

Lava™ Precision Solutions

Lava™ Zirconia – Clinically Proven



Expertise™

Clinical Study Results
2000 – 2011





¹⁾ If fabricated by an Authorized Lava™ Milling Center on Lava Equipment in strict compliance with approved indications and instructions for use for Lava™ Crowns and Bridges: Only approved indications for Lava™ Zirconia are covered and the warranty does not cover any breakage resulting from accidents or misuse. Additional costs such as the cost of preparation and veneering are also not covered.



Introduction

Since its introduction in 2001, Lava™ Zirconia has become a huge success story. Millions of restorations have been produced and Lava™ Systems are running in 40 countries around the globe.

Lava Zirconia is one of the best investigated materials on the market with over 100 studies published by researchers world wide. Lava™ stands for high-strength restorations with outstanding marginal fit and excellent esthetics. Lava zirconia clinical excellence is proven by more than 10 clinical studies with more than 1,500 restorations placed and followed up to seven years. Due to its proven reliability, 3M™ ESPE™ warrants for 15 years from the date of placement that structures made out of Lava Zirconia will not break.'

This booklet provides you a complete overview of all clinical Lava study results published to date by researchers world wide. They have investigated anterior and posterior Lava crowns and bridges and followed them up to seven years. We have summarized these study results according to framework success and cohesive chipping of the veneering porcelain:

- Number of restorations initially placed /recalled for the publication.
- Framework success rate in % of the recalled restorations.
- Number of restorations with minor cohesive chipping of the veneering porcelain with no impact on clinical function. Chipped area either did not need any smoothing or polishing or could be polished and smoothed satisfactorily.
- Number of restorations with major chipping of the veneering porcelain with impact on clinical function. Replacement would be indicated, however clinicians and patients decided not to replace.
- Number of replacements.

At present, porcelain chipping is discussed in dentistry since the introduction of PFM restorations. When looking at the available literature, veneering of zirconia has today a similar survival rate as the veneering of PFM restorations which are used for clinical applications for decades. Key success factors for the longevity of the veneering of zirconia are the correct framework design, the correct firing protocol for the porcelain and the correct adjustment and re-polishing of the restoration intra-orally.

3M ESPE has understood these success factors and continuously improved the Lava System and the Lava Materials. Lava Zirconia frameworks are designed to optimally support the porcelain layer and are handled by trained, certified Lava Milling Centers.

3M ESPE's goal is to help dentists and labs to serve patients best with information, clinical tips and an outstanding Zirconia Material:

Lava™ Zirconia – For clinical experts from clinical experts!





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Anterior maxillary Lava™ crowns with 0.3 mm customized copings after 2 years in clinical service

Cited from: Raigrodski AJ, Zhang H, Dogan S. Clinical efficacy of zirconia-based anterior maxillary crowns with customized copings. IADR 2009; #374

AIM: This study evaluated the clinical efficacy of Lava™ Zirconia anterior maxillary single crowns with 0.3 mm customized copings in terms of esthetics and survival.

STUDY OUTLINE: 20 anterior maxillary teeth were prepared in a standardized manner and restored with a Lava crown supported by a 0.3 mm customized coping. The restorations luted with RelyX™ Unicem were evaluated according to the modified Ryge criteria after 2 weeks, 6, 12, and 24 months.

RESULTS: After up to 2 years of clinical service (mean follow-up of 12.7 months), all 20 restorations were rated clinically successful in terms of survival and esthetics. No chipping of veneering porcelain was detected.

CONCLUSION: Anterior maxillary single crowns with customized anatomic copings with 0.3 mm thickness performed well after a period of up to two years.

Note: With these study results, 3M ESPE was confirmed that Lava™ Zirconia provides pink and white esthetic suited for anterior restorations and are durable with a coping thickness of only 0.3 mm.

SUMMARY:

Restorations placed / recalled	20/20
Framework Success Rate (%):	100%

Minor Chipping (n):	0
Major Chipping (n):	0
Replacement (n):	0



Lava™ Crown on upper right central incisor at 2 year recall.

Clinical Picture by Dr. Ariel Raigrodski

Anterior maxillary Lava™ crowns with 0.3 mm coping and feather-edged Margin Preparation after 3 years in clinical use

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Cited from: Schmitt J, Wichmann M, Holst S, Reich S. Restoring Severely Compromised Anterior Teeth with Zirconia Crowns and Feather-Edged Margin Preparations: A 3 Years Follow-up of a Prospective Clinical Trial. Int J Prosthodont 2010; 23; 107-109

AIM: This study evaluated the 3-year clinical performance of anterior maxillary teeth restored with 0.3 mm copings and feather-edged marginal preparation.

STUDY OUTLINE: 10 patients received 19 single-tooth restorations in the anterior maxilla to restore severely decayed teeth. All abutment teeth were prepared with a feather-edged finish line and restorations were cemented with Ketac™ Cem. Surface, Color, Anatomic Form and Marginal Integrity were evaluated annually.

RESULTS: After a mean observation time of 39.2 months, 17 of the 19 restorations demonstrated that no material fracture occurred and all crowns had acceptable surfaces, although a minor chipping was present. A survival rate and success rate of 100 % was recorded.

Note: With these study results, 3M ESPE was confirmed that also in challenging clinical case where a marginal wall thickness of 0.3 mm and special feather-edged margin preparations are required, Lava™ Zirconia performs clinically successful in the anterior region in terms of strength, precision and esthetics. The coping of 0.3 mm wall thickness proved stable even with conventional cementation that does not deliver adhesive stabilization.

SUMMARY:

Restorations placed / recalled	19 / 17
Framework Success Rate (%):	100 %

Minor Chipping (n):	1
Major Chipping (n):	0
Replacement (n):	0



Anterior Lava™ crowns (upper right lateral and 2 upper central) at baseline.

Clinical Pictures by PD Dr. Sven Reich

Full acknowledgement will be given to the author, journal, and to Quintessence Publishing Co Inc, Chicago as the copyright holder.

Anterior and posterior 3- and 4-unit Lava™ bridges evaluated in UK general practice after 3 years of clinical service

Cited from: Crisp RJ, Cowan AJ, Lamb J, Thompson O, Tulloch N, Burke FJT. A clinical evaluation of all-ceramic bridges placed in patients attending UK general dental practices: three-year results. Dent.Mater. In press.

AIM: The clinical evaluation of the performance of Lava™ bridges placed in adult patients in 4 UK general dental practices and luted using a self-adhesive resin-based cement.

STUDY OUTLINE: Tooth preparation, bridge construction and cementation were all performed to manufacturer's instructions. Each bridge was reviewed annually (± 3 months) by a calibrated examiner, together with the clinician who had placed the restoration. The examiners evaluated the integrity of the restoration, its anatomic form, marginal adaptation, surface quality, and sensitivity, the condition of the adjacent gingivae, and the presence or absence of secondary caries.

RESULT: 42 bridges have been placed, and a total of 34 bridges have been reviewed at three-years. All Y-TZP frameworks were intact and no bridge retainers had debonded. Two veneering ceramic chips, in total, were detected over the three year period of observation: the patients in whom this had occurred were unconcerned. A further abutment tooth had been successfully endodontically treated, through an occlusal access cavity, in addition to the two already reported at year one.

Note: These study results confirm that, after 3 years' observational period, Lava™ Zirconia Bridges performed clinically successfully in "real life" conditions in UK general dental practices.

SUMMARY:

Restorations placed / recalled	42/34
Framework Success Rate (%):	100%

Minor Chipping (n):	2
Major Chipping (n):	0
Replacement (n):	0



Posterior 3-unit Lava™ Bridge at 3 year recall.

Clinical Picture by Dr. Russell J. Crisp

Anterior and posterior 3- and 4-unit Lava™ bridges evaluated after 2 years of clinical service

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Cited from: Perry R, Sharma S, Ferreira S, Kugel G, Orfanidis J. Two year clinical evaluation of zirconia bridges. AADR 2008, #1085.

OBJECTIVE: To evaluate the 24 month clinical performance of Y-TZP CAD/CAM generated ceramic system in fixed prosthodontics.

METHODS: 16 bridges (15 three- and 1 four-unit) were done on 15 subjects. The bridges were cemented using RelyX™ Unicem Self-Adhesive Universal Resin Cement. Evaluation was done at 6, 12, 24-months recall visits. Evaluation criteria were Color stability and matching, Marginal integrity, Marginal discoloration, Incidence of caries, Changes in the restoration-tooth interface, Changes in surface texture, Postoperative sensitivity, Maintenance of periodontal health, Changes in proximal and opposing teeth and Maintenance of anatomic form. The bridges were rated in one of three possible categories, "A" (alpha), "B" (bravo) or "C" (charlie).

RESULTS: At 6-, 12-, 24-month recalls 100 % of the bridges were rated "A" for Color Stability & Matching, Marginal Discoloration, Marginal Integrity (24 month recall 93.75 % "A" and 6.25 % "B"), Incidence of Caries, Restoration-tooth-interface, Surface Texture & Changes in Proximal or Opposing Teeth. Maintenance of Anatomic Form was rated "A" in 100 % of the bridges at 6-month recall but at 12 month 93.75 % of the bridges were rated "A" and 6.25 % were rated "C". At the 24 month recall was rated "A" for 87.5 % of the bridges and 12.5 % were rated "C". Post Operative Sensitivity was rated "A" for 93.75 % of the bridges at 6, 12, & 100 % at 24 months. Soft Tissue Health was rated "A" in 81.25 % of the bridges and "B" in 18.75 % of the bridges at 6-month recall but at 12 and 24 month recalls, 68.75 % and 93.75 % of the bridges were rated "A" and 31.25 % and 6.25 % were rated "B" respectively.

CONCLUSION: After 24 months, 12.5 % (2 out of 16) was unacceptable due to failure in maintenance of anatomic form. The CAD/CAM Generated Y-TZP bridges were clinically acceptable.

SUMMARY:

Restorations placed / recalled	16 / 16
Framework Success Rate (%):	100 %
Minor Chipping (n):	0
Major Chipping (n):	2
Replacement (n):	0



3-unit anterior Lava™ Bridge at 2 year recall.

Clinical Picture by Dr. Ronald D. Perry

Abstract reprinted with permission from the Journal of Dental Research, Vol. 87, Special Issue A, 2008

Comparison of PFM, Zirconia and Alumina posterior prosthesis after 3 years of clinical service

Cited from: Christensen R, Ploeger B. A clinical comparison of zirconia, metal and alumina fixed-prosthesis frameworks veneered with layered of pressed ceramic. A three-year report. JADA 2010; 141(11) 1317-1329

Posted online at [http://jada.ada.org/article/S0002-8177\(14\)60442-6/fulltext](http://jada.ada.org/article/S0002-8177(14)60442-6/fulltext). Copyright © 2010 American Dental Association. All rights reserved. Excerpted by permission.

BACKGROUND: This randomized controlled clinical trial investigated whether the performance differed between metal, zirconia and alumina fixed partial denture (FPD) frameworks veneered with pressed or layered ceramics designed for each framework type.

METHODS: Posterior three-unit FPDs (N = 293) of 10 different framework/veneer ceramic combinations were placed by 115 dentists in 259 patients from their practices according to a masked protocol. Yearly, the clinicians graded the prostheses and the opposing dentition in vivo according to 17 criteria, and two independent scientists graded them in vitro by using gold-sputtered dies, scanning electron micrographs and clinical photographs.

RESULTS: Three metal and five zirconia frameworks tested were not statistically different, with zero and two fractures, respectively. Alumina frameworks were statistically worse, with 11 fractures. The veneer ceramics CZR Press (Noritake Dental, Aichi, Japan) and Pulse interface (Jensen Dental, North Haven, Conn.) performed best with zirconia and metal frameworks, respectively. Four nonleucite-containing veneer ceramics used with zirconia frameworks had substantially more fractures.

CONCLUSIONS: Five zirconia framework brands performed equally well and were statistically comparable with metal frameworks at three years. Two leucite-containing veneer ceramics applied by means of pressing techniques had the statistically lowest number of fractures.

Posterior 3- and 4-unit Lava™ bridges after 18 months of clinical service

Cited from: Sorensen JA, Lusch R and Yokoyama K. Clinical Longevity of CAD/CAM Generated Y-TZP Posterior Fixed Partial Dentures, AADR 2006, #0270.

AIM: The purpose of this prospective longitudinal trial was to evaluate the clinical performance of 3- and 4-unit all-ceramic posterior fixed partial dentures (FPD) made with the LAVA™ (3M ESPE) zirconia system.

STUDY OUTLINE: 52 Lava Bridges were prepared with 1.3 mm of axial reduction, a circumferential shoulder margin with rounded axial-gingival line angles and 1.5 mm occlusal reduction. The substructure was designed with a 0.5 mm axial wall thickness and minimum connector height of 3 mm. The FPDs were veneered with Lava™Ceram and cemented with RelyX™ Unicem. Evaluation of clinical fracture, veneer porcelain luster, marginal adaptation, cement behavior and incidence of post-cementation sensitivity were measured at baseline, 6 months and annually.

RESULTS: A total of 52 Lava™ FPD were cemented. One patient died, one patient with 2 FPD dropped out of study. Of the remaining 49 FPD, the recall rate was 98 %. After a mean service time of 18.7 +/- 5 the 49 Lava™ restorations performed well as none had a catastrophic failure for a 100 % success rate. One unit had a small chip in the Lava™ Ceram veneering porcelain.

SUMMARY:

Restorations placed / recalled	52 / 49
Framework Success Rate (%):	100 %
Minor Chipping (n):	1
Major Chipping (n):	0
Replacement (n):	0

Abstract reprinted with permission from the Journal of Dental Research, Vol. 85, Special Issue A, 2006

Posterior 3- and 4-unit Lava™ bridges after 5 years of clinical service

Cited from: Schmitt J, Holst S, Wichmann M, Reich S, Goellner M. Zirconia Posterior Fixed Partial Dentures: 5-Year Clinical Results, IADR 2011, #145974.

AIM: The aim of this prospective clinical trial was to evaluate the reliability of three- and four-unit posterior fixed partial dentures (FPDs) with Lava™ Zirconia frameworks after five years of clinical function.

STUDY OUTLINE: Thirty Lava™ Bridges replacing one or two missing teeth were prepared according to Preparation guidelines. All FPDs were cemented with glass-ionomer cement. At baseline and 12, 24, 36, 48 and 60 months after cementation, survival and success of the zirconia framework and the ceramic veneer were evaluated. Gingival Index, Plaque Index, sulcus bleeding index, and pocket depth at abutment (test) and contralateral analogous teeth (control) were assessed.

RESULTS: Of the 30 initial subjects, 23 patients with 23 zirconia FPDs were examined after a mean testing period of 62.1 months. Two FPDs failed because of technical complications (one framework fracture, one delamination of veneering after endodontic treatment of abutment tooth) and had to be replaced. The 5-year survival rate was 92%. Chipping of the veneering material was found in six FPDs (two major and four minor chippings). No significant differences between the periodontal parameters of the test and the control teeth were observed.

SUMMARY:

Restorations placed / recalled	30 / 23
Framework Success Rate (%):	96%

Minor Chipping (n):	4
Major Chipping (n):	2
Replacement (n):	2



Posterior 3-unit Lava™ Bridge at 2 year recall with contact points marked.

Clinical Picture by PD Dr. Sven Reich

Posterior 3-unit Lava™ bridges evaluated after 5 years of clinical service

Cited from: Yu A, Raigrodski AJ, Chiche GJ, Hochstedler JL, Mohamed SE, Billiot S, Mercante DE. Clinical efficacy of Y-TZP-based posterior fixed partial dental dentures – Five year results. IADR 2009, #1637.

AIM: Assessment of the clinical efficacy of Y-TZP-based posterior three-unit Lava™ Bridges.

STUDY OUTLINE: Twenty posterior 3-unit Lava™ bridges were placed in 16 subjects. Abutments were prepared in a standardized manner and luted with the resin-modified glass ionomer cement RelyX™ Luting. Recall appointments were made at 2 weeks, 6, 12, 18, and 24 months, and annually thereafter. Fracture measurements, marginal discoloration, marginal adaptation, radiographic proximal recurrent decay, and periapical pathoses were assessed with modified Ryge criteria.

RESULTS: Eighteen FPDs were evaluated at 5 years and 1 at 48 months (one patient moved away without providing contact information). Fifteen were rated Alpha for fracture measurements and 2 were rated Bravo (minor veneering porcelain chipping). Two were rated Charlie (major veneering porcelain fracture). Nineteen FPDs were rated Alpha for marginal integrity excluding one rated Bravo. All restorations were rated Alpha for marginal discoloration. One subject experienced root fracture after 60 months, while another was treated surgically for a periapical pathosis on an endodontically treated abutment. Y-TZP posterior three-unit FPDs performed well after 5-year of service.

Note: After 5 years of clinical service, 3M ESPE was confirmed that 3-unit posterior Lava™ bridges reveal a good long-term clinical performance.

SUMMARY:

Restorations placed / recalled	20 / 18
Framework Success Rate (%):	100 %

Minor Chipping (n):	2
Major Chipping (n):	2
Replacement (n):	0

Posterior 3-unit Lava™ bridges with standard coping geometry after 5 years of clinical service

Cited from: Nothdurft FP, Rountree PR, Pospiech PR. Clinical long-term behavior of zirconia-based bridges (Lava): Five year results. PEF 2006; #0312

AIM: The purpose of this prospective study was to observe the clinical performance of zirconia posterior bridges for the replacement of molars.

STUDY OUTLINE: 31 bridges were included and the abutment teeth were prepared with a maximum 1.2 mm chamfer. All zirconia copings were designed with 0.6 mm wall thickness. All restorations were cemented conventionally with the glass-ionomer cement Ketac™ Cem. Judgements were made on the fit of the bridges on the abutment teeth, discoloration of the marginal gingiva, the quality of the surface, failures and allergenic reactions after 1 year, 3 and 5 years.

RESULTS: After 5 years of clinical service, 15 bridges could be evaluated clinically and the survival of 6 bridges could be proven by questioning the patients by phone. 10 bridges were dropped out due to several reasons not related to the material performance. No changes in fit or secondary caries were observed. No total failures regarding the restoration's integrity happened. Slight chipping of the veneering material took place in single cases, but there was no need for retreatment. No allergenic reactions and negative influences on the marginal gingiva could be observed. After five years of clinical service one can conclude a high performance of zirconia based posterior bridges

Note: After 5 years of clinical service, 3M ESPE concluded high performance of 3-unit zirconia based posterior bridges, although these study restorations were still created with a standardized coping design. Meanwhile Software-updates of the Lava™ Design Software allow an anatofom coping design to optimally support the veneering porcelain.

SUMMARY:

Restorations placed / recalled	31 / 15+6
Framework Success Rate (%):	100 %
Minor Chipping (n):	5
Major Chipping (n):	0
Replacement (n):	0



3-unit posterior Lava™ Bridge, 5 years *in situ*.

Clinical Picture by Prof. Dr. P Pospiech

The Dental Advisor: 3M ESPE Lava™ Crowns and Bridges (7 years)



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Cited from September 2010 Volume 27, Issue No. 07 of **THE DENTAL ADVISOR™**
<http://www.dentaladvisor.com/clinical-evaluations/evaluations/3m-espe-lava-crowns-and-bridges-7-yr.shtml>

AIM: This study evaluates the long-term clinical performance of 1500 Lava™ restorations which were placed and documented in dental offices.

STUDY OUTLINE: 1,500 restorations have been placed and documented. These restorations include anterior and posterior crowns, 3- to 6-unit bridges and implant abutments. Most restorations were cemented with RelyX™ Unicem Self-Adhesive Universal Resin Cement. After 7 years, restorations were evaluated according to resistance to fracture and chipping, aesthetics, resistance to marginal discoloration and wear.

RESULTS: 574 restorations could be evaluated at 7 years recall. After 7 years of clinical service, 2.8% of the 1,500+ restorations revealed porcelain fractures that led to replacement. None of these fractures affected the framework. 6.1% of 1,500+ placed restorations revealed a minor chipping that either did not need any smoothing or polishing or could be polished and smoothed satisfactorily. The summary of the consultant panel was that “3M ESPE Lava™ Crowns and Bridges performed exceptionally well over the seven-year evaluation period with excellent resistance to fracture and marginal discoloration and minimal wear.”

Note: After 7 years of clinical service, the Dental Advisor concludes an exceptionally good performance of 3M ESPE Lava™ Crowns and Bridges. However, the causes of the fractures could be the thickness of unsupported porcelain or possibly too rapid heating or cooling of the veneering ceramic. Rapid cooling of the restoration can result in the build up of undesirable stresses within the restoration.

SUMMARY:

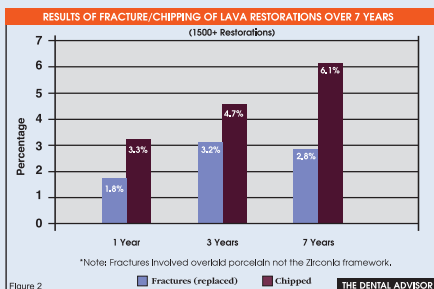
Restorations placed/
recalled 1,500/574

Framework Success
Rate (%): 100%

Minor Chipping (n): 35

Major Chipping (n): 0

Replacement (n): 16



Clinical Evaluation of the Lava™ C.O.S. Intraoral Scanning System

Cited from: Syrek A, Reich G, Ranftl D, Brodesser J, Cerny B, Klein C. Clinical evaluation of all-ceramic crowns fabricated from intraoral digital impressions based on the principle of active wavefront sampling. J Dent. 2010 Jul; 38(7): 553-9

AIM: This study compared the fit of all-ceramic crowns fabricated from Lava™ C.O.S. impressions to the fit of all-ceramic crowns fabricated from silicone impressions.

STUDY OUTLINE: Twenty patients were included to receive two Lava™ crowns each for the same preparation. One crown was fabricated using the Lava™ Chairside Oral Scanner (Lava™ C.O.S.), and the other crown from a two-step silicone impression. Prior to cementation the marginal, occlusal and interproximal fit of both crowns was clinically evaluated by two calibrated and blinded examiners; the marginal fit was also scored from replicas.

RESULTS: Median marginal gap in the conventional impression group was 71 µm (Q1:45 µm; Q3:98 µm), and in the digital impression group 49 µm (Q1:32 µm; Q3:65 µm) revealing significant difference between the groups ($p < 0.05$). No differences were found regarding the occlusion, and there was a trend for better interproximal fit for the digitally fabricated crowns.



SUMMARY:

1. Crowns from Lava™ C.O.S impressions revealed significantly better marginal fit than crowns from silicone impressions.
2. Marginal discrepancies in both groups were clinically acceptable.
3. Crowns from intraoral scans tended to show better interproximal contact area quality.
4. Crowns from both groups performed equally well as regards occlusion.



Posterior Single-unit Lava™ restoration at baseline.

Clinical Picture by Dr. Dr. A. Syrek

Summary

The individual clinical situation and the human perception of beauty are challenging the practitioner striving to provide a reliable and esthetic restoration to the patient. Therefore, the clinical approach is always the final proof to demonstrate the practicability of a dental material. In 10 years of clinical history, Lava™ Zirconia was intensely investigated by 3M ESPE and independent researchers around the globe. The studies summarized here prove that with Lava™ Zirconia dentists choose reliability, precision and beauty for their patients.

3M ESPE's goal is to provide continuously actual clinical information about the latest Lava™ material developments and Lava indication releases. Therefore, we sustain to involve excellent independent researchers around the world to evaluate Lava™ Precision Solutions.



Currently ongoing clinical studies and evaluations of Lava™ materials, indications and Lava™ C.O.S.:

Clinical Study of Lava™ Anterior Adhesive (Maryland-) Bridges

Survival of 3-unit Lava™ Anterior Adhesive Bridges in comparison to 3-unit NPM Adhesive Bridges to replace upper lateral incisivi.



Clinical Study of Lava™ Cantilever Bridges

Survival of 3- and 4-unit Lava™ Cantilever Bridges in comparison to 3- and 4- unit PFM Cantilever Bridges.



Clinical Evaluation of Lava™ All-Zirconia

Clinical Evaluation of the overall clinical performance of Lava™ All-Zirconia monolithic restorations.



Clinical Studies of Lava™ DVS

Long-term observational studies on overall clinical performance of Lava™ DVS.



Clinical Studies of Lava™ C.O.S.

Several clinical studies ongoing to evaluate the overall clinical performance and handling of Lava™ C.O.S. and its delivered accuracy.







3M ESPE AG
ESPE Platz
82229 Seefeld · Germany
E-Mail: info3mespe@mmm.com
Internet: www.3mespe.com

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