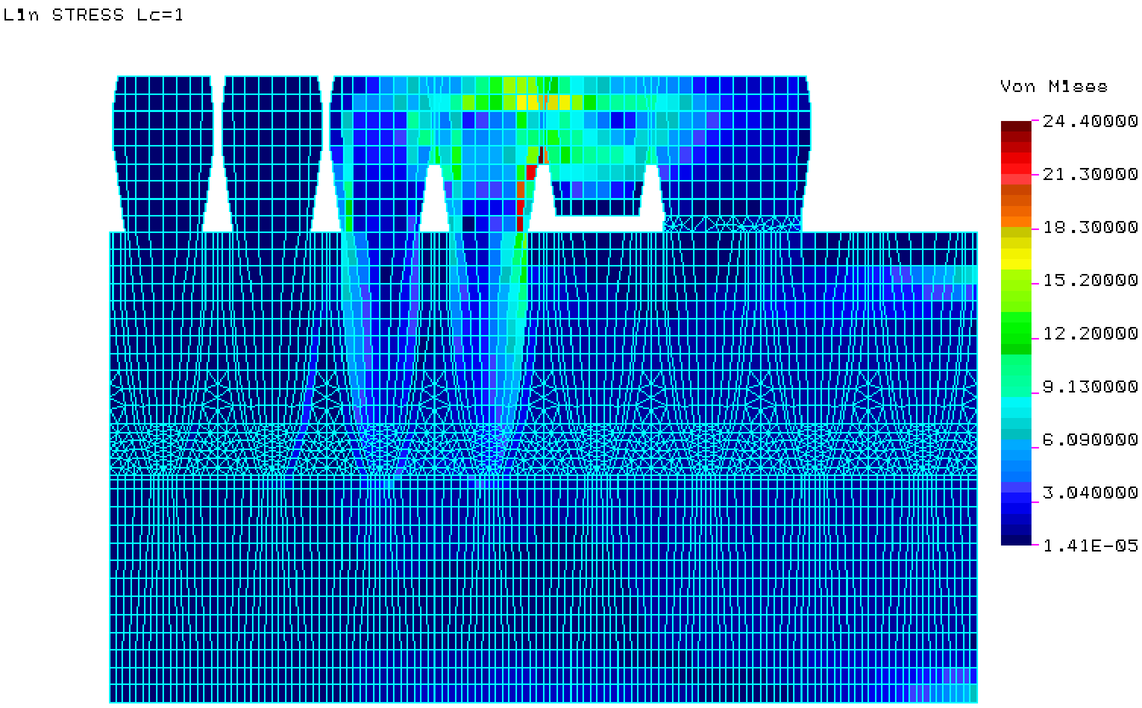
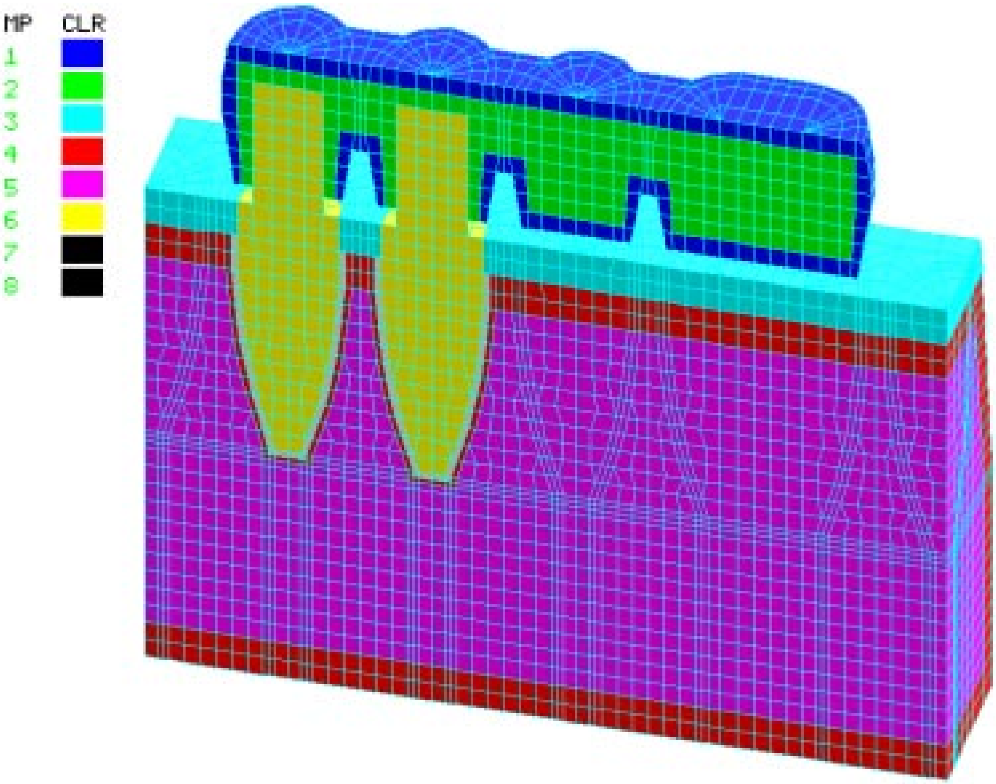


Glass-abutment support

Finite element networks

Load: 100 N (vertical force)



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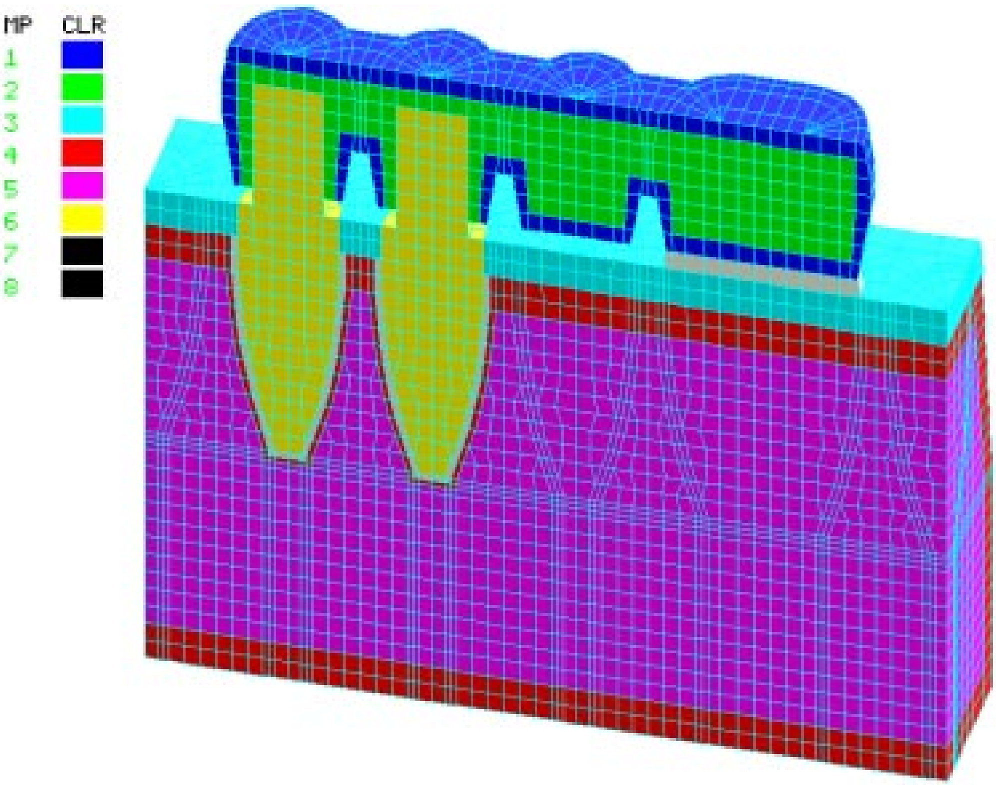
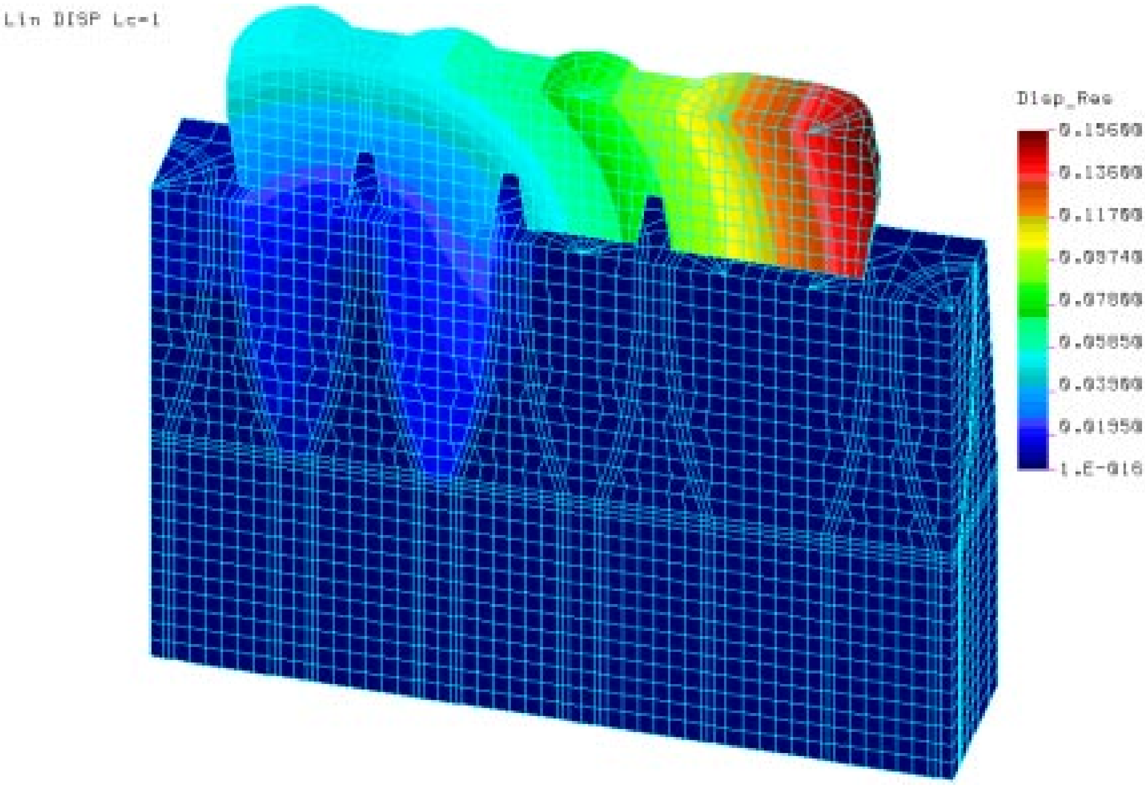


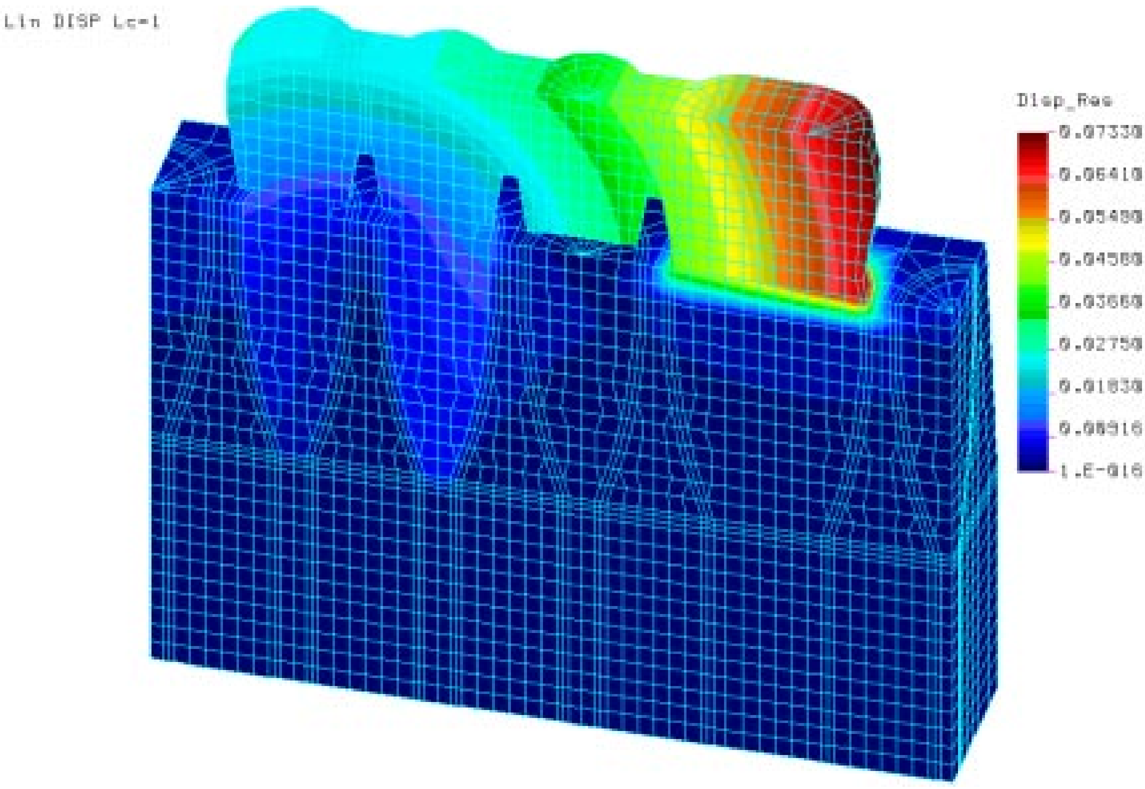
Glass-abutment support

Resultant dislocation

Load: 100 N (vertical force)



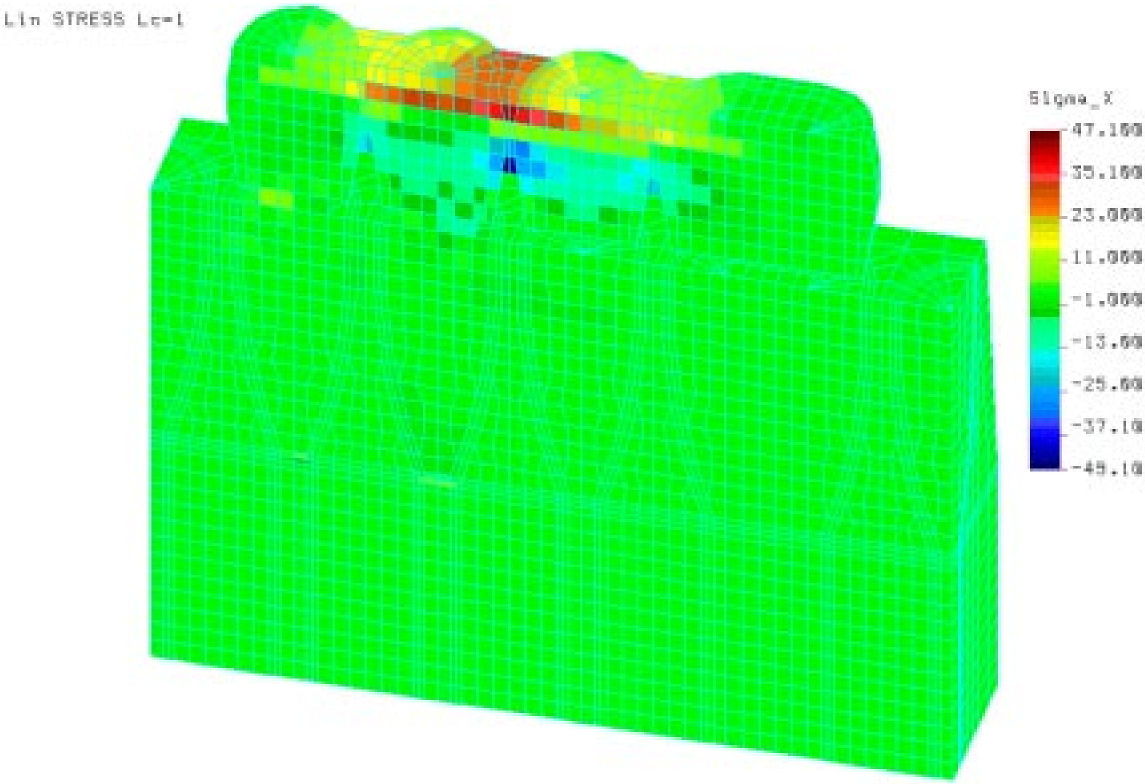
Non-supported, open-ended bridge



Glass-abutment support

Longitudinal direct stress

Load: 100 (vertical force)



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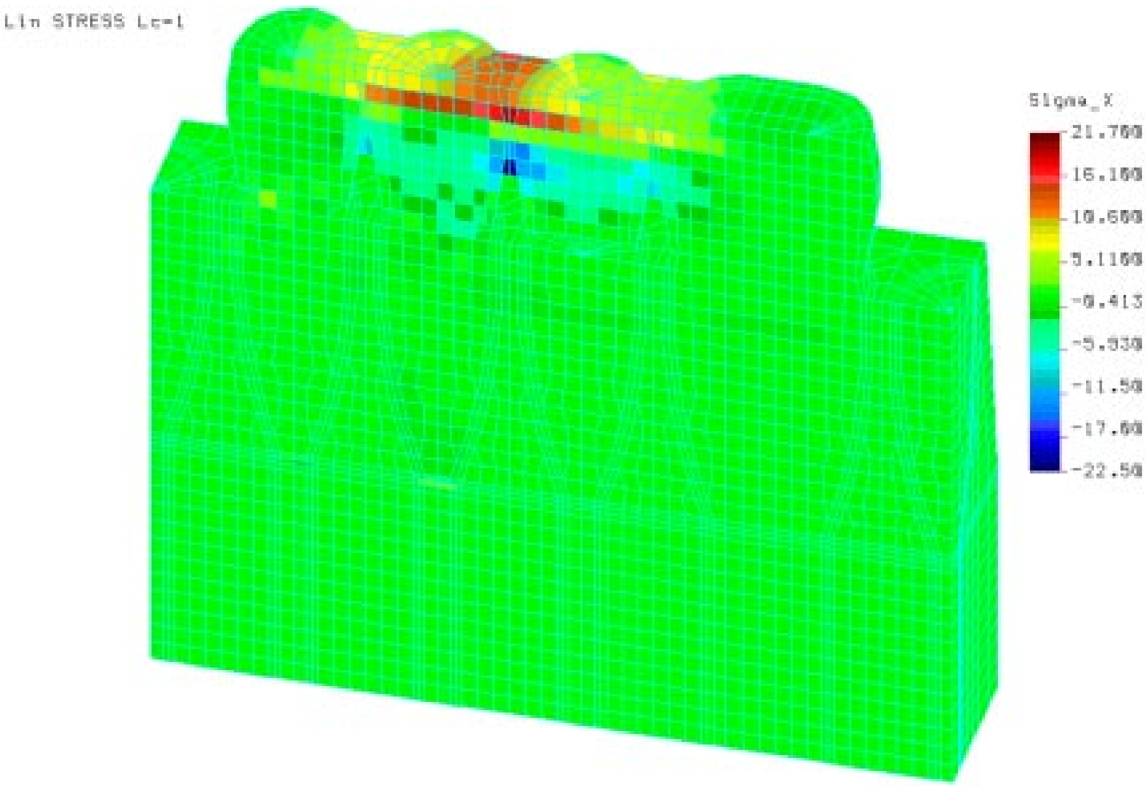
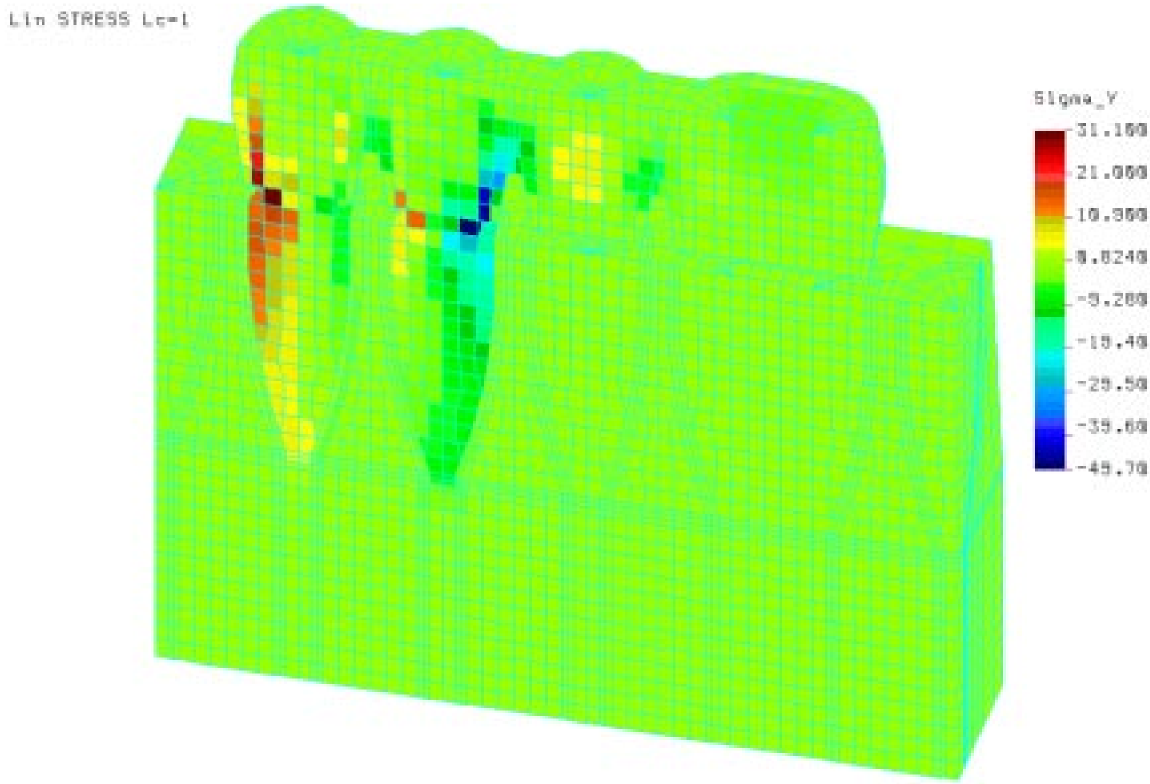


Glass-abutment support

Vertical direct stress

Load: 100 N (vertical force)



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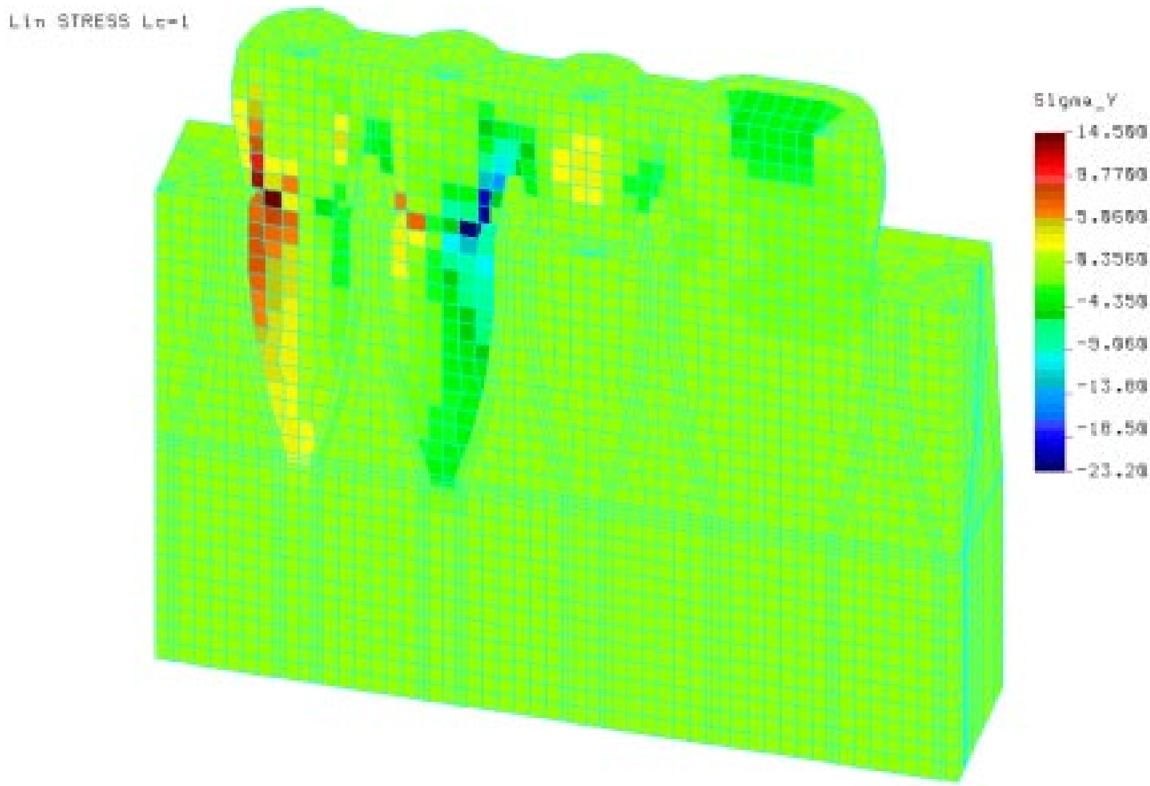
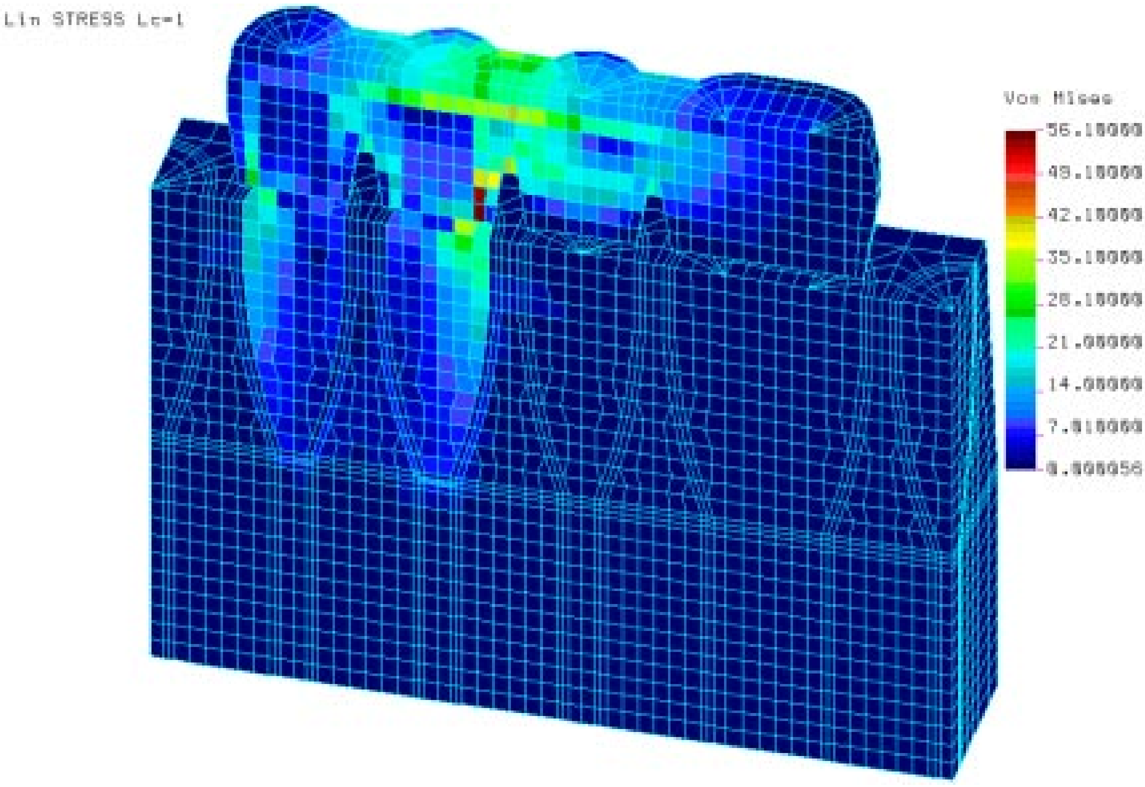


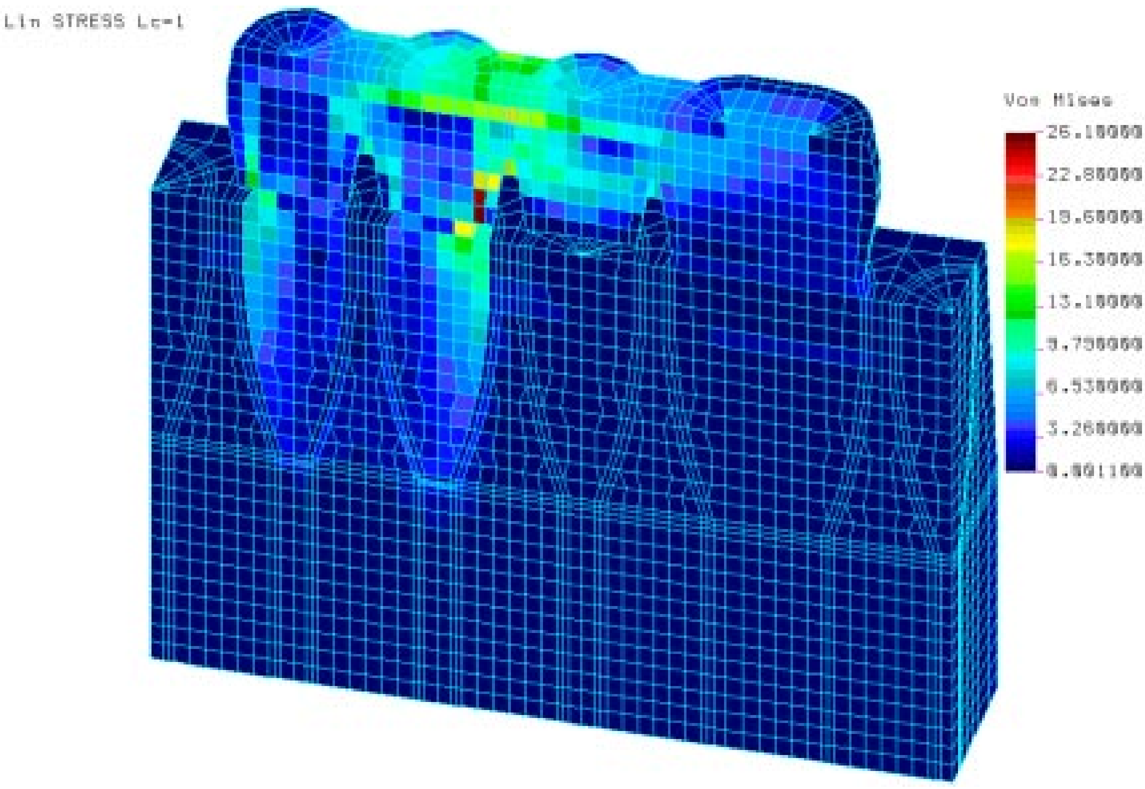
Glass-abutment support

Equivalent stress

Load: 100 N (vertical force)



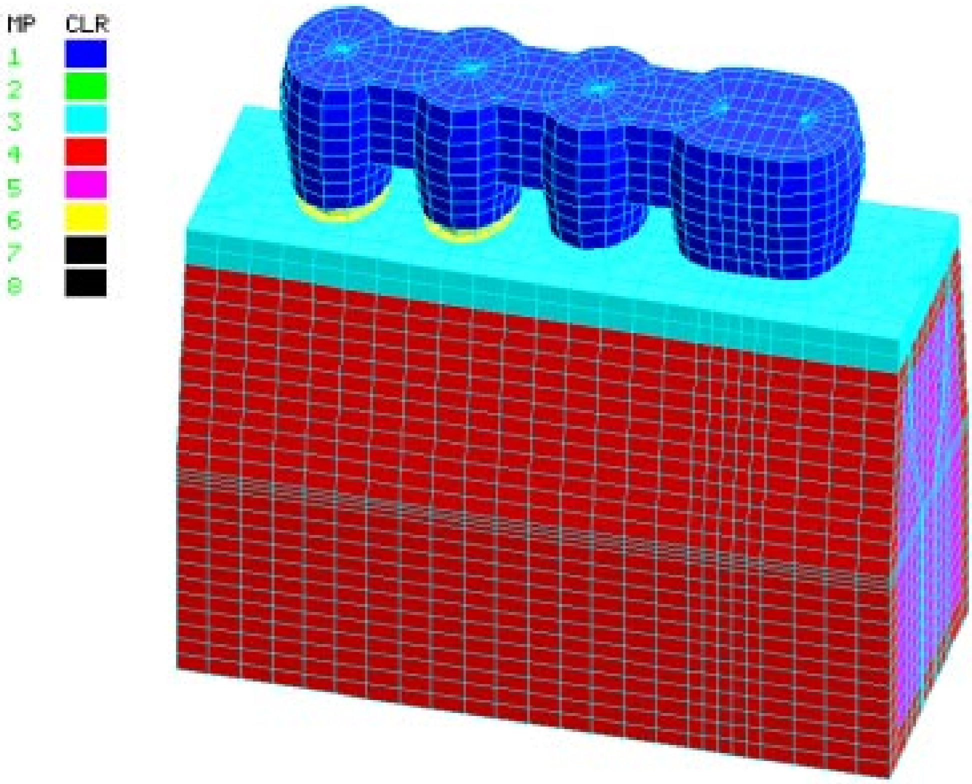
Non-supported, open-ended bridge



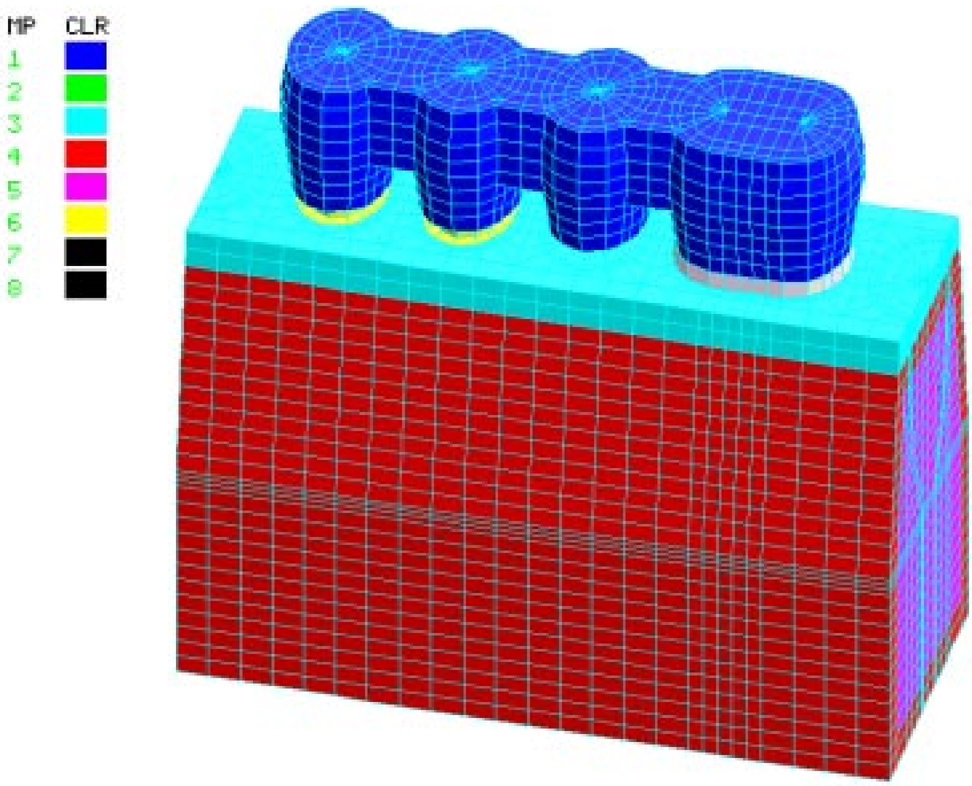
Glass-abutment support

Finite element networks

Load: 100+100 N (vertical and lateral)



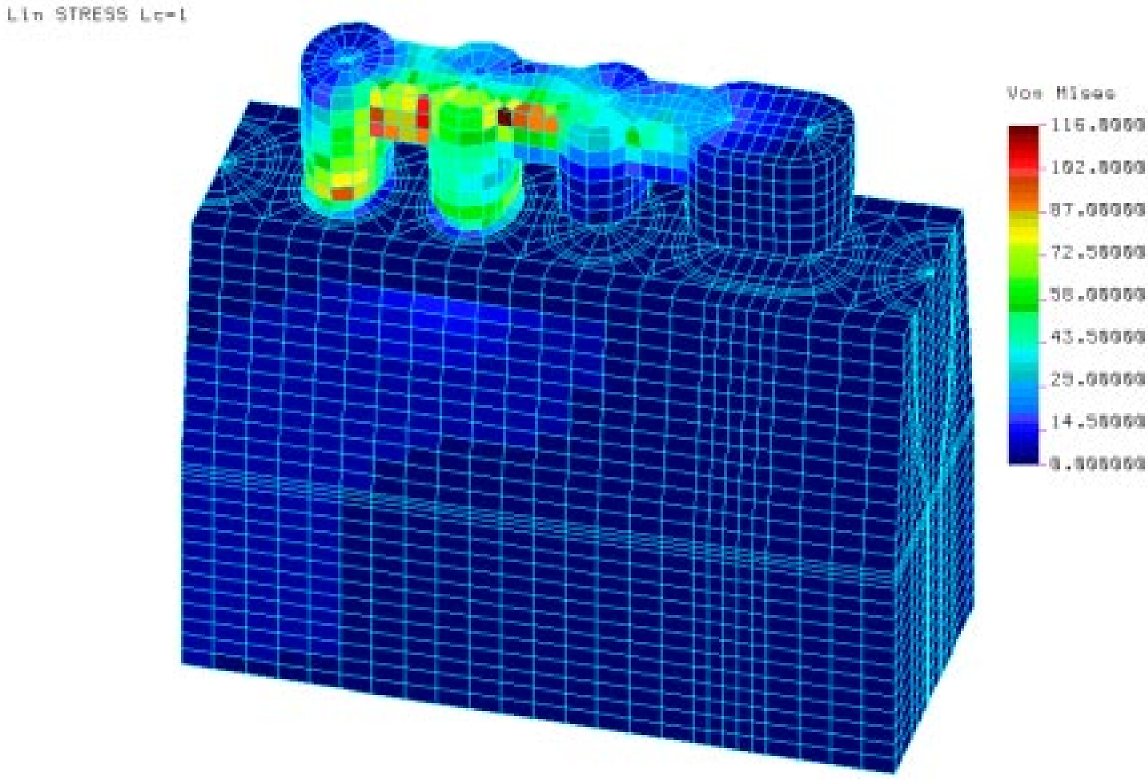
Non-supported, open-ended bridge



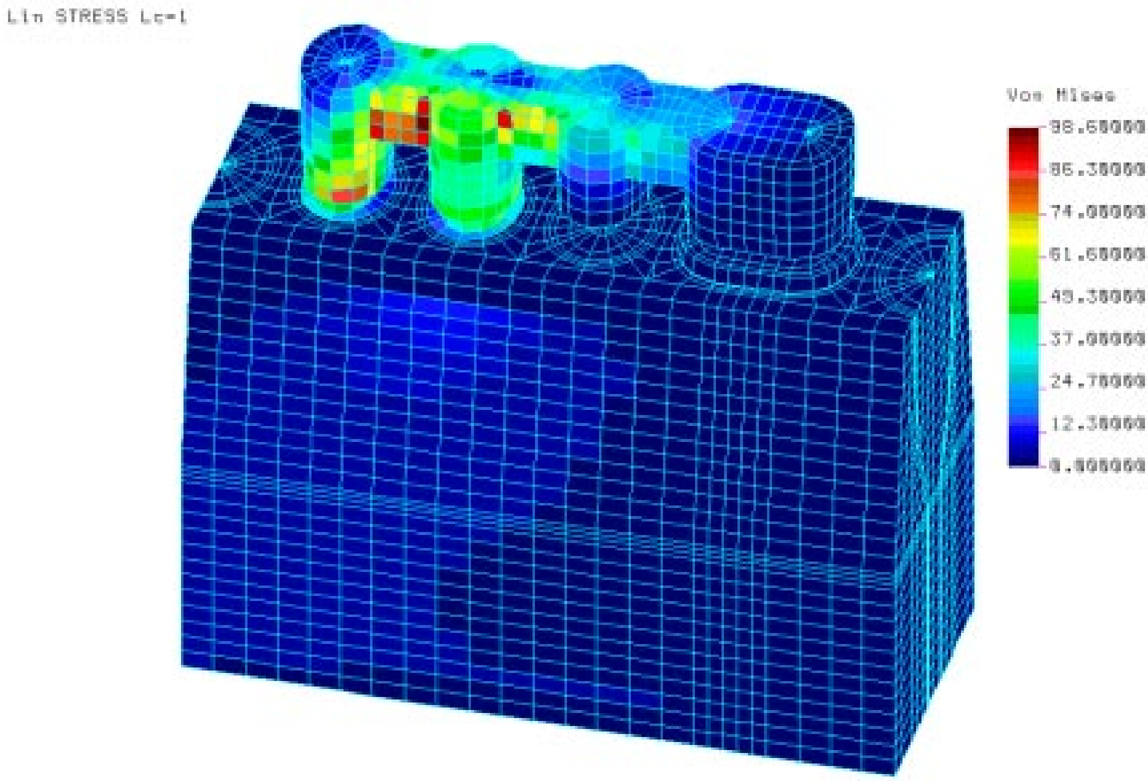
Glass-abutment support

Equivalent stress (without porcelain cover)

Load: 100+100 N (vertical and lateral)



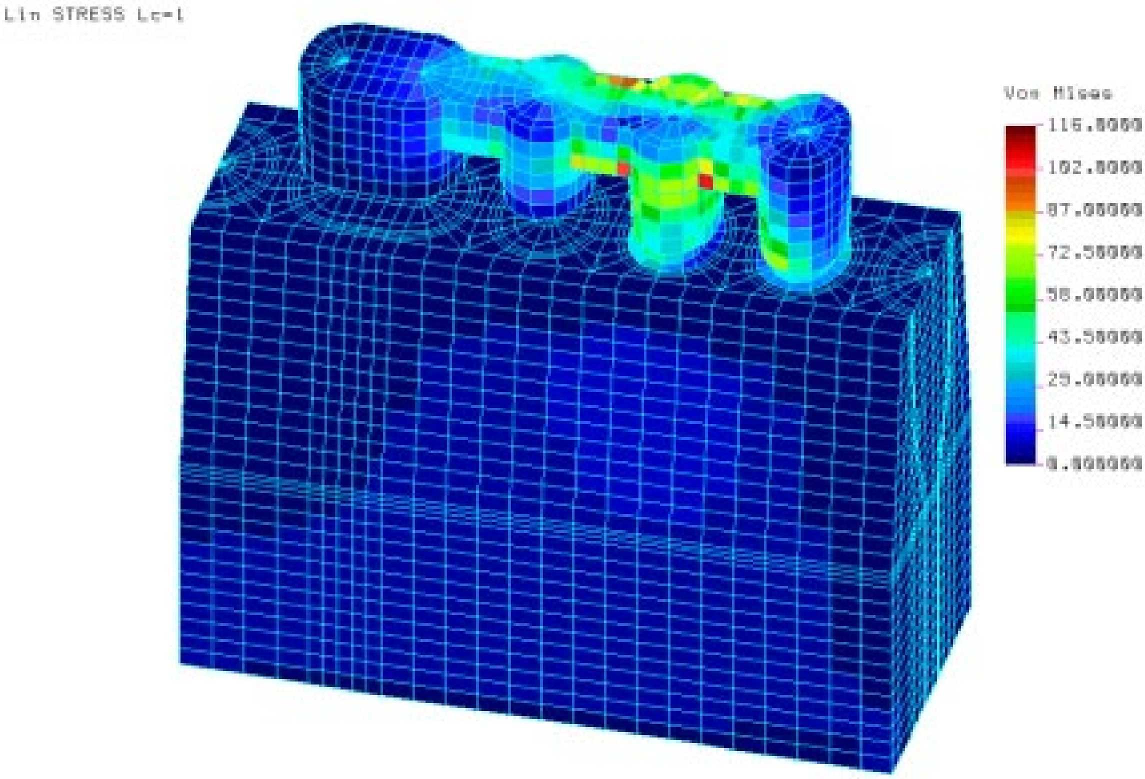
Non-supported, open-ended bridge



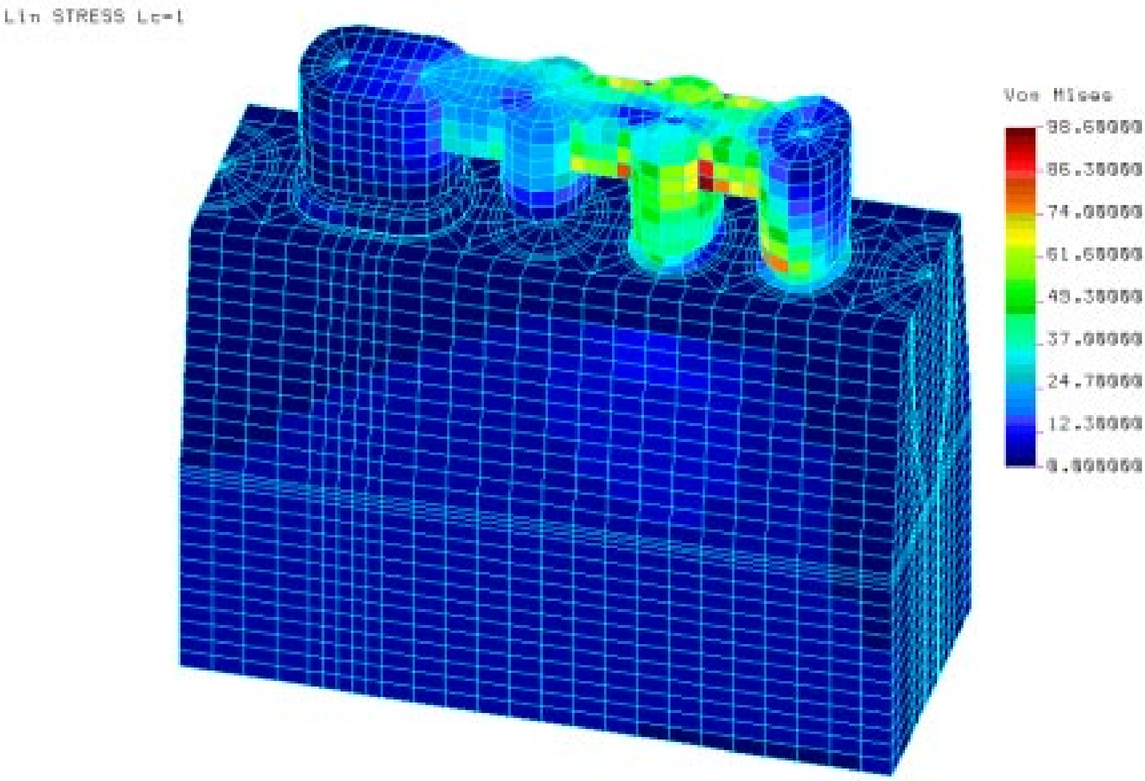
Glass-abutment support

Equivalent stress (without porcelain cover)

Load: 100+100 N (vertical and lateral)

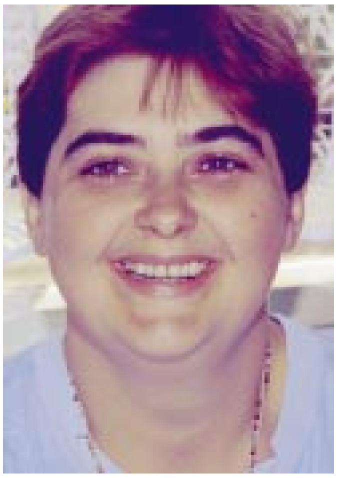


Non-supported, open-ended bridge



Glass-abutment support

My name is Krajcsics Ferencné. I'm 34 year-old.
I had the luck to hear about the new technology that could solve the problem of my set of teeth.
After the childbearing my teeth had got spoiled unfortunately and that became worse as I had been ill.



The dental plate was the only possibility for me.
However at this time I heard about the system called glasspier.
I was very glad of the fact that this is a bridge but not a dental prosthesis.
That was no problem to place the glasspier in and
I have been enjoying its advantages ever since.
I am able to bite everything with them as they were my own teeth however remain only two teeth from my bottom row.
I'm very cheerful when I look at myself in the mirror because I see wonderful teeth.
You dont't can imagine my joy from this solution.
I have got the bridge executed with glasspier and this have changed my life.
It would be very good to spread this kind of plate as soon as possible so everyone who has the same problem like me could make oneself familiar with this real enjoyable feeling I'll never be able to repay.

Krajcsics Ferencné
secretary

To Mr. Németh László

Sopron

Dear Laci,

I am sending my statement of several lines on basis of our personal talk.
When I was 52 I decided to use dentures combined with glasspier.
Because of removing of my intervening grinders at the age of 24 I needed to solve the adequate chewing surface with semi-bridges.

The dental plate is why the smoothing of the pierteeth -end of the line becomes necessary and the change of the bridges drives - or can drives - to the loss of them gradually.
Before the glasspier prosthesis only the chewing surface operates on the left-side however because of the breaking of the bridgepart and the loss of an intervening grinder it was necessary to make a decision between the removable plate and the solution with glasspier. I decided properly.
In the interest of the forming of the adequate chewing surface it was essential to adopt a glasspier in each of the bottom and the higher circlebridges.
The finished dental plate can be well-burdened from the first day and that didn't cause a feeling of foreign-body for a moment.
If I had used a removable plate I would have been troubled in practicing my work.
So this stable solution assures me of the feeling of my own teeth chewing as equivalent to theirs usage.
That causes no problem for me to bite into a massive thing and this plate makes the perfect grinding of hard fruits and vegetables as well as bacon rind and the cartilages at the end of bones.
The new plate makes me self-confident appearance as it adjustes to my personality and it has a magnificent fitting as well as its perfect operating assures the perfect biting to my nutrition.
I owe people thanks for contribution.

Yours sincerely:

Dr. K. József
lawyer

Dear Mr. Németh László and Labour,

This is the fourth year of my asking for help desperatively because of my dental technology problems.
The reason for this is that – my teeth number 6–7–8 on the bottom row would be extract

and the solution would be only a partial removable prothesis.
It seems to be that I went to the best place.
My dentist assured me of the curing as he said that this wasn't a big problem and he saw the place of absences.
In one week I got a wonderful bridge – having 4 part – as a fixed substitute with a glasspearl brace and I use it from that time happily – in this way I got a total set of teeth.
It means a perfect solution not only aesthetically but practically as well.
Above of all the colour of the china crowns is the same with the colour of my original teeth.
So I am a happy and satisfied owner of a fix bridge finished with a 7*27 supports instead of the removable bridge.
Hereby I'd like to thank for your help and I wish that you can give please a lot of people.

A very satisfied and happy women:

L. Éva
pharmacy professional assistant

B.Boglár, 1st July, 1997.