The Primary Stability of a Bioabsorbable Poly-L-Lactic Acid Suture Anchor for Rotator Cuff Repair Is Not Improved with Polymethylmethacrylate or Bioabsorbable Bone Cement Augmentation

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Abstract *Background:* The incidence of osteoporosis and rotator cuff tears increases with age. Cement augmentation of bones is an established method in orthopedic and trauma surgery. *Questions/Purposes:* This study analyses if polymethylmethacrylate or bioabsorbable cement can improve the primary stability of a bioabsorbable suture anchor in vitro in comparison to a non-augmented suture anchor in osteoporotic human humeri. *Methods:* The trabecular bone mineral density was measured to ensure osteopenic human specimens. Then the poly-L-lactic acid Bio-Corkscrew® FT was implanted in the greater tuberosity footprint with polymethylmethacrylate Refobacin® cement augmentation ($n = 8$), with Cerament™ Bone Void Filler augmentation ($n = 8$) and without augmentation ($n = 8$). Using a cyclic testing protocol, the failure loads, system displacement, and

failure modes were recorded. *Results:* The Cerament™ augmented Bio-Corkscrew® FT yielded the highest failure loads (206.7 N), followed by polymethylmethacrylate Refobacin® augmentation (206.1 N) and without augmentation (160.0 N). The system displacement was lowest for Cerament™ augmentation (0.72 mm), followed by polymethylmethacrylate (0.82 mm) and without augmentation (1.50 mm). Statistical analysis showed no significant differences regarding the maximum failure loads ($p = 0.1644$) or system displacement ($p = 0.4199$). The main mode of failure for all three groups was suture slippage. *Conclusion:* The primary stability of the Bio-Corkscrew® FT is not influenced by bone cement augmentation with polymethylmethacrylate Refobacin® or with bioabsorbable Cerament™ in comparison to the non-cemented anchors.

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The cement augmentation of rotator cuff suture anchors in osteoporotic bones remains questionable since biomechanical tests show no significant advantage.

Keywords rotator cuff · osteoporosis · bone cement · augmentation · bone mineral density · biomechanics · poly-L-lactic acid suture anchor

Introduction

Bone cement augmentation of implants such as in total hip arthroplasty or pedicle screws in spine surgery is an established procedure in orthopedics and trauma surgery, especially when treating elderly patients with impaired bone mineral quality. Not only the incidence of osteoporosis but also the incidence of rotator cuff tears increase with age [1, 2, 9, 13, 19]. Tingart et al. and Kirchhoff et al. found significant bone mineral density differences between the different regions of the greater tuberosity [10–12, 20]. In addition to the anatomical BMD differences, the presence of rotator cuff tears furthermore increases the rate of osteopenia of the greater tuberosity and may therefore impair the healing of the rotator cuff tendon to the bone after rotator cuff repair and increase the failure rate [4, 5, 21]. To reduce the osteopenia-associated failure rate of rotator cuff repairs with suture anchors, the cement augmentation of suture anchors could be considered a favorable adjuvant option.

Very few studies have analyzed the cement augmentation of rotator cuff anchors until now. Postl et al., for example, presented a case report where a cyst in the greater tuberosity was filled with bone void filler and a rotator cuff tear was subsequently repaired [18]. In an experimental biomechanical setup using osteoporotic and osteopenic polyurethane foam blocks, Er et al. could show that the forces to failure of certain screw-type metal anchors could be increased using polymethylmethacrylate (PMMA) and bioabsorbable tricalcium phosphate (TCP) augmentation [7]. Giori et al. analyzed the effect of PMMA augmentation of a screw-type metal suture anchor in human cadaveric humeri and also observed a significant increase in the failure loads [8]. Braunstein et al. also retrieved significantly higher pull-out strengths of PMMA-augmented metal Corkscrew FT 1 (Arthrex Inc., Naples, FL, USA) in osteoporotic cadaveric bones in comparison to non-augmented screw anchors [3]. Similar results were obtained by Oshtory et al. where also a screw-type metal suture anchor was augmented with bioabsorbable cement in human cadaveric humeri [14].

Recently, there has been an increase in the use of polymer material suture anchors for rotator cuff (RC) repair, especially with poly-L-lactide (PLLA) and polyetheretherketone (PEEK) anchors rather than metal anchors. Although metal anchors are regarded as physically superior and biologically more inert, the mentioned polymers have a broader acceptance by surgeons because of their radiolucency and magnetic resonance imaging (MRI) clarity, thus allowing a better visualization of potential re-ruptures.

The purpose of this in vitro biomechanical study was to analyze the primary stability of a bioabsorbable screw type

PLLA suture anchor for RC repair without bone cement augmentation (reference group), with PMMA cement augmentation (experimental group 1), and with bioabsorbable bone cement augmentation (experimental group 2—all absorbable setup) in osteoporotic human humeri. We hypothesized that the cement augmentation of bioabsorbable suture anchors would significantly improve their biomechanical stability and that bioabsorbable bone cement would yield similar results as the PMMA.

Materials and Methods

The Specimens and Quantitative Bone Mineral Quality Determination

The specimens used in this study were provided by the Pathological Institute of the Institute of Forensic Medicine of our university. The prerequisites of the German Medical Association and the Ethics Committee of our university for postmortem studies were fulfilled; an additional IRB approval was therefore not necessary. A total of 34 shoulder specimens were removed 24 h postmortem and were fresh frozen at a temperature of -21°C Celsius (C). Prior to testing, all specimens underwent serological human immunodeficiency virus (HIV) and hepatitis B and C screening; four specimens from two patients were tested positive and immediately disposed of and excluded. Further exclusion criteria were bones with osteosynthesis materials, prostheses, fractures, or signs of previous surgical interventions.

Prior to the biomechanical testing, a quantitative computer tomography (qCT) bone mineral density (BMD) measurement of the specimens was conducted with the SOMATOM Sensation 64® computer tomogram (Siemens AG, Munich, Germany). Five slices with a thickness of 3 mm were analyzed at the greater tuberosity where the anchors were intended to be implanted with the *syngo* OSTEO CT software application (Siemens AG, Munich, Germany). The trabecular and cortical BMD in milligrams Calcium²⁺-hydroxylapatite/ml (mg Ca²⁺ HA/ml) was recorded to ensure an osteoporotic bone condition [16, 17]. In addition to the qCT BMD scan, we also measured the radiodensity in Hounsfield units (HU) of the anterior, middle, and posterior anchor implantation sites of the greater tuberosity of the same CT slices by placing three regions of interest (ROI) with an area of 0.54 cm²; the results are summarized in Table 1.

From the initial 34 specimens, a total of eight macroscopically intact fresh frozen cadaveric human proximal humeri with evident osteoporosis with BMD below 80 mg Ca²⁺ HA/ml were selected for this study. The mean age of the specimens was 81.88 years (SD 10.72) at the time of death, ranging between 59 and 88 years. The sex ratio of female to male was 7:1.

The humeri were thawed slowly at 4°C over a time period of 24 h. Then, all soft tissue such as muscles, ligaments, tendons, and capsule, were removed from the bone. The experiments were conducted at room temperature of 22°C. During the testing phase, the humeri were kept moist with gauze soaked in physiological saline solution (0.9% NaCl) which was then wrapped around the humeri.

Table 1 Mean trabecular and cortical BMD, as well as the anterior, medial, and posterior radiodensity of the greater tuberosity of the tested specimens

Specimen	Sex	Age	Trabecular BMD	Cortical BMD	Anchor position	Radiodensity (HU)	Cement	$F_{\max}$ (N)	Displacement (mm)
1	Female	88	21.54	387.06	Anterior	1.18	PMMA	225.1	0.89
					Medial	−4.04	Cerament	182.4	0.15
					Posterior	4.92	None	117.3	1.30
2	Female	88	26.38	456.92	Anterior	10.02	None	195.0	0.61
					Medial	0.58	PMMA	209.5	0.75
					Posterior	2.86	Cerament	210.9	0.38
3	Female	88	37.54	500.12	Anterior	11.28	Cerament	198.8	1.02
					Medial	−19.54	None	133.0	0.72
					Posterior	−18.00	PMMA	189.9	0.92
4	Female	88	24.52	500.34	Anterior	4.00	PMMA	142.8	1.12
					Medial	−22.06	Cerament	179.2	1.59
					Posterior	−25.28	None	135.2	0.92
5	Female	86	45.20	350.50	Anterior	37.46	None	184.2	1.37
					Medial	−1.00	PMMA	175.8	1.04
					Posterior	7.50	Cerament	188.1	1.16
6	Female	86	43.64	348.20	Anterior	4.48	Cerament	136.0	0.93
					Medial	10.62	None	150.2	0.81
					Posterior	29.50	PMMA	162.7	0.40
7	Female	59	78.06	561.26	Anterior	77.52	PMMA	292.8	0.70
					Medial	39.52	None	101.3	5.00
					Posterior	52.62	Cerament	274.1	0.39
8	Male	72	40.04	453.84	Anterior	20.46	Cerament	219.9	0.60
					Medial	11.68	None	250.0	0.70
					Posterior	27.04	PMMA	328.1	0.82
Mean		81.88	39.62	444.78					
SD		10.72	17.97	76.99					

There were no significant differences between the anterior, medial, or posterior aspect of the greater tuberosity

The Suture Anchors and Sutures

The fully threaded and bioabsorbable PLLA Bio-Corkscrew® FT (Arthrex Inc., Naples, FL, USA) with a 5.5 mm diameter and 14.7 mm length was used in this study (Fig. 1a). The Bio-Corkscrew® FT suture anchor is preloaded with two United States Pharmacopeia number 2 (USP No. 2) ultrahigh molecular weight polyethylene (UHMWPE) FiberWire® sutures (Arthrex Inc., Naples, FL, USA). The USP 2 FiberWire® sutures are grasped in the anchor body with a USP 2-0 FiberWire® suture loop knotted at the distal tip of the anchor; this is regarded as the suture-retaining mechanism of this system (Fig. 1b).

Anchor Implantation and Cement Augmentation

In every specimen, three bone sockets were prepared in the anterior, middle, and posterior RC footprint of the greater tuberosity using the 5.5 mm Bio-Corkscrew® punch as recommended by the manufacturer. The distance between the bone sockets measured at least 1 cm so that these would not interfere with each other, i.e., bone cement flow inside another bone socket. The pre-punched bone sockets of the footprint were either left un-augmented ($n = 8$), were augmented with PMMA Refobacin® Bone Cement R (Biomet GmbH, Berlin, Germany) ($n = 8$), or were augmented with the bioabsorbable Cerament™ Bone Void Filler (Bonesupport AB, Lund, Sweden) ($n = 8$). The position of the three different groups of anchors was alternated evenly between the anterior, middle,

and posterior implantation sites of the greater tuberosity to minimize variations of potential bone density differences.

The high viscous and x-ray positive Refobacin® Bone Cement R consists of a PMMA and Gentamicin powder component and a liquid methyl methacrylate (MMA) monomer. Cerament™ consists of 40% osteoinductive hydroxyapatite (HA) [$\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$] and 60% bioabsorbable component α -calcium sulfate hemihydrate. Like PMMA Refobacin®, Cerament™ is delivered in two components (powder and liquid). The two types of cement were thoroughly manually mixed, refilled into a 10-ml syringe, and injected flush into the bone sockets while still in a runny state. Immediately after the bone sockets were filled with the cement, the Bio-Corkscrew® anchor was inserted flush with the cortical layer of the bone. The excessive bone cement running out of the bone socket was removed from the footprint to prevent fixation of the FiberWire® sutures. The handle with the driver was then removed from the anchor. The cement-anchor systems were then left to harden for at least 10 min prior to testing.

Biomechanical Testing

Biomechanical testing was conducted using the universal testing machine Zwick Z010/TN2A (Zwick GmbH & Co. KG, Ulm, Germany) with a measuring range of 20 N and 10 kN and an uncertainty of measurement of 0.21%. The proximal humeri were fixed to the testing machine with a custom-engineered adjustable mounting plate (Fig. 2). The sutures were positioned at a 135° angle to the longitudinal axis of the humeral

Fig. 1. **a** Close-up view of the Bio-Corkscrew® FT suture anchor with its fully threaded anchor body. **b** Illustration of the longitudinal section of the Bio-Corkscrew® FT anchor in the bone with the USP 2-0 FiberWire® suture knotted at the tip of the anchor holding two USP 2 FiberWire® sutures. [Figures and illustrations used with permission from Arthrex Inc. represented by Arthrex Medizinische Instrumente GmbH, Karlsfeld, Germany.]

shaft—simulating the physiological pull of the supraspinatus tendon—and affixed to the crosshead of the testing machine with clamping jaws [16, 17]. Every anchor was tested individually. The distance between the implantation site of the anchors and the distal end of the suture clamps on the crosshead of the testing measured 30 mm. An established stepwise cyclic fatigue

Fig. 2. After the bone sockets were prepared and the anchors implanted, the proximal humeri were affixed in a custom-engineered holding device mounted to the base of the testing machine. The FiberWire® sutures were affixed to the crosshead of the testing machine with clamps.

Radiodensity of the footprint

Kruskal-Wallis Test: $p = 0.2815$ (n.s.)

Fig. 3. No significant differences in the radiodensity between the anterior, middle, and posterior aspect of the greater tuberosity footprint.

test protocol was utilized to simulate postoperative early functional movement. A 25 N preload was set to remove the slack from the system. Then, 50 cycles were run between the 25 N preload at an initial tensile force of 75 N at an extension rate of 20 mm/min. After running the 50 cycles, the tensile force was increased in 25 N steps until failure occurred [16, 17].

The maximum failure loads ($F_{\max}$) in Newton, the system displacement in millimeters (mm), and the modes of failure were recorded. The $F_{\max}$ is the force necessary for the suture anchor system to fail. The system displacement or displacement of the anchor system is regarded as the irreversible lengthening of the suture and suture anchor complex in the bone after the first testing cycle at 75 N measured in millimeters; this comprises the lengthening of the suture in the anchor and relieving of slack, as well as the movement of the anchor in the bone socket until a firm gripping or fixation is obtained. The anticipated modes of failure are anchor dislocations out of the bone, dislocation or “slippage” of the FiberWire® sutures between the anchor body and bone socket, and perhaps even tearing/rupturing of the FiberWire sutures at higher tensile strain.

Power Analysis and Statistical Analysis

An a priori power analysis was conducted with the G*Power statistical power analysis software version 3.1.9.2 (<http://www.gpower.hhu.de/>). We analyzed the values provided by a similar study conducted by Pietschmann et al. using a similar anchor design in healthy and osteopenic bone [17]. A sample size of at least $n = 7$ was determined using an effect size d of 1.465 and α error probability of 0.05 to retrieve a power value of 0.8 ($1 - \beta$ error probability).

Statistical analysis was performed using the GraphPad Prism statistical software version 5.02 (GraphPad Software, San Diego, CA, USA). The non-parametric unpaired Kruskal-Wallis test was used to test for significances between the groups, as well as Dunn’s post hoc test. Significances were calculated based on a 5% level ($p < 0.05$). The data is visualized in box plot diagrams.

Results

The mean BMD of the humeri specimens was 39.62 mg Ca^{2+} HA/ml (SD ± 17.97) and evidently osteoporotic.

Analysis of the radiodensity of the greater tubercle ($n = 8$) showed no significant differences between the anterior, middle, and posterior aspect of the footprint with $p = 0.2815$ as opposed to the differences observed by Tingart et al. or Kirchhoff et al. with a larger sample size (range, $n = 36$ to 64) [10–12, 20] (Fig. 3; Table 1).

The all-bioabsorbable setup with the Cerament™ augmented anchors yielded the highest mean $F_{\max}$ with 206.7 N (SD ± 65.91) followed by PMMA Refobacin® augmentation with 206.1 N (SD ± 49.12) and the non-augmented anchor with $F_{\max}$ of 160.0 N (SD ± 41.16). The statistical analysis showed no significant differences between the three tested groups with $p = 0.1624$ (Fig. 4a).

The Cerament™ augmented anchors yielded the lowest mean system displacement values with 0.72 mm (SD ± 0.36) followed by PMMA Refobacin® augmentation with 0.82 mm (SD ± 0.23) and the non-augmented anchors with 1.50 mm (SD ± 1.46). Statistical testing was non-significant with $p = 0.4199$ (Fig. 4b).

The mean radiodensity of the trabecular footprint of the greater tuberosity is clearly osteoporotic in the utilized specimens. A post hoc correlation analysis was conducted to compare the radiodensity to the yielded mean $F_{\max}$ and system displacement of the three groups—independent of the anchor implantation sites. There was no significant correlation between the radiodensity and the $F_{\max}$ or between the radiodensity and the system displacement in the tested groups except for Cerament™ and its $F_{\max}$ (Fig. 5).

The modes of failure observed were anchor dislocations and suture slippage; suture tears did not occur. The non-cemented Bio-Corkscrew® anchors of the reference group failed in seven tests by anchor dislocations and in one test by suture slippage. The bioabsorbable Cerament™ augmented Bio-Corkscrew® anchors failed in all eight tests by anchor dislocations. The modes of failure for the PMMA Refobacin® augmented anchor were seven anchor dislocations and one suture slippage.

Discussion

The results of this current biomechanical study show that there is no statistical difference in the primary stability of the bioabsorbable fully threaded screw type PLLA Bio-

Corkscrew® suture anchor system with PMMA Refobacin® augmentation or bioabsorbable Cerament™ augmentation in comparison to the non-augmented setup in osteoporotic proximal humerus bones. Our hypothesis that the cement augmentation of bioabsorbable suture anchors using PMMA or bioabsorbable cement would significantly improve their biomechanical stability was rejected. Cement augmentation, with the classical PMMA or the bioabsorbable Cerament™, does not positively influence the primary stability of the Bio-Corkscrew® anchor in osteoporotic humeral bone. There were no significant differences regarding the maximum failure loads and system displacement values in the three groups.

Only the post hoc correlation analysis showed a positive correlation between the radiodensity of the trabecular bone where the Cerament™ cement was utilized and its maximum failure load; all other groups showed no significant correlation. While there were no consistent significant differences detected in this study, the results seem to trend towards significance.

We recognize potential limitations of this study. This study analyzes solely the biomechanics of rotator cuff repair at time zero, so therefore, it is not possible to evaluate the osteoinductive process of the bioabsorbable cement and the deterioration of the PLLA anchor in the bone over time. To assess the effect of time and the local biological factors influencing the healing, an experimental in vivo study, for example in an animal model, would be necessary.

The utilization of a fully threaded anchor might also be considered a limitation itself since the anchor grasps not only the clearly weaker trabecular bone but also, to a certain extent, the rigid cortical bone. In previous studies, anchors tilting in the subcortical trabecular bone or press-fit anchors appeared to yield a relatively lower primary stability than, for example, cortical bone-grasping screw-type anchors or subcortically wedging anchors [15, 17]. If these allegedly biomechanically inferior anchors were to be augmented with cement, would it be possible for them to perhaps yield a higher primary stability? Biomechanical testing in this direction could perhaps retrieve results showing if bone cement augmentation does have a direct influence in the stability of anchors with a different design.

The non-significant results may be explained by the firm grip of the Bio-Corkscrew® anchor in the bone which does

Fig. 4. **a** The $F_{\max}$ shows no statistical significance between the three tested groups. **b** The system displacement shows no statistical significance between the three tested groups.

Fig. 5. Correlation analysis shows no significant between radiodensity and F_{max} or system displacement values except for the radiodensity of the bone where the Cerament™ was utilized and its F_{max} .

not seem to be influenced by the cement mantle. The fully threaded design of the Bio-Corkscrew® anchor grasps not only the weaker cancellous bone but also the rigid cortical bone to a certain extent. The fully threaded anchor body can be considered to be of a greater advantage than bone cement augmentation when implanting anchors in osteoporotic human bones. This hypothesis can be strengthened by the study conducted by Er et al., where the fully threaded metal Corkscrew FT II® anchor without cement augmentation yielded similar results in a biomechanical testing setup using osteoporotic foam blocks in comparison to cement-augmented metal Corkscrew® anchor without a fully threaded body [7]. Pietschmann et al. also supports this hypothesis by showing that knotless cortical screw type

and subcortical wedging anchors show better primary stability than other designs, i.e., press-fit anchors [17].

The predominant modes of failure for all groups were anchor dislocations ($n = 22$), where the Bio-Corkscrew® FT was released out of the bone socket at mean forces exceeding the 160 N threshold. In the groups where the Bio-Corkscrew® FT was augmented with Cerament™ or PMMA Refobacin®, the anchor dislocated with a cement jacket. In Fig. 6a, we see a relatively large PMMA Refobacin® jacket around the anchor where the anchor and cement complex measures almost 13 mm in diameter. This could eventually result in a large bony defect of the footprint, and, as seen in Fig. 6b, lost bone stock can limit the implantation of suture anchors in potential revision RC surgery. In vivo, it is very unlikely for the suture

Fig. 6. **a** A BioCorkscrew FT anchor is bonded with PMMA Refobacin® cement and dislocated out of the bone socket. The diameter of the anchor-cement complex measures approximately 12 mm. **b** Large bony defect of the greater tuberosity footprint due to anchor dislocation.

Fig. 7. Rare case of suture dislocation where the suture retaining mechanism of the Bio-Corkscrew® FT failed by loosening of the USP 2-0 FiberWire® sutures in the anchor body.

anchor to dislocate since the tendon-to-suture interface is considered to be the weakest link in rotator cuff reconstruction using suture anchors and is likely to fail at lower tensile loads [6]. Nevertheless, a big foreign body, as in a dislocated anchor, still represents a great risk since it can create vast damages to the shoulder joint. Suture slippage (Fig. 7) would be the preferred mode of failure since this is less likely to create joint damages than a dislocated anchor but would, nevertheless, also require revision.

Very little data exists on the clinical applicability of cement in RC repair. If suture anchor augmentation should be required in RC repair, bioabsorbable cement might be a viable alternative to PMMA since it yielded almost identical results as the classical PMMA cement. Potential revision surgery with bioabsorbable cement might be of advantage in comparison to the inert PMMA if implantation of a new suture anchor should be necessary in the footprint. The integration of the RC to the bone might also be interfered by PMMA under the cortical layer of the footprint as opposed to bioabsorbable cements with their osteoinductive properties. There are no studies to support these ideas, and experimental research in this direction is therefore favored.

In conclusion, the primary stability of the Bio-Corkscrew® FT is not influenced by bone cement augmentation with PMMA Refobacin® or with bioabsorbable Cerament™ in comparison to the non-cemented anchors. The cement augmentation of rotator cuff suture anchors in osteoporotic bones remains questionable since biomechanical tests show no significant advantage. While the results did not reach significance, there were differences between the groups, thus spurring the need for future studies.

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Compliance with Ethical Standards

Conflict of Interest: Mehmet F. Güleçyüz, Dr. med.; Michael Kraus-Petersen, Dipl.-Ing. (FH); Christian Schröder, Dr. rer. biol. hum. fDipl.-

Ing. (FH); Andreas Ficklscherer, PD Dr. med.; Markus U. Wagenhäuser, Dr. med.; Christian Braun, Dr. med.; Peter E. Müller, Prof. Dr. med. and Matthias F. Pietschmann Prof. Dr. med. declare that they have no conflict of interest.

Human/Animal Rights: All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 (5).

Informed Consent: Informed consent was obtained from all patients for being included in the study.

Required Author Forms Disclosure forms provided by the authors are available with the online version of this article.

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