DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS

17 FEB 2017

MEMORANDUM FOR SGDTG
ATTN: CAPT EVAN ROBERTS

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **Fracture Strength of Titanium-Based Lithium Disilicate and Zirconia Abutment Crowns** presented at/published to **International Association of Dental Research, San Francisco, CA, 22-26 March 2017** in accordance with MDWI 41-108, has been approved and assigned local file #**17078.**

2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.

3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are 59 MDW staff member, we can forward your request for funds to the designated wing POC.

4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

Linda Steel-Goodwin

LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

INSTRUCTIONS

USE ONLY THE MOST CURRENT 59 MDW FORM 3039 LOCATED ON AF E-PUBLISHING

1. The author must complete page two of this form:
   a. In Section 2, add the funding source for your study [e.g., 59 MDW CRD Graduate Health Sciences Education (GHSE) (SG5 O&M); SG5 R&D; Tri-Service Nursing Research Program (TSNRP); Defense Medical Research & Development Program (DMRDP); NIH; Congressionally Directed Medical Research Program (CDMRP) ; Grants; etc.]

   b. In Section 2, there may be funding available for journal costs, if your department is not paying for figures, tables or photographs for your publication. Please state "YES" or "NO" in Section 2 of the form, if you need publication funding support.

2. Print your name, rank/grade, sign and date the form in the author's signature block or use an electronic signature.

3. Attach a copy of the 59 MDW IRB or IACUC approval letter for the research related study. If this is a technical publication/presentation, state the type (e.g. case report, QA/QI study, program evaluation study, informational report/briefing, etc.) in the "Protocol Title" box.

4. Attach a copy of your abstract, paper, poster and other supporting documentation.

5. Save and forward, via email, the processing form and all supporting documentation to your unit commander, program director or immediate supervisor for review/approval.

6. On page 2, have either your unit commander, program director or immediate supervisor:
   a. Print their name, rank/grade, title; sign and date the form in the approving authority's signature block or use an electronic signature.

7. Submit your completed form and all supporting documentation to the CRD for processing (59crdpubspres@us.af.mil). If you have any questions or concerns, please contact the 59 CRD/ Publications and Presentations Section at 292-7141 for assistance.

8. The 59 CRD/Publications and Presentations Section will route the request form to clinical investigations, 502 ISG/JAC (Ethics Review) and Public Affairs (59 MDW/PA) for review and then forward you a final letter of approval or disapproval.

9. Once your manuscript, poster or presentation has been approved for a one-time public release, you may proceed with your publication or presentation submission activities, as stated on this form. **Note:** For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.

10. If your manuscript is accepted for scientific publication, please contact the 59 CRD/Publications and Presentations Section at 292-7141. This information is reported to the 59 MDW/CC. All medical research or technical information publications/presentations must be reported to the Defense Technical Information Center (DITC). See 59 MDWI 41-108, *Presentation and Publication of Medical and Technical Papers,* for additional information.

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement:
"The views expressed are those of the [author(s)] [presenter(s)] and do not reflect the official views or policy of the Department of Defense or its Components"

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving humans:
"The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40-402."

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving animals, as required by AFMAN 40-401_IP :
"The experiments reported herein were conducted according to the principles set forth in the National Institute of Health Publication No. 80-23, Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act of 1966, as amended."

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1. TO: CLINICAL RESEARCH	2. FROM: (Author's Name, Rank, Grade, Office Symbol)	3. GME/GHSE STUDENT:	4. PROTOCOL NUMBER:
	Roberts, Evan, Capt, SGDTG	☒ YES ☐ NO	FWH20160024N

5. PROTOCOL TITLE: (**NOTE:** For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.)

Fracture Strength of Titanium-based Lithium Disilicate and Zirconia Abutment Crowns

6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED:

Fracture Strength of Titanium-based Lithium Disilicate and Zirconia Abutment Crowns

7. FUNDING RECEIVED FOR THIS STUDY? ☒ YES ☐ NO FUNDING SOURCE: 59 MDW Clinical Research Division, JBSA-Lackland, TX

8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: ☐ YES ☒ NO

9. IS THIS MATERIAL CLASSIFIED? ☐ YES ☒ NO

10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.?

☐ YES ☒ NO **NOTE:** If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.

11. MATERIAL IS FOR: ☒ DOMESTIC RELEASE ☐ FOREIGN RELEASE

CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED.

☐ 11a. PUBLICATION/JOURNAL (List intended publication/journal.)

☐ 11b. PUBLISHED ABSTRACT (List intended journal.)

☒ 11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.)
International Association of Dental Research, San Francisco, CA, 22 -26 March, 2017

☐ 11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meting.)

☐ 11e. OTHER (Describe: name of meeting, city, state, and date of meeting.)

12. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC
NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC).

DATE	
1 Feb 2017	

13. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email)	14. DUTY PHONE/PAGER NUMBER
Vandewalle, Kraig, S. kraig.s.vandewalle.civ@mail.af.mil	210-671-9822

15. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.

LAST NAME, FIRST NAME AND M.I.	GRADE/RANK	SQUADRON/GROUP/OFFICE SYMBOL	INSTITUTION (If not 59 MDW)
a. Primary/Corresponding Author Roberts, Evan E.	Capt	59 DTS/59 DG/SGDTG	
b. Bailey, Clifton W.	Lt Col	59 DTS/59 DG/SGDTG	
c. Ashcraft-Olmscheid, Deborah L.	Col	59 DTS/59 DG/SGDTG	
d. Vandewalle, Kraig S.	Civ	59 DTS/59 DG/SGDTG	
e.			
f.			

I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401_IP, AND 59 MDWI 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION.

16. AUTHOR'S PRINTED NAME, RANK, GRADE	17. AUTHOR'S SIGNATURE	18. DATE
Evan Roberts, Capt	ROBERTS.EVAN.E.1296756152 Digitally signed by ROBERTS.EVAN.E.1296756152 Dn: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USAF, cn=ROBERTS.EVAN.E.1296756152 Date: 2017.01.03 11:25:42 -08'00'	

19. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE	20. APPROVING AUTHORITY'S SIGNATURE	21. DATE
Nancy Motyka, Col	MOTYKA.NANCY.C.1262633256 Digitally signed by MOTYKA.NANCY.C.1262633256 Dn: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USAF, cn=MOTYKA.NANCY.C.1262633256 Date: 2017.01.31 13:46:49 -08'00'	

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1st ENDORSEMENT (59 MDW/SGVU Use Only)

TO: Clinical Research Division 59 MDW/CRD Contact 292-7141 for email instructions.	22. DATE RECEIVED February 02, 2017	23. ASSIGNED PROCESSING REQUEST FILE NUMBER 17078
24. DATE REVIEWED February 14, 2017		25. DATE FORWARDED TO 502 ISG/JAC

26. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: ☒ NO ☐ YES If yes, give date. _____ ☐ N/A

27. COMMENTS ☒ APPROVED ☐ DISAPPROVED

Dental materials research with determination letter and appropriate disclosures. Approved

28. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	29. REVIEWER SIGNATURE	30. DATE
Kevin Kupferer/GS13/Human Research Subject Protection Expert	KUPFERER.KEVIN.R.1086667270 Digitally signed by KUPFERER.KEVIN.R.1086667270 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USAF, cn=KUPFERER.KEVIN.R.1086667270 Date: 2017.02.14 10:58:21 -06'00'	February 14, 2017

2nd ENDORSEMENT (502 ISG/JAC Use Only)

31. DATE RECEIVED	32. DATE FORWARDED TO 59 MDW/PA

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34. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	35. REVIEWER SIGNATURE	36. DATE

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37. DATE RECEIVED	38. DATE FORWARDED TO 59 MDW/SGVU
February 14, 2017	February 14, 2017

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40. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	41. REVIEWER SIGNATURE	42. DATE
Kevin Iinuma, SSgt/E-5, 59MDW Public Affairs	IINUMA.KEVIN.MITSUGU.1296227613 Digitally signed by IINUMA.KEVIN.MITSUGU.1296227613 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USAF, cn=IINUMA.KEVIN.MITSUGU.1296227613 Date: 2017.02.14 13:06:03 -06'00'	February 14, 2017

4th ENDORSEMENT (59 MDW/SGVU Use Only)

43. DATE RECEIVED	44. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL ☐ YES ☐ NO ☐ COULD NOT BE REACHED ☐ LEFT MESSAGE

45. COMMENTS ☐ APPROVED ☐ DISAPPROVED

46. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	47. REVIEWER SIGNATURE	48. DATE

ABSTRACT #

Fracture Strength of Titanium-based Lithium Disilicate and Zirconia Abutment Crowns

E. Roberts[1], C.W. Bailey[2], D.L. Ashcraft-Olmscheid [1], C. Salmon[1], K.S. Vandewalle[1]
[1]USAF, JBSA-Lackland, TX, USA; [2]USAF, Goodfellow AFB, TX, USA

INTRODUCTION

Ivoclar Vivadent has combined the concept of CAD-CAM fabrication and esthetic-ceramic abutments. The IPS e.max CAD abutment is a lithium-disilicate block with a screw channel which can be milled to fabricate a hybrid abutment or hybrid-abutment crown. The hybrid abutment or hybrid-abutment crown is cemented onto a titanium-based platform, creating a hybrid of metal and ceramic. One permutation, involves drilling a access in the crown's occlusal surface, cementing the abutment and crown extraorally and then delivering the final restoration as a screw-retained prosthesis.

OBJECTIVE

The purpose of this study was to evaluate the strength properties of lithium disilicate to act as a hybrid-abutment crown, hybrid abutment, and "screwmentable" hybrid-abutment and crown in comparison to zirconia as a hybrid abutment when cemented to a titanium base.

MATERIALS and METHODS

An implant (Certain 4.1mm, Biomet 3i) was cemented into a resin cylinder using a flowable composite, scanned with a ScanPost (Sirona) and OmniCam Acquisition Unit (Sirona). A premolar-shaped crown was designed. Four groups of 10 specimens each were milled (MCXL, Sirona). Group 1: lithium-disilicate hybrid-abutment crown; Group 2: lithium-disilicate hybrid abutment/lithium-disilicate crown; Group 3: "screwmentable" lithium-disilicate hybrid abutment/lithium-disilicate crown with screw channel created with a bur and filled with composite resin; and Group 4 (control): zirconia hybrid abutment (InCoris ZI meso, Sirona)/lithium-disilicate crown. A TiBase (Sirona) was placed in each of the forty mounted implants. The groups were cemented onto the TiBase following manufacturer's recommendations, thermocycled (2000 cycles, 5 – 55° C) and cyclically loaded (150N, 100,000 cycles, 1Hz). Specimens were fractured in an Instron using a 6mm-diameter cylindrical piston resting on the buccal and lingual cusps. Fracture load data was analyzed with a One-Way ANOVA/Tukey's (alpha=0.05). Fracture modes were categorized as restoration intact, >50% of abutment intact with some intact crown remaining, <50% of abutment intact with some intact crown remaining, >50% of abutment intact without intact crown remaining, <50% of abutment intact without intact crown remaining, only the TiBase remaining, and finally prosthetic screw fracture.

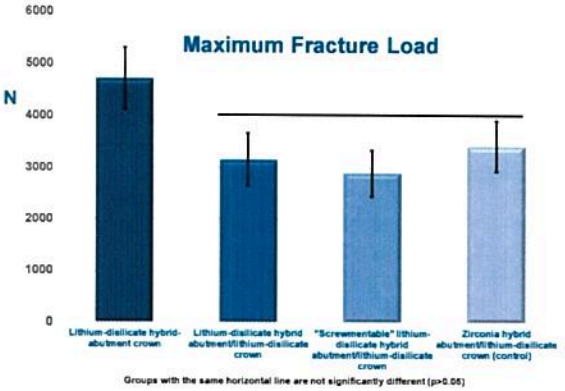
Lithium Disilicate Hybrid Abutment Crown

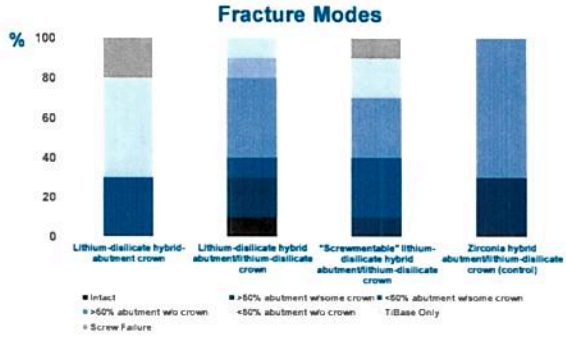
Zirconia abutment and Lithium Disilicate Crown

RESULTS

A significant difference was found in maximum fracture load between groups ($p<0.001$). The lithium-disilicate hybrid-abutment crown had significantly greater fracture strength than all the other groups which were not significantly different from each other.

The most frequently observed fracture mode for each group was as follows: Group 1) lithium-disilicate hybrid-abutment crown - only the TiBase remaining; Group 2) lithium-disilicate hybrid abutment/lithium-disilicate crown - >50% of the abutment without intact crown Group 3: "screwmentable" lithium-disilicate hybrid abutment/lithium-disilicate crown - an equal number (30% each) where >50% of the abutment remained without intact crown and <50% of the abutment remained with some intact crown remaining; and Group 4: zirconia hybrid abutment/lithium-disilicate crown - >50% of the abutment without intact crown





CONCLUSIONS

Based on fracture strength properties, the new lithium-disilicate abutment material may serve as a viable alternative to the use of the zirconia abutment/lithium-disilicate crown (control). The lithium-disilicate hybrid-abutment crown had the greatest fracture strength.

59th Medical Wing (59th MDW)
Institutional Review Board (IRB)
59th Clinical Research Division/SGVUS/(210) 292-7143
2200 Bergquist Dr, Bldg 4430, Lackland AFB, TX 78236-5300

25 Nov 15

FINAL DETERMINATION – NON-HUMAN RESEARCH

Determination Date: 25 Nov 2015

Project Lead: Capt Evan Roberts/SGDTG

Reference Number: FWH20160024N

Project Title: Fracture Strength of Titanium-based Lithium Disilicate and Zirconia Abutments

You may begin your project, as you would any other clinical or operational activity, with the approval and sponsorship of your leadership.

Your project was determined on 25 Nov 2015 to be considered **not human research** as defined by DoD regulation **32 CFR 219 and FDA regulation 21 CFR 56**. Continued IRB oversight for this activity is not required. The proposed project does not include non-routine intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction, nor do the researchers obtain private, identifiable information about living individuals.

Since the IRB does not have regulatory oversight for your study, it is the investigator's responsibility to validate the study's scientific merit and research design and to ensure the conduct of the study is upheld by the highest ethical standards, as required by the Wing. Should you require assistance in reviewing the scientific merit and research design of your study, please contact the Protocol Office. Protection of subjects' rights safety and welfare and responsibility for protecting PHI/PII and research data now fall on the investigator and their commander.

In accord with DoDI 6000.08 any intramural funding of this study as research or as a clinical investigation may continue to be received or sought regardless of this IRB determination.

Your study has received a one-time research determination. If the goals and/or activities of the project change during the course of the project, or if new activities are proposed that would constitute human subjects research, re-contact the Protocol Office, so that a regulatory expert may determine whether or not the revised plan involves human subject research activities.

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DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USAF, cn=GRANT.EARL.JR.1126544380
Date: 2015.11.30 08:27:38 -06'00'

Earl Grant, Jr., PhD
Designated Exempt Reviewer