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Novel ultrasound assisted suture anchor system using the BoneWelding® technology yields a comparable primary stability in osteopenic and healthy human humeri as a benchmark anchor

Mehmet F. Güleçyüz [a, *], Christian Schröder [b], Matthias F. Pietschmann [a], Stephanie Göbel [c], Mario Lehmann [d], Jörg Mayer [d], Andreas Ficklscherer [e], Volkmar Jansson [a], Peter E. Müller [a]

[a] Department of Orthopaedics, Physical Medicine and Rehabilitation, Medical Center of the University of Munich (Ludwig-Maximilians-University), Munich, Germany
[b] Laboratory for Biomechanics and Experimental Orthopaedics of the University of Munich (Ludwig-Maximilians-University), Germany
[c] TÜV SÜD Product Service GmbH, Active Medical Products 3, Munich, Germany
[d] SportWelding GmbH, Schlieren, Switzerland
[e] Orthopädie Oberland, Weilheim, Germany

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ABSTRACT

Introduction: The aim of this biomechanical study was to evaluate the primary stability of the SportWelding® Sombrero 3.6 mm suture anchor system in osteopenic and healthy cadaveric humeri.
Methods: The Sombrero® and BioCorkscrew® anchors were deployed in 8 osteopenic and 4 healthy cadaver humeri after the bone mineral density (BMD) measurements of the 32 specimens. Both anchors were loaded with a USP Nr. 2 FiberWire® suture. An established cyclic testing protocol was performed. The maximum failure load (Fmax), the system displacement and the modes of failure were recorded.
Results: The F_{max} and system displacement of the Sombrero® in osteopenic and healthy humeri was equivalent to the Bio-Corkscrew® benchmark anchor; there were no significant differences in the maximum failure loads and system displacement values. Only anchor and suture dislocations were observed; suture ruptures did not occur.
Conclusion: This study shows that the Sombrero® yields similar maximum failure loads and system displacement values as the established Bio-Corkscrew® benchmark anchor. The primary stability of the Sombrero® and Bio-Corkscrew® seems to be independent of the bone mineral quality. This relatively small-sized polymer anchor is independent of the BMD and may be an alternative to established suture anchors in rotator cuff repair.

Introduction

It is undisputed tat the incidence of osteoporosis and rotator cuff tears increase with progressing age. The cancellous or trabecular bone quality is one factor out of many playing a big role in the clinical outcome of arthroscopic rotator cuff (RC) repair which cannot be influenced by the surgeon.[1–4] Factors that can be influenced are the utilised suture anchors, sutures, suturing techniques etc. It is therefore crucial to limit the osteoporosis related failure rates of rotator cuff with the available methods and materials.

The fast developing medical technology industry presents a number of innovative suture anchors for arthroscopic rotator cuff repair varying not only in size, but also in design (e.g. screw-type, wedging-type), material (e.g. metal, PEEK, PLA), and fixation properties (e.g. press-fit, force-fit). One of these novel systems is the SportWelding Sombrero® 3.6 mm suture anchor (SportWelding GmbH, Schlieren, Switzerland) for rotator cuff repair which uses an ultrasound assisted anchoring technique (BoneWelding®

* Corresponding author. Department of Orthopaedics, Physical Medicine and Rehabilitation, Medical Center of the University of Munich (Ludwig-Maximilians-University) Marchioninistrasse 15, 81377 Munich, Germany. Fax: +49 89 4400 76780.
E-mail address: Mehmet.guelecyuez@med.uni-muenchen.de (M.F. Güleçyüz).
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technology) to mould a biodegradable polymer subcortically in a pre-punched hole in cancellous bone.

The ultrasound assisted anchoring technique using BoneWelding® technology with the utilisation of bioabsorbable implants to anchor in bone tissue is being used in neurosurgery and maxillofacial surgery since several years and has shown a very reliable stability in biomechanical tests.[5–10] The use of this technology is a first in rotator cuff repair.

The purpose of this biomechanical *in-vitro* study was to see if a novel, ultrasound assisted, subcortically wedging anchor measuring only 3.6 mm in diameter can yield the same primary stability as a benchmark suture anchor with a greater diameter. The Bio-Corkscrew® (Arthrex Inc., Naples, FL, USA), suture anchor system was chosen as a benchmark anchor since it yields a high degree of stability in biomechanical single suture anchor tests and has been recommended by Brady et al to be used if osteoporotic bone is suspected.[11–13]

Our hypothesis is that the biomechanical primary stability of the Sombrero® anchor is similar to that of the benchmark Bio-Corkscrew® anchor and that the integrity of the Sombrero® anchor is independent of the bone mineral quality of the human humeri due to its unique subcortical fixation mechanism.

Materials and methods

The human cadaveric humeri specimens

A total number of 36 human proximal humerus specimens were available for this study. The proximal humerus specimens were removed 24 h post mortem and were fresh frozen at a temperature of 21°Celsius (C). Prior to the testing, all specimens underwent serological human immunodeficiency virus (HIV) and Hepatitis B and C screening; four specimens were tested positive for Hepatitis and were immediately disposed of and excluded. Further exclusion criteria were bones with osteosynthesis materials, prostheses, fractures or signs of previous surgical interventions. The cadaver specimens fulfilled the prerequisites of the German Medical Association for conducting post-mortem studies in our University. An additional approval of the Local Ethics Committee was therefore not necessary.

Prior to biomechanical testing, the Bone Mineral Density (BMD) of the proximal humerus was quantified with quantitative computer tomography (qCT) using the SOMATOM Sensation 64 computer tomogram by Siemens (Siemens AG, Munich, Germany) and *syngo* OSTEO CT software application. Five measurements with a slice thickness of 3 mm were conducted in the proximal region of the humeral head at the greater tuberosity where the anchors were intended to be implanted. The trabecular and cortical BMD (mg Calcium^{2+}-Hydroxylapatite/ml) of the humeral head was evaluated with the *syngo* OSTEO CT software application (Siemens AG) and the specimens were divided into an osteopenic and healthy group at a cut-off threshold of 100 mg Calcium^{2+}-Hydroxylapatite/ml (mg Ca^{2+}-HA/ml).[1,2] We also assessed the radiodensity of the potential implantation sites of the anterior, middle and posterior aspects of the footprint of the greater tuberosity by placing 3 regions of interest (ROI) with an area of 0.54 cm^2.[2–4] The results of the bone scans are summarized in Table 1.

From the remaining 32 specimens a total number of 8 osteoporotic and 4 healthy specimens were chosen for testing the two different anchor systems. The 8 osteoporotic specimens had an average age of 76.8 years (SD 7.19) at time of death (range 68–86 years) and a trabecular BMD of 53.99 mg Ca^{2+}-HA/ml (SD 15.71); the sex ratio was 5 males to 8 females (Table 1). The 4 healthy specimens had an average age of 76 years (SD 2.09) at time of death (range 74–78 years) and a trabecular BMD of 117.95 mg Ca^{2+}-HA/ml (SD 16.20); the sex ratio was 6 males to 6 females (Table 1). All soft tissue such as muscles, tendons, ligaments, capsule etc. was removed from the bones. During the whole testing phase, the proximal humeri were kept moist with gauze soaked in physiological saline solution (0.9% NaCl).

Suture anchor system deployment

The suture anchor systems were deployed in the greater tuberosity in the anterior, middle or posterior aspect at intervals of at least 10 mm^2 in osteoporotic and healthy specimens. The position of the anchor systems were equally altered between the anterior, medial and posterior implantation sites to minimize the influence of possible BMD differences of the greater tuberosity.[14] All anchor systems were deployed according to the manufacturers' instructions.

The Sombrero® anchor measures Ø 3.6 mm in diameter and 16 mm in length and consists of an approx. 7 mm PEEK eyelet and an approx. 9 mm poly-l D-lactide (PLDLA) anchoring element with thermoplastic properties. The Sombrero® anchor system was preloaded with United States Pharmacopoeia (USP) Nr. 2 FiberWire® sutures (Arthrex Inc., Naples, FL, USA). With a handle, the Sombrero® is inserted subcortically into a pre-punched or pre-drilled bone socket (Ø 3.8 mm) of the greater tuberosity. The BoneWelding® technology applies ultrasound energy to the PLDLA element to liquefy it where it then infiltrates the meshwork of cancellous bone and solidifies within seconds. After removing the handle, the two preloaded USP 2 FiberWire® sutures are available for suture knotting (Fig. 1A). A total number of 7 anchors were deployed for testing.

The Bio-Corkscrew® FT 5.5 mm, a screw-type anchor made of bioabsorbable poly-L-lactide (PLLA) measuring Ø 5.5 mm in diameter and 15 mm in length, is also inserted in a pre-punched hole with a handle. In contrast to the Sombrero® anchor which is implanted solely subcortically, the threading mechanism of the Bio-Corkscrew® grasps the trabecular bone as well as the cortical bone to a certain extent. After deployment, the handle is removed for knotting of the two preloaded USP 2 FiberWire® sutures (Fig. 1B). A total number of 6 anchors were deployed for testing.

The biomechanical testing

The universal testing machine Zwick Z010/TN2A (Zwick GmbH & Co. KG, Ulm, Germany) was utilised for the biomechanical testing of the suture anchor systems; the machine possesses a measuring range between 20 and 10,000 N and an uncertainty of measurement of 0.21%. The proximal humeri were fixed to the testing machine with a custom-engineered adjustable mounting plate. The sutures were positioned at a 135° angle to the longitudinal axis of the humeral shaft – simulating the physiological pull of the

Table 1
Suture anchor systems and failure mechanisms in osteopenic and healthy humeri.

Bone quality	Osteopenic			Healthy		
Modes of failure	Anchor dislocation	Suture dislocation	Suture rupture	Anchor dislocation	Suture dislocation	Suture rupture
Sombrero®	7	0	0	6	0	0
Bio-Corkscrew®	5	1	0	3	3	0

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