Mechanical Performance of the SonicAnchor

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Abstract

Introduction: Biodegradable suture anchors for soft tissue fixation in the human body may be preferred over metallic implants as they do not cause significant artifacts in NMR and CT examinations and could be substituted by newly formed bone matrix. However, conventional biodegradable implants may entail the risk of implant failure either due to insufficient material strength/anchorage or too fast degradation compared to healing of the soft tissue. The SonicAnchor was developed to offer enhanced fixation of soft tissue at the time of surgery combined with slow resorption characteristics. This should allow for sufficient fixation strength over the healing period. The aim of this paper was to assess (a) the fixation strength at the time of surgery (pull-out strength) of single SonicAnchors, double inserted SonicAnchors side-by-side (worst case scenario when two anchors are implanted) and (b) the long term post-operative mechanical strength (median fatigue limit) of single SonicAnchors by taking worst case conditions e.g. degradation and cyclic loading into account.

Material: Besides Stryker SonicAnchor (REF: 1910-1253S) five established suture anchors with similar indication have been tested as reference devices: Arthrex 2.5 mm PushLock (REF: AR-8825B), Arthrex Suture Anchor Biocomposite SutureTak 3 x 14.5 mm (REF: AR-1934BCF), Arthrex Suture Anchor Bio-PushLock 4.5 x 24 mm (REF: AR-1922B), Depuy Mitek Inc. GII Quickanchor Plus (REF: 222983) and Biomet JuggerKnot Soft Anchors (double loaded) 2.9 mm (REF: 110005241) tested in artificial standardized bone matrix (CR 20 pcf, Pacific Research Laboratories, Inc) without cortical layer.

Method: Single pull-out testing was performed with the SonicAnchor and the above mentioned devices. Furthermore, the fatigue strength was determined for the SonicAnchor at worst case conditions and the Arthrex 2.5 mm PushLock without consideration of potential adverse effects from additional sterilization, aging or degradation. For statistical evaluation, a Mann-Whitney U and Monte Carlo Exact test for independent groups, a one-sample t-test and the F-test for testing of equivalence of variances in combination with the t-test for unpaired groups were used. Thereby, the significance level was defined as 95 % ($\alpha = 0.05$) and the power was defined as 80 % (1-ß = 0.80).

Results: The pull-out strength was statistically significantly higher ($p < 0.05$) for the SonicAnchor (Mean±Standard Deviation (SD): 222±17 N) than for the Arthrex 2.5 mm PushLock (Mean±SD: 46±4 N) and other reference devices. Furthermore, the normalized pull-out strength (in relation to implant diameter) was statistically significantly higher for the SonicAnchor compared to all other tested devices. There was a statistically significant increase of the pull-out strength (approximately +69 %) if two SonicAnchors were inserted side-by-side and simultaneously loaded. The median fatigue limit (MFL) was statistically significantly higher for the SonicAnchor (MFL±SD: 53±3 N) than for the Arthrex 2.5 mm PushLock (MFL±SD: 28±3 N).

Discussion: By the use of in vitro test setups, the pull-out strength and the fatigue strength were successfully determined. Limitations of this study (using sutures of size #2 for Arthrex 2.5 mm PushLock, using closed porous structured artificial bone matrix in combination with degradation, statistical power not always ≥ 80 %) were evaluated and considered as acceptable for the comparison of the mechanical performance of the implants.

Conclusion: Both superior pull-out strength and fatigue strength of the SonicAnchor were successfully shown by the use of in vitro test setups designed to simulate clinical conditions. The pull-out strength of single loaded SonicAnchors was negligibly affected by double insertion even when the SonicAnchors were implanted side-by-side. The total pull-out strength could be increased by load sharing using two anchors side-by-side.

1 Introduction

Soft tissue fixation to bone in the human body with suture anchors is a common operative technique to provide adequate stability needed for successful healing. Biodegradable suture anchors made of polylactic acids may be preferred over metallic implants as they do not cause significant artifacts in NMR and CT examinations and could be substituted by newly formed bone matrix [1]. However, these biodegradable polymers potentially have the risk of implant failure due to insufficient material strength/anchorage or degradation that occurs to quickly after implantation [1].

The SonicAnchor was developed to offer enhanced fixation of soft tissue at the time of surgery combined with slow resorption characteristics. This should allow for sufficient fixation strength over the healing period. Fixation is achieved by using the SonicFusion technology for implantation. The implant is locally liquefied by ultrasound and penetrates into the bony intertrabecular spaces, thereby fixing the trapped suture to the bone (Figure 1).

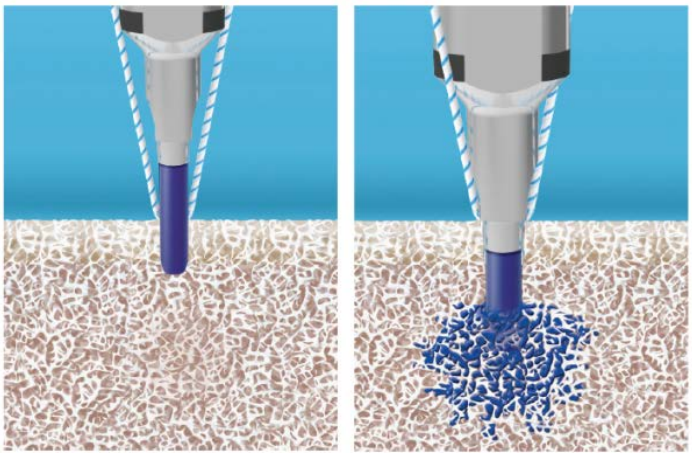

Figure 1: Fixation of the sutures by the SonicAnchor implant to the bone matrix by interdigitation of the liquefied polymer into the intertrabecular spaces.

The aim of this paper was to assess (a) the fixation strength at the time of surgery and (b) the post-operative mechanical strength by taking worst case conditions e.g. degradation and cyclic loading into account. Therefore, the quasi-static pull-out strength and the dynamic fatigue strength was determined and compared for the SonicAnchor and the Arthrex 2.5 mm PushLock, which is a well-established suture anchor in the market. Additional testing on the quasi-static pull-out strength was performed with other reference devices (differing in material and size) and with double inserted SonicAnchors implanted side-by-side to broaden the evaluation of the mechanical performance of the SonicAnchor.

2 Material

The Stryker SonicAnchor (REF: 1910-1253S) is a biodegradable implant made of poly (L-lactide-co-D,L-lactide) copolymer with an outer diameter of 2.5 mm (Figure 2). The Arthrex 2.5 mm PushLock (REF: AR-8825B) has an outer diameter of 2.5 mm and is made of biodegradable PLLA with a non-degradable PEEK eyelet (Figure 2). Both implants were equipped with Stryker Force Fiber sutures of size #2 (REF: DR19101253) prior to implantation into artificial standardized bone matrix (CR 20 pcf, Pacific Research Laboratories, Inc) without cortical layer. Additional reference devices (Figure 2) also implanted into the same standardized bone matrix were:

- Arthrex Suture Anchor, Biocomposite SutureTak, 3 x 14.5 mm (REF: AR-1934BCF) made of PLDLA/βTCP
- Arthrex Suture Anchor, Bio-PushLock 4.5 x 24 mm made of PLLA and PEEK (REF: AR-1922B) in combination with #2 FiberWire (REF: AR-7233) as recommended by Arthrex

- Depuy Mitek, Inc. GII Quickanchor Plus made of Titanium and Nitinol (REF: 222983)
- Biomet JuggerKnot Soft Anchors (double loaded) 2.9 mm made of ABS/PE/PP/PET (REF: 110005241)

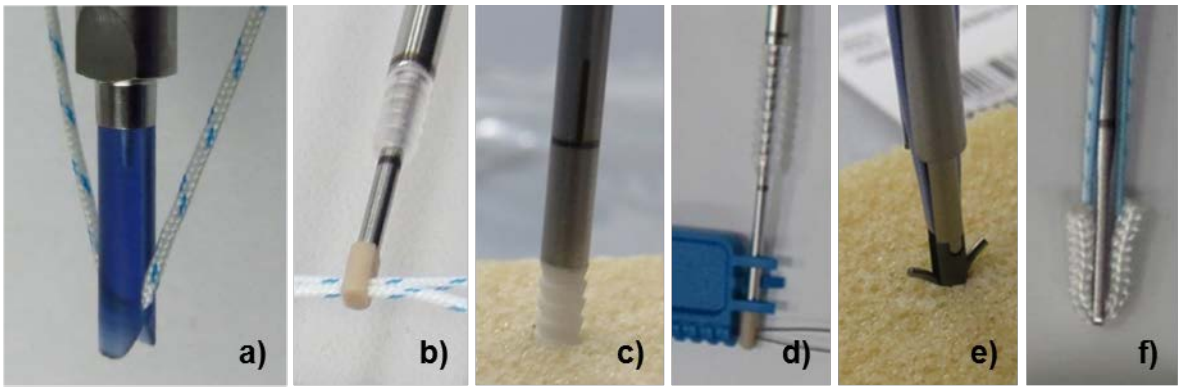

Figure 2: a) Stryker SonicAnchor, b) Arthrex 2.5 mm PushLock, c) Arthrex SutureTak 3 mm, d) Arthrex 4.5 mm PushLock, e) DePuy Mitek GII 2.4 mm, f) Biomet JuggerKnot 2.9 mm.

3 Method

The primary fixation stability (pull-out strength) and the long-term stability (median fatigue limit) were determined for the implants by using in vitro pull-out test setups equipped with a temperature controlled water bath filled with deionized water kept at 37±1 °C to simulate in vivo temperature conditions (Figure 3).

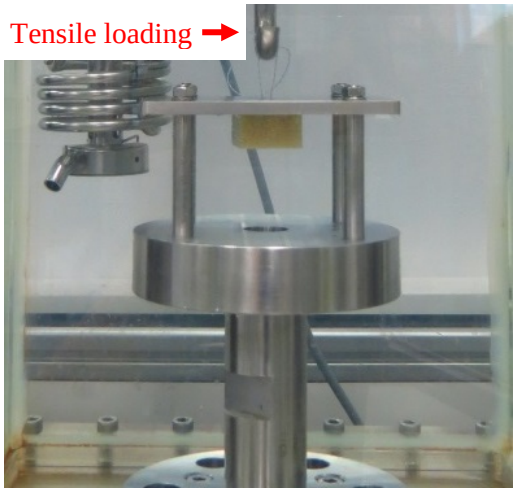

Figure 3: SonicAnchor pull-out test setup within a water bath at 37±1 °C.

All devices were implanted according to their corresponding operative procedures into artificial standardized bone matrix (CR 20 pcf, Pacific Research Laboratories, Inc), except for the suture size of the Arthrex 2.5 mm PushLock (see discussion section for detailed information). To allow direct comparison of the mechanical test results and to avoid rupture of the sutures before implant failure, all implants were tested with sutures of size #2. For testing, suture loops with standardized lengths were created, threaded through the hole of the test setup baseplates and hung over a steel hook connected with the material testing machine by which tensile loading was applied.

3.1 Pull-out strength

After treatment, the patient must be advised to immobilize the surgical site to prevent disturbance of the healing process and avoid implant failure [2]. However, peak loading scenarios due to undesired muscle contractions or movements may not be fully avoided. Therefore, high pull-out strength immediately after surgery may be needed.

To test the primary stability of the suture anchors, a single pull-out test was performed according to Meyer et al., 2003 within a water bath at a temperature of 37±1 °C at a displacement rate of 60 mm/min [1]. Thereby, the pull-out strength was determined as the maximum pull-out force during testing for the implants with a sample size of n=6 for each group. In addition, the pull-out normalized to implant diameter was calculated by division of the measured pull-out strength of each sample by the implant diameter.

The load bearing capacity of the soft tissue anchorage could be increased by usage of two anchors which leads to a load sharing mechanism. Insertion of the SonicAnchors close to each other could be detrimental to the pull-out strength, since the amount of bone matrix for each anchor is then reduced. Thereby, insertion of the SonicAnchors side-by-side represents the worst case scenario. For evaluation of the influence of double insertion of two SonicAnchors side-by-side, drill holes were created using a custom-made drill guide to enable implantation of two SonicAnchors with contact to each other (Figure 4). The SonicAnchors were implanted until fusion stop following the same procedure and parameters used for the single tested SonicAnchors. However, since two SonicAnchors were implanted side-by-side into one bone matrix block, the following groups were created to differentiate the implantation sequence (Table 3.1).

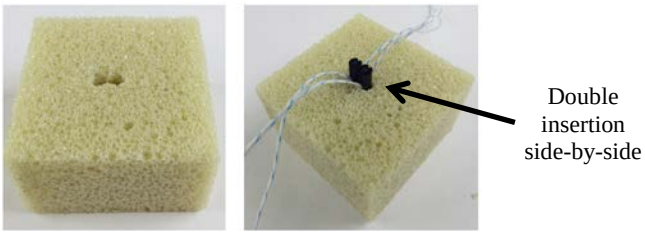

Figure 4: Double insertion of SonicAnchors side-by-side: prepared bone matrix (left) and bone matrix with anchors in drill holes prior to fusion (right).

Table 3.1: Implantation procedure of double implanted SonicAnchors side-by-side.

Group	Procedure
I	Standard single anchor implantation
IIa	2x drill + 2x fusion, pull-out 1st anchor: two drill holes were created, then both anchors were implanted, then pull-out testing with 1st anchor solely
IIb	2x (drill + fusion), pull-out 1st anchor: creation of drill hole for and implantation of 1st anchor, then drilling for and implantation of 2nd anchor, then pull-out testing with 1st anchor solely
IIIa	2x drill + 2x fusion, pull-out 2nd anchor: same procedure as IIa but pull-out testing with 2nd anchor solely
IIIb	2x (drill + fusion), pull-out 2st anchor: same procedure as IIb but pull-out testing with 2nd anchor solely
IV	2x drill + 2x fusion, pull-out both anchors: same procedure as IIa and IIIa but pull-out testing with both anchors simultaneously

For evaluation of the influence of implantation of two SonicAnchors side-by-side, the relative pull-out strength of the double inserted SonicAnchor groups (IIa, IIb, IIIa, IIIb, IV) was calculated by division of the pull-out strength of each double inserted sample by the median of group I (Table 3.1).

3.2 Fatigue strength

Within the healing phase, the patient is advised to actively move the treated extremity with assistance and to integrate it carefully into normal daily activities [2]. Hence, the loading scenario will change from single loadings after the operation to periodic cyclic loading during the healing process, which represents a worst case scenario compared to the single pull-out test described in 3.1. Based on recommendations for patients after treatment of tendon ruptures at the rotator-cuff [2], the healing period was assumed to be 12 weeks with 150,000 loading scenarios in total.

Therefore, cyclic sinusoidal mechanical loading was applied at a frequency of 3 Hz using the in vitro test setup shown in Figure 3 and the median fatigue limit (MFL) was determined [8]. Thereby, the upper and lower load limits were scaled up or down to achieve 50 % survival of the implants over the above mentioned 150,000 cycles [4]. The MFL represents the load level at which 50 % of the implants will survive (run-out) and 50 % will fail. Failure was defined at a drift of the maximum displacement of > 3 mm under maximal loading, because gap formations, i.e. the distance between the soft tissue and the bone surface beyond this value, were found to be critical for the healing process [10]. For both implants, testing was performed until a nominal sample size (samples after first change from failure to run-out) of n=6 for each implant was reached.

The SonicAnchor was evaluated within this long-term stability test under worst case conditions. The material properties of the SonicAnchor are negatively influenced by gamma irradiation and aging. Hence, the standardly packaged and gamma sterilized implants were additionally gamma irradiated with minimum 25 kGy and stored at 45±1 °C for minimum 74 days in a climate chamber corresponding to minimum 1 year storage at 22 °C [6]. In addition, loss of stability due to degradation of the SonicAnchor during the healing time was considered by storage of the SonicAnchors after implantation in phosphate buffered solution (PBS) at pH 7.4±0.2 prior to mechanical testing. Degradation was performed in an accelerated manner at 45 °C for 13 days corresponding to 37 °C for 12 weeks based on Lyu et al, 1997 [3].

3.3 Statistical analysis

The SonicAnchor was tested on superiority against the Arthrex 2.5 mm PushLock and the other reference devices with regard to pull-out strength using a Mann-Whitney U and Monte Carlo Exact test for independent groups according to [6]. The side-by-side inserted SonicAnchors were tested on superiority against the single inserted SonicAnchor with regard to pull-out strength using a one-sample t-test according to [6].

The median fatigue limit of the SonicAnchor was tested on superiority against the Arthrex 2.5 mm PushLock using the F-test for testing of equivalence of variances in combination with the t-test for unpaired groups [6]. The tests were analyzed with the statistics software “IBM SPSS Statistics Ver. 20” and categorized as “stress test” because the implants were tested to failure. Therefore, the significance level was defined as 95 % ($\alpha = 0.05$) and the power was defined as 80 % ($1-ß = 0.80$) according to [7].

4 Results

4.1 Pull-out strength

The single pull-out strength was statistically significantly higher for the SonicAnchor (Mean±SD: 222±17 N) than for the Arthrex 2.5 mm PushLock (Mean±SD: 46±4 N) and the additional reference devices (Figure 5) [8]. Superiority was more pronounced for the normalized pull-out strength (in relation to implant diameter) and was also statistically significantly higher for the SonicAnchor compared to all other tested devices (Figure 6) [8].

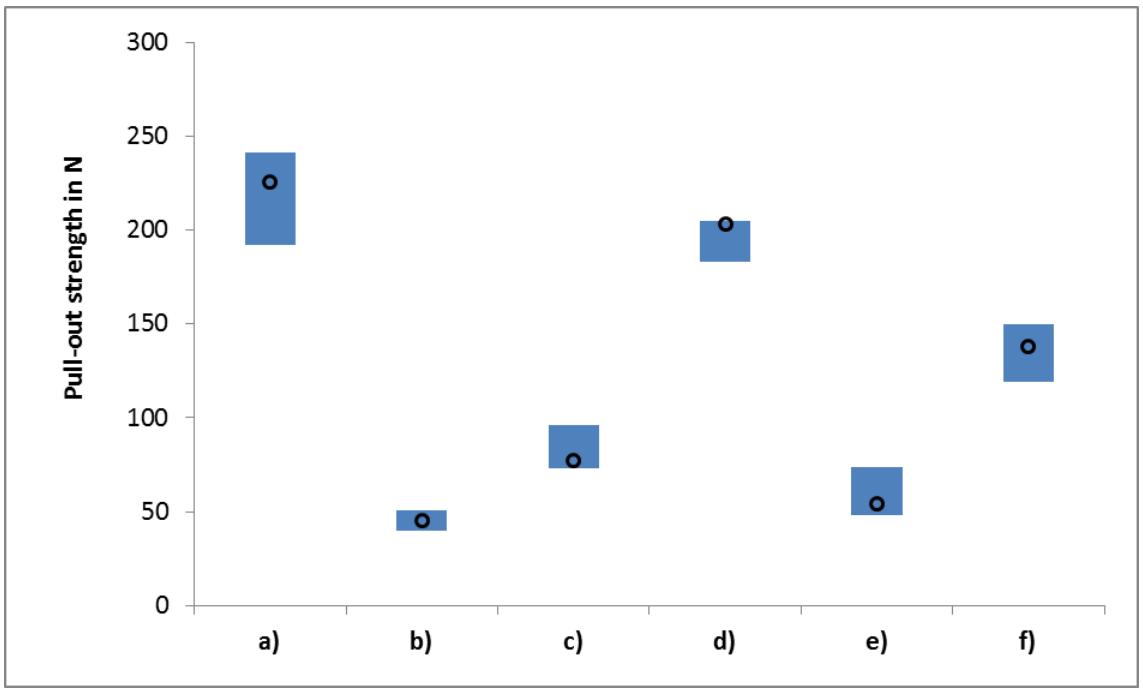

Figure 5: Pull-out strength of the SonicAnchor and the reference devices illustrated in high-low plots: a) Stryker SonicAnchor, b) Arthrex 2.5 mm PushLock, c) Arthrex SutureTak 3 mm, d) Arthrex 4.5 mm PushLock, e) DePuy Mitek GII 2.4 mm, f) Biomet JuggerKnot 2.9 mm. The box represents the range and the circle the median value. The SonicAnchor was statistically significantly higher than all other groups ($p \leq 0.05$).

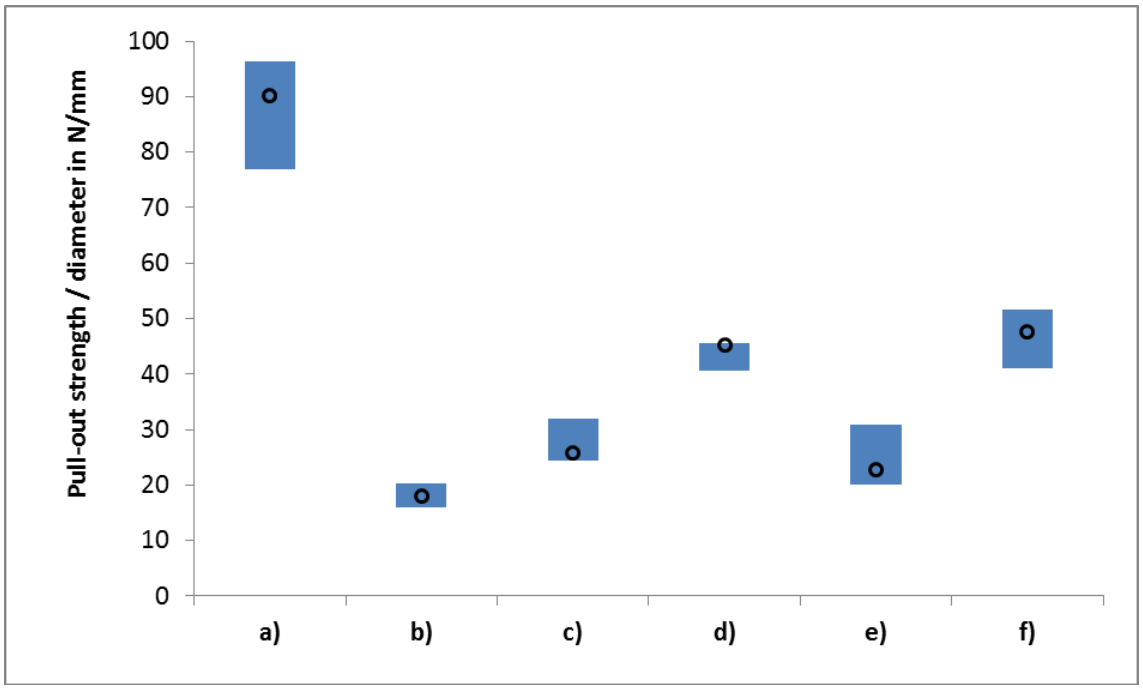

Figure 6: Normalized pull-out strength of the SonicAnchor and the reference devices (in relation to implant diameter) illustrated in high-low plots: a) Stryker SonicAnchor, b) Arthrex 2.5 mm PushLock, c) Arthrex SutureTak 3 mm, d) Arthrex 4.5 mm PushLock, e) DePuy Mitek GII 2.4 mm, f) Biomet JuggerKnot 2.9 mm. The box represents the range and the circle the median value. The SonicAnchor was statistically significantly higher than all other groups ($p \leq 0.05$).

There was no statistically significant difference in relative pull-out strength between the double inserted single loaded and the single inserted SonicAnchor (power was less than 80 %). However, the relative pull-out strength of the double inserted double loaded SonicAnchors was statistically significantly higher (approximately 69 %) compared to the single inserted SonicAnchors (Figure 7). The failure mode of the single loaded SonicAnchors

(group I to IIIb) was mostly eyelet failure, whereas the double inserted double loaded SonicAnchors failed through pull-out of the anchors from the bone matrix (Figure 5.4).

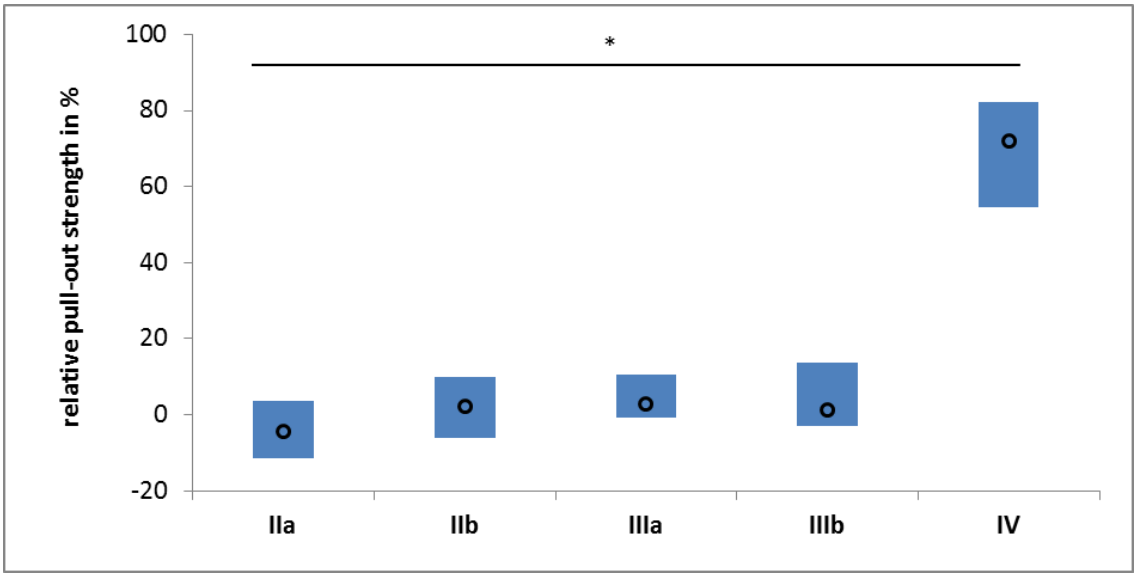

Figure 7: Relative pull-out strength of the SonicAnchors illustrated in high-low plot. The box represents the range and the circle the median value. The "*" indicates statistically significant differences ($p \leq 0.05$).

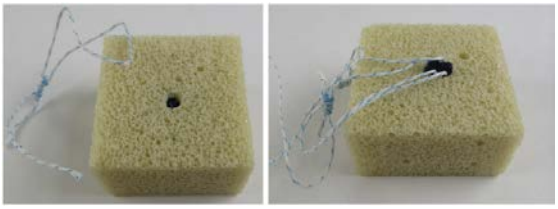

Figure 8: Representative sample of group I (single anchor) after pull-out testing (left) and representative sample of group IV (double inserted, double loaded anchors) after pull-out testing (right).

4.2 Fatigue strength

The median fatigue limit was statistically significantly higher for the SonicAnchor (MFL±SD: 53±3 N) than for the Arthrex 2.5 mm PushLock (MFL±SD: 28±3 N) (Figure 9) [9].

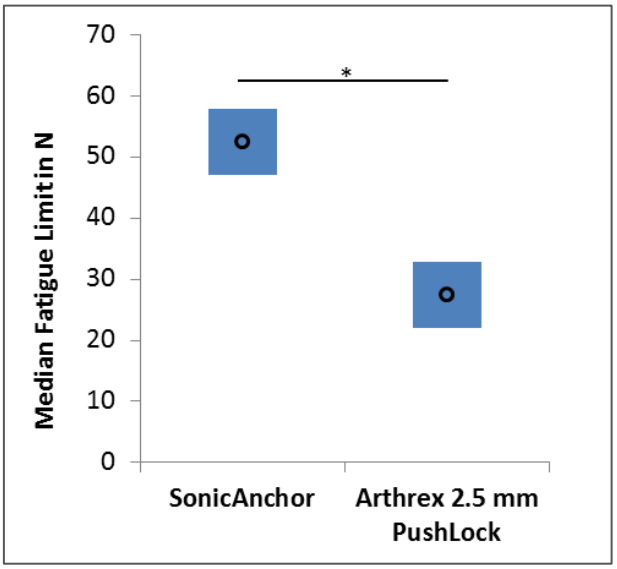

Figure 9: Median fatigue limit (MFL) of both implants. The box represents the 95 % confidence interval, the circle the median fatigue limit. The "*" indicates statistically significant differences ($p \leq 0.05$).

5 Discussion

By the use of in vitro test setups, the single pull-out strength was successfully determined for the SonicAnchor (single and double insertion), the Arthrex 2.5 mm PushLock and additional reference devices differing in material and size. Furthermore, the median fatigue limit was successfully determined for the SonicAnchor and the Arthrex 2.5 mm PushLock. Superior pull-out strength and fatigue strength were shown for the SonicAnchor.

The Arthrex 2.5 mm PushLock is intended to be used with sutures of sizes #2-0 and #0. However, we used sutures of size #2 for both the SonicAnchor and the Arthrex 2.5 mm PushLock to allow direct comparison of the mechanical test results and to avoid rupture of the sutures before implant failure. The pull-out strength of the Arthrex 2.5 mm PushLock relies on the press fit of the biodegradable polymer into the surrounding bone matrix with the sutures trapped in between. Hence, the usage of the Arthrex 2.5 mm PushLock with thinner sutures may potentially lead to worse mechanical performance. Therefore, the limitation of using sutures of size #2 for both implants was considered to be acceptable.

The artificial bone matrix (sawbones CR 20 pcf) used in this study exhibited a closed porous structure which potentially limited the exchange of the degradation products of the polymer during degradation in PBS. These acetous products lead to a decrease of the pH value resulting in an autocatalytic degradation effect in particular when a smaller surface/volume ratio is present [11]. Hence, the potentially accelerated degradation resulted in a worst case scenario for the SonicAnchor. Therefore, the limitation of using a closed porous structured bone matrix was considered to be acceptable.

No statistically significant difference was detected between the double inserted single loaded SonicAnchors and the single inserted single loaded SonicAnchors (Figure 7). However, the power was less than 80 % for these comparisons, i.e. a type II error cannot be excluded. Otherwise, the maximum reduction of the pull-out strength due to double insertion was only 5 %, i.e. negligible with regard to the much better normalized pull-out strength of the SonicAnchor compared to the tested reference devices (at least +86 %).

The pull-out strength of the double inserted double loaded SonicAnchors were statistically significantly higher than the single inserted single loaded SonicAnchors. However, the pull-out strength was only 69 % higher, i.e. it was not doubled. This may have been due to a change of the failure mode (mostly eyelet failure of the single loaded anchors and pull-out of the double inserted double loaded anchors) indicating a shift of the weakest point of the system from the implant to the bone matrix / bone-implant interface.

Pure tensile loading, perpendicular to the bone surface in line with the anchor axis, was applied according to Meyer et al., 2003 [1]. Furthermore, artificial bone matrix without cortical layer was used which may have an influence on the results. Therefore, the results of this study might not be representative for all clinical scenarios/indications, especially if a cortical layer with load bearing capability is present.

6 Conclusion

Both superior pull-out strength and fatigue strength of the SonicAnchor were successfully shown by the use of in vitro test setups designed to simulate clinical conditions. The pull-out strength of single loaded SonicAnchors was negligibly affected by double insertion even when the SonicAnchors were implanted side-by-side. The total pull-out strength could be increased by load sharing using two anchors side-by-side.

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