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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

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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®

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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

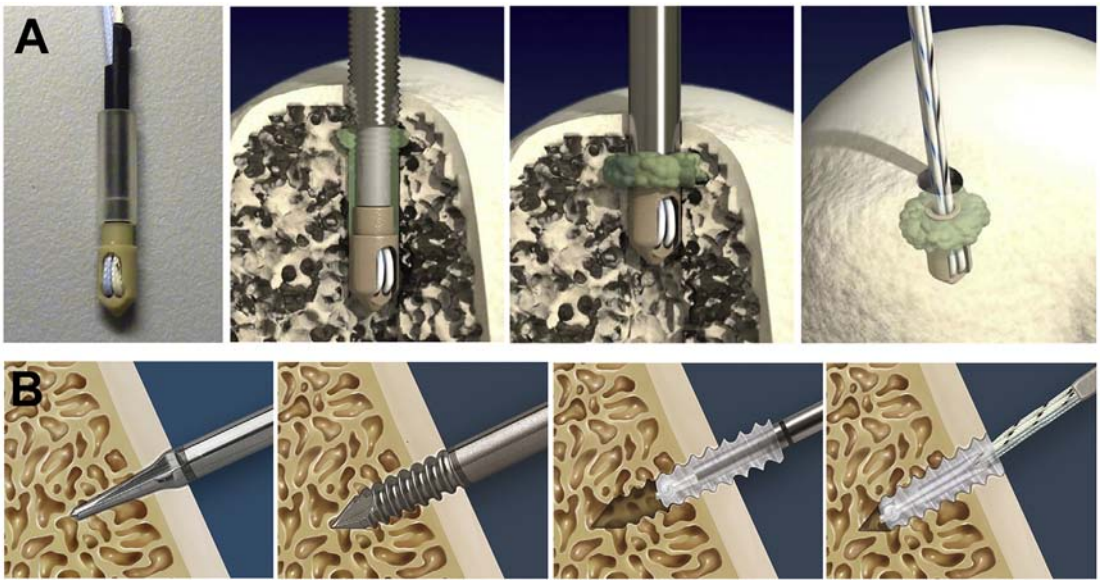

Fig. 1. Deployment of the Sombrero® anchor system (A) and the Bio-Corkscrew® FT 5.5 mm anchor system (B). [*Used with permission from SportWelding GmbH and Arthrex Inc. represented by Arthrex Medizinische Instrumente GmbH – Germany*].

supraspinatus tendon[15] – and affixed to the crosshead with clamping jaws and additionally knotted 8 times to the apparatus (Fig. 1A). Every anchor was tested individually. The distance between the implantation site of the anchors and the distal end of the clamping jaws measured approximately 30–35 mm (Fig. 2A). The anchors were cyclically loaded to simulate postoperative *in vivo* conditions. A continuous preload was set at 20 N on the suture anchor systems to remove slack from the system. With an extension rate of 20 mm/min on the crosshead, 50 cycles were performed per tensile load starting at 75 N. Starting from the preload tension at 20 N the anchor system was strained until the 75 N threshold was reached and then the tension was reduced back to the preload of 20 N before initiating the next cycle. After 50 cycles at 75 N, the strain was increased in 25 N steps to 100 N, 125 N, 150 N, etc. until system failure occurred.[15–19] The maximum failure loads (F_{max}), the initial system displacement at 75 N and the respective modes of failure (anchor dislocation, suture slippage, suture rupture) were recorded. The testing process of the anchor system can be visualised with the maximum failure load – system displacement – diagram (Fig. 2B).

Statistics

The data was statistically analysed by using the GraphPad Prism statistical software, version 5.02 (GraphPad Software, San Diego, CA). The non-parametric Mann–Whitney *U* test was performed for the analysis of two independent groups i.e. comparison of the BMD, F_{max}, etc. The non-parametric Kruskal–Wallis test was performed to compare 3 or more independent groups i.e. the radiodensity of the 3 implantation sites of the greater tuberosity footprint. Statistical significances were calculated based on a 5% level ($p < 0.05$).

Results

Bone mineral density

There was a significant difference ($p < 0.001$) between the trabecular BMD of the osteopenic 53.99 mg Ca^{2+}-HA/ml (SD 16.02) and the healthy group 117.9 mg Ca^{2+}-HA/ml (SD 16.20) (Table 1 and Fig. 3). A significant difference in the radiodensity (Hounsfield units) between the anterior, middle or posterior implantation sites of the greater tuberosity in osteopenic ($p = 0.155$) or healthy (0.0775) humeri could not be detected.

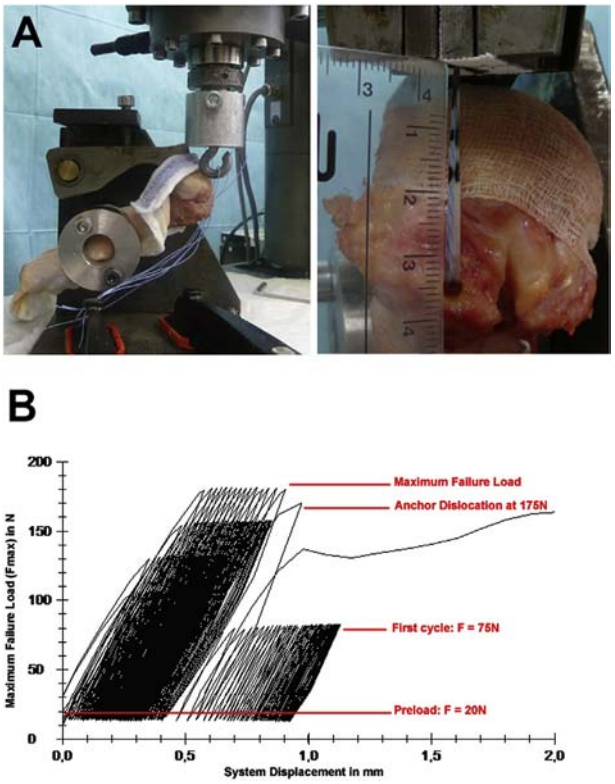

Fig. 2. A) fixation of the humerus in the custom engineered mounting plate at the base of the testing machine; the angle of the strain of the sutures is 135° simulating the pull of the rotator cuff. The picture on the top right shows how the sutures were grasped by clamps at the crosshead of the testing machine; additionally, the sutures were knotted to the crosshead (not depicted). B) Load – displacement diagram: starting from the preload at 20 N the anchor system was strained until the 75 N threshold was reached and then the tension was reduced back to the preload of 20 N before initiating the next cycle. After 50 cycles at 75 N, the strain was increased in 25 N steps to 100 N, 125 N, 150 N, etc. until system failure occurred.

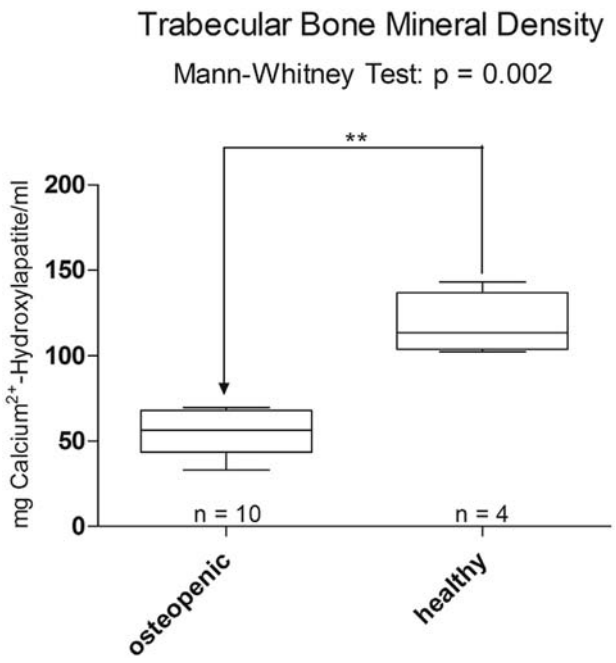

Fig. 3. Significant BMD difference between the osteopenic and healthy group.

Maximum failure loads

The mean maximum failure load (F_{max}) for the SportWelding Sombrero® 3.6 mm was 217.5 N (SD 78.68) in osteopenic humeri; this value was almost equivalent to the F_{max} of the Bio-Corkscrew® FT 5.5 mm with 220.8 N (SD 67.85) in osteopenic specimens. There were no significant differences between the two anchors (Fig. 4).

In healthy humeri, F_{max} values of 279.2 N (SD 57.92) and 245.8 N (SD 60.03) were recorded for the SportWelding® Sombrero 3.6 mm and Bio-Corkscrew® FT 5.5 mm anchor systems respectively. No significant differences were evident between the two anchors (Fig. 4).

The system displacement

The system displacement is defined as the initial irreversible displacement of the anchor system including the bone deformation during testing, displacement of the anchor in the bone and irreversible lengthening of the sutures during the first cycle at 75 N.[2] The system displacement of the Sombrero® 3.6 mm and Bio-Corkscrew® FT 5.5 mm measured 0.37 mm (SD 0.12) and 0.57 mm (SD 0.18) respectively in osteopenic humeri and 0.49 mm (SD 0.36) and 0.71 mm (SD 0.24) in healthy humeri. There were no significant differences evident between the two anchor systems in osteopenic or healthy humeri (Fig. 5).

Modes of failure

The modes of failure observed during this testing were anchor dislocations and suture slippage; suture ruptures did not occur at all (Table 1).

In the Sombrero® anchor system, either the PEEK eyelet-body slipped through the molten PLDLA in the trabecular bone and dislocated or the whole PEEK/PLDLA-complex dislocated out of the bone (Fig. 6A and B). In osteopenic and healthy humeri, the PEEK anchor body dislocated twice through the PLDLA ring; in all other cases the whole PEEK/PLDLA-complex dislocated. Suture slippage could not be observed for the Sombrero® system in either osteopenic or healthy bone.

In osteopenic humeri, the Bio-Corkscrew FT 5.5 mm anchor system failed five times due to anchor dislocation where the sutures and the whole anchor body were pulled out of the bone leaving behind a relatively large bone defect. This mode of failure was observed in three cases in healthy humeri (Fig. 6D). In the Bio-Corkscrew® where the USP 2-0 FiberWire® eyelet recessed into the body of the anchor with a knot, loosened once in osteopenic and three times in healthy humeri resulting in the slippage of the two USP-2 FiberWire® sutures (Fig. 6C).

Discussion

The results of this biomechanical *in-vitro* study shows that the ultrasound assisted anchoring technique for rotator cuff repair using the SportWelding Sombrero® 3.6 mm suture anchor system in combination with USP 2 FiberWire® sutures provides a biomechanical stability in osteopenic and healthy humeri that is very comparable to the established Bio-Corkscrew® FT 5.5 mm benchmark system.

Our hypothesis stating that the biomechanical primary stability of the Sombrero® anchor is similar 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 has been proven.

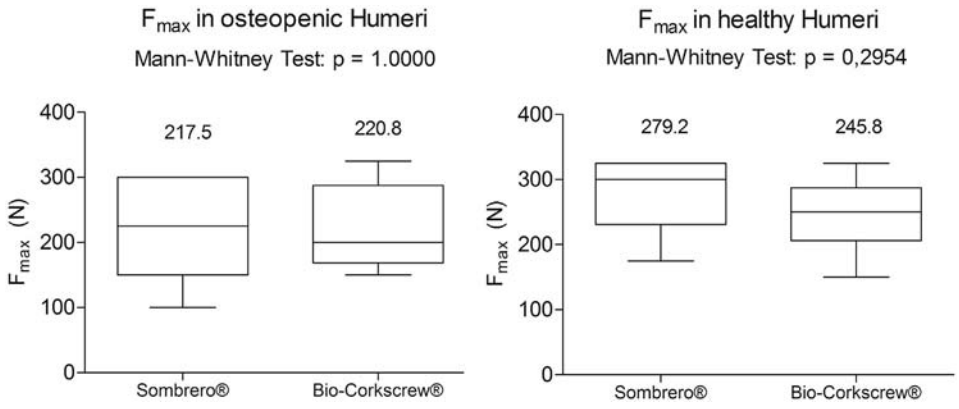

Fig. 4. No significant F_{max} differences evident between the Sombrero® and Bio-Corkscrew® in osteopenic and healthy humeri.

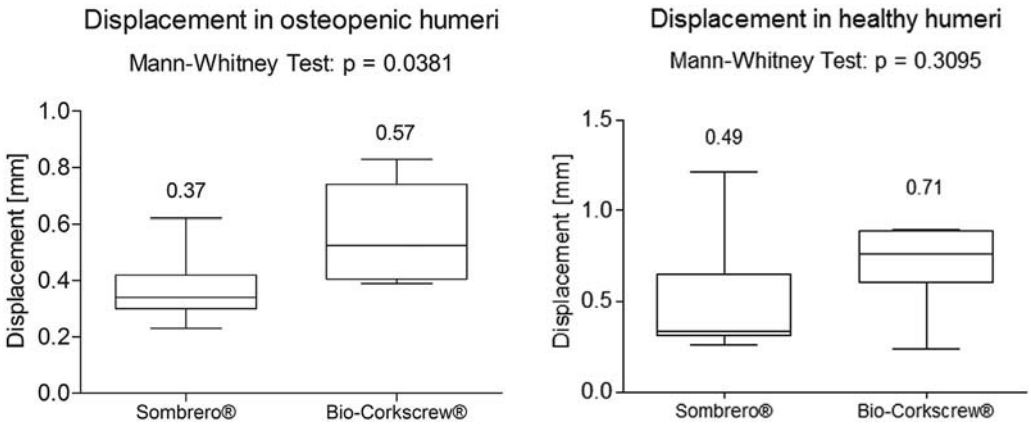

Fig. 5. No significant displacement differences evident between the Sombrero® and Bio-Corkscrew® in osteopenic and healthy humeri.

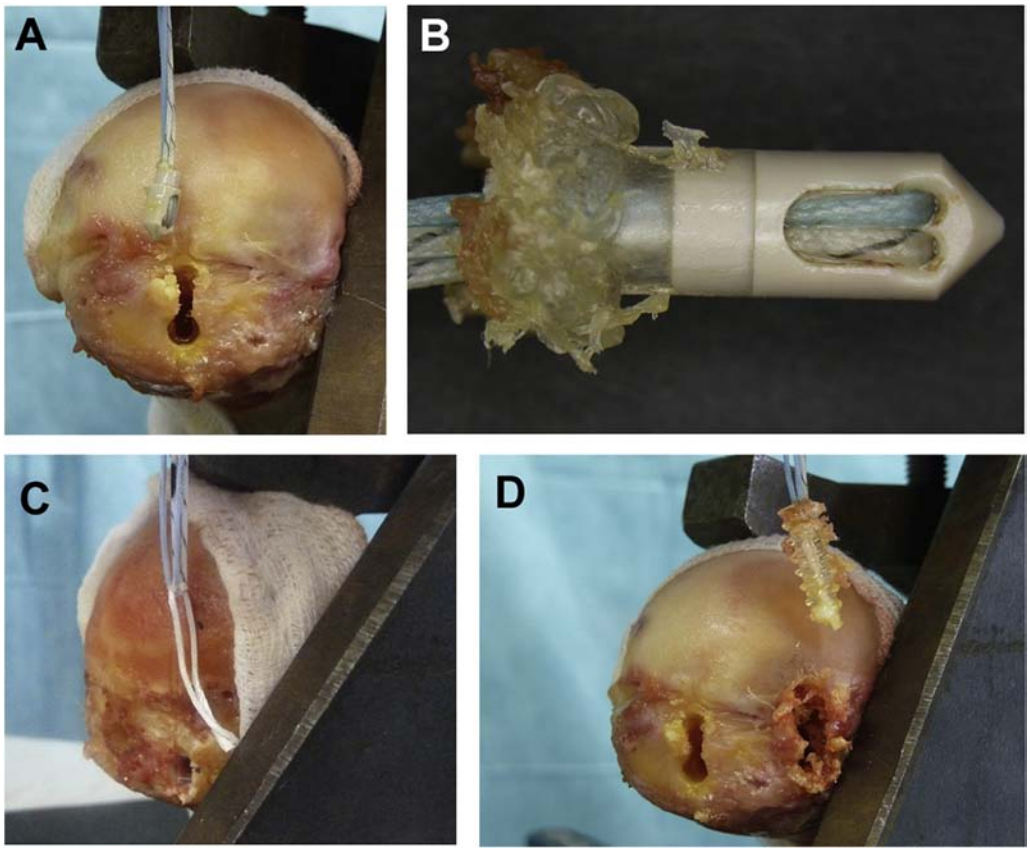

Fig. 6. A. Dislocation of solely the PEEK Sombrero anchor eyelet-body. **B.** Dislocation of the whole PLDLA-PEEK complex in the Sombrero system. **C.** Dislocation of the two USP 2 FiberWire® sutures due to the loosening of the USP 2-0 FiberWire® eyelet knot of the Bio-Corkscrew system. **D.** Dislocation of the whole Bio-Corkscrew® system.

The mean maximum failure loads of the Sombrero® system also seem to be independent of the bone mineral quality. The design of the Sombrero® system, especially its subcortical, force-fit anchoring mechanism – a positive form fit by polymeric integration-in the cancellous bone meshwork under the rigid cortical bone allows a sturdy fixation of the system, hence the high tensile loads and minimal displacements. The biomechanical stability of the Bio-Corkscrew® can be explained by the firm grasping of the cancellous and the rigid cortical bone with its screw-type mechanism. The mean F_{max}-values of the two systems in both the healthy and osteopenic bone groups, was higher than suture anchor systems tested in previous studies.[1,2,19]

The system displacement is a variable that can remarkably affect the clinical outcome of rotator cuff repair. The mean values generated in this study for both anchor systems in both bone quality groups are lower than 1 mm and lie clearly under the 5 mm clinical failure threshold.[14,17] It can therefore be assumed, that the anchor, the suture and the suture-retaining mechanism finds a strong halt in the bone – independent of its quality, thus reducing the probability of a gap formation at the tendon-to-bone interface.

Anchor dislocation was the only form of failure observed for the Sombrero® system. The suture-retaining mechanism of the Sombrero® system deflects the two USP 2 FiberWire® sutures in the

PEEK eyelet-body; neither the PLDLA anchoring element nor the surrounding cancellous bone affects this mechanism (Fig. 6A and B). The PLDLA anchoring element infiltrates the cancellous bone meshwork in its liquid phase in an amorphous manner. High F_{max} loads are necessary to dislocate the PEEK eyelet body or the PEEK-PLDLA complex out of the bone. The slippage of the PEEK eyelet body through the molten PLDLA anchoring element implies that two polymers do not always fuse together during deployment and that the PLDLA anchoring element could potentially withstand higher F_{max} loads. Another advantage of the sole PEEK eyelet body slippage is the smaller bone lesion while being pulled out in comparison to the dislocation of the whole PEEK-PLDLA complex.

The insignificant higher frequency of Bio-Corkscrew® dislocations in osteopenic bone in comparison to healthy bone could suggest that this system – to a certain extent – is influenced by bone mineral quality of the greater tuberosity. The turnover in osteoporosis initially affects the trabecular bone and as it progresses with age, the cortical bone can be impaired as well.[20] This cortical bone impairment could explain the Bio-Corkscrew® dislocations at high F_{max} loads. The retaining mechanism of the two USP-2 FiberWire® sutures with a single-knotted USP 2-0 FiberWire® in the Bio-Corkscrew® anchor body loosens at high F_{max} loads resulting in a slippage of the two USP-2 FiberWire® sutures out of the anchor body and the bone (Fig. 7). This mechanism is also independent of the bone quality. The positive effect of suture dislocation rather than dislocation of the whole suture-anchor complex is the smaller lesion of the cortical bone area of the greater tuberosity while being pulled out (Fig. 6C and D).

Forces necessary to rupture the FiberWire® sutures could not be reached in this experimental setup even though Barber et al observed rupturing of the USP 2 and USP 2-0 FiberWire® sutures at a mean of 118 N and 82 N, respectively.[21] Bisson et al on the other hand, determined a mean pullout strength of 349 N for USP 2 FiberWire® sutures.[22] Nevertheless, the modes of failure as in suture ruptures, anchor dislocations or suture slippages play a subordinate role when considering the higher probability of failure at the weakest link of rotator cuff repair – at the suture-to-tendon interface with tendon cut-outs.[22–24]

The incidence of retears after rotator cuff repair lies between 11% and 94% when reviewing the current literature as summarized by Scheibel.[25] It is therefore crucial to provide maximum primary stability and good functional outcome during the primary repair of rotator cuff tears. The patients' age, the fatty infiltration of the muscle, bone and tendon quality are factors for example which cannot be influenced by the surgeon, but the utilised techniques of repair, the materials such as the anchors and sutures are. An advantage of the SportWelding Sombrero® anchor system is its positive form fit by polymeric integration into the existing trabecular meshwork of the cancellous bone and its property to preserves the bone structures (Fig. 8). This may be of advantage in a case of revision rotator cuff surgery. The size of the Sombrero® anchor system, better off its diameter of only 3.6 mm, can also be regarded as advantageous since it creates a smaller defect of the cortical footprint than other anchors with a larger diameter. This is of greater importance in cases of rotator cuff revision surgery where one or more suture anchors of perhaps larger diameter are to be implanted and a greater area of intact cortical bone of the greater tuberosity is required.

PEEK and polylactic acid (PLA) including its enantiomeres (PLLA, PDLA, PLDLA, etc.) differ in their physical and biological properties. For example, the tensile strength of PEEK measures up to 100 N/mm^2 whereas PDLA measures 50–60 N/mm^2 and PLLA 70 N/mm^2 depending on its production method, form and molecular weight.[26,27] Since PEEK is an inert material, no clinically relevant foreign body reactions, osteolysis, cytotoxicity or genotoxicity was observed in the current literature.[28–30] In contrast to PEEK, polylactic acid enantiomeres bear a very low risk of osteolysis, foreign body reactions and arthritis regardless of its organic origin.[31–33] The biological degradation of polylactic acid depends on its molecular size, its *in-vivo* setting and may take up to several years.[32,34,35] Nevertheless, these synthetically produced materials find a broad acceptance in modern surgery in the last years.

This study analyzes solely the biomechanics of rotator cuff repair at time zero. The suture anchors were implanted on human humeri cadaver specimens after being removed of the skin and soft tissues and does not simulate arthroscopic anchor implantation as in a operation room setup.

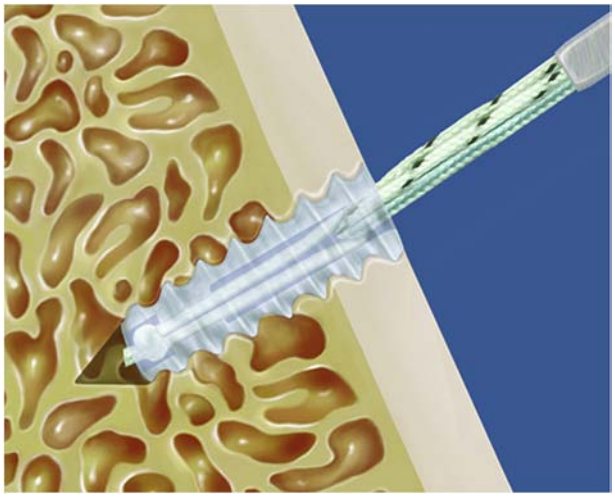

Fig. 7. Longitudinal section of the Bio-Corkscrew® anchor body with the suture retaining mechanism; a USP 2-0 FiberWire® deflects two USP-2 FiberWire® sutures in the anchor body. [*Used with permission from Arthrex Inc. represented by Arthrex Medizinische Instrumente GmbH – Germany*].

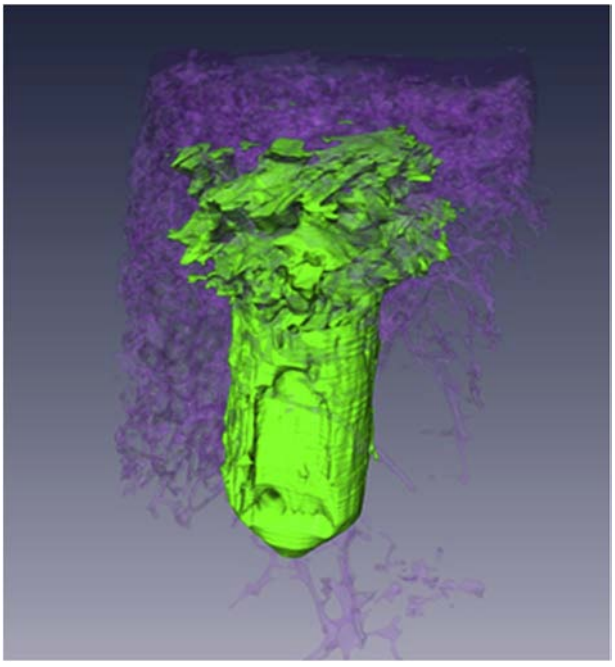

Fig. 8. Micro computer tomography scan of the Sombrero® suture anchor shows the integration of the liquefied and hardened thermoplastic anchor body (green) in the trabecular mesh of the subcortical bone socket (violet).

It is not possible to evaluate the biological healing and anchor integration in the human cadaver bone. It would be interesting to see how biological processes *in-vivo* affect the biomechanical stability of the Bio-Corkscrew® over time and if this results in a significant difference.

Conclusions

This study shows that a relatively small-sized anchor such as the SportWelding Sombrero® with its 3.6 mm diameter and novel deployment technology can yield a comparable biomechanical stability as the established Bio-Corkscrew® FT 5.5 mm anchor system. The stability of both the Sombrero® and Bio-Corkscrew® appear to be independent of the bone mineral density. The Sombrero® preserves cortical footprint bone stock since a smaller bone socket is necessary.

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