

Mechanical Strength and Stiffness of the Biodegradable SonicWeld Rx Osteofixation System

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Purpose: To determine the mechanical strength and stiffness of the new 2.1 mm biodegradable ultrasound-activated SonicWeld Rx (Gebrüder Martin GmbH & Co, Tuttlingen, Germany) osteofixation system in comparison with the conventional 2.1 mm biodegradable Resorb X (Gebrüder Martin GmbH & Co) osteofixation system.

Materials and Methods: Plates and screws were fixed to 2 polymethylmethacrylate blocks to simulate bone segments and were subjected to tensile, side bending, and torsion tests. During testing, force and displacement were recorded and graphically presented in force-displacement diagrams. For the tensile tests, the strength of the osteofixation system was measured. The stiffness was calculated for the tensile, side bending, and torsion tests.

Results: The tensile strength and stiffness as well as the side bending stiffness of the SonicWeld Rx system presented up to 11.5 times higher mean values than the conventional Resorb X system. The torsion stiffness of both systems presents similar mean values and standard deviations.

Conclusions: The SonicWeld Rx system is an improvement in the search for a mechanically strong and stiff as well as a biodegradable osteofixation system. Future research should be done to find out whether the promising in vitro results can be transferred to the in situ clinical situation.

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J Oral Maxillofac Surg 67:782-787, 2009

Biodegradable plates and screws are used increasingly in oral and maxillofacial practice. These biodegradable plates and screws have several advantages over conventional titanium plates and screws including: 1) no need for a second intervention to remove the devices¹⁻³; 2) no interference with imaging or radiotherapeutic techniques⁴⁻⁶; 3) no possible growth disturbance or mutagenic effects^{4,5,7-9}; 4) no potential brain damage^{8,10}; and 5) no thermal sensitivity.¹¹ However, the use of biodegradable plates and screws also has introduced several disadvantages. First, that the boreholes need to be tapped before the screws

can be inserted is time-consuming. A second disadvantage could be that the biodegradable plates and screws represent inferior mechanical strength and stiffness compared with conventional titanium plates and screws.¹² To resolve these disadvantages, a new biodegradable osteofixation system, SonicWeld Rx (Gebrüder Martin GmbH & Co, Tuttlingen, Germany), has been developed. In contrast to conventional biodegradable osteofixation systems, tapping of the cortical bone layer is not necessary before inserting the SonicWeld Rx biodegradable pins. A biodegradable pin is placed onto an ultrasound-activated sonic elec-

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0278-2391/09/6704-0011\$36.00/0

doi:10.1016/j.joms.2008.07.022

Table 1. CHARACTERISTICS OF INCLUDED BIODEGRADABLE OSTEOFIXATION SYSTEMS

Brand Name	Manufacturer	Composition	Sterility	Screw/Pin (mm)		Plate (mm)		
				Diameter†	Length†	Length†	Width†	Thickness†
Resorb X	Gebrüder Martin GmbH & Co*	100 D(50%), L(50%)-lactide	Sterile	2.1	7.0	26.0	6.0	1.1
SonicWeld Rx	Gebrüder Martin GmbH & Co*	100 D(50%), L(50%)-lactide	Sterile	2.1	7.0	26.0	6.0	1.1

*Tuttlingen, Germany.

†According to the specifications of the manufacturers.

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trode, called a sonotrode, and inserted into the borehole. As a result of the added ultrasound energy, the thermoplastic biodegradable pin will melt, resulting in a flow of biodegradable polymers into the cortical bone layer and the cavities of the cancellous bone. There is no cellular reaction due to thermal stress during insertion.¹³ The biodegradable plate and pin-head fuse at the same time. Theoretically, the fusion of plate and pinhead will result in superior mechanical device characteristics in comparison with conventional biodegradable osteofixation systems.

The mechanical strength and stiffness of 7 biodegradable as well as 2 titanium osteofixation systems have been investigated recently.¹² One of these investigated biodegradable systems is the Resorb X biodegradable osteofixation system (Gebrüder Martin GmbH & Co). The SonicWeld Rx and the Resorb X biodegradable osteofixation systems are made of the same copolymer compositions and have the same device dimensions. These systems are both supplied by Gebrüder Martin GmbH & Co. The question arises to what extent the biodegradable ultrasound-activated SonicWeld Rx osteofixation system presents superior mechanical strength and stiffness as compared with the conventional biodegradable Resorb X osteofixation system.

The objective of this study was to determine the mechanical strength and stiffness of the biodegradable ultrasound-activated SonicWeld Rx osteofixation system in comparison with the conventional biodegradable Resorb X osteofixation system.

Materials and Methods

The specimens to be investigated were 2 commercially available biodegradable osteofixation systems (ie, 2.1 mm Resorb X and 2.1 mm ultrasound-activated SonicWeld Rx). All the specimens consisted of biodegradable amorphous poly-(50%D, 50%L)-lactide. The plates under investigation were 4-hole extended plates. The manufacturer supplied sterile implants. The general characteristics of the included plates and screws are summarized in Table 1. Eighteen plates

and 72 screws/pins of each system were available to carry out 3 different mechanical tests. The osteofixation plates and screws were fixed in 2 different ways to 2 polymethylmethacrylate (PMMA) blocks (with polished surface) that simulated bone segments. For the Resorb X osteofixation system, the screws were inserted in both PMMA blocks according to the prescriptions of the manufacturer (using prescribed burs and taps). The applied torque for inserting the screws was measured to check whether it was comparable to the clinically applied torque (hand tight) defined in a previous study.¹⁴ For the SonicWeld Rx system, the biodegradable pins were inserted into the boreholes (after the use of prescribed burs) with the sonotrode. The biodegradable polymers melted due to the ultrasound vibrations of the sonotrode. Subsequently, the biodegradable material flowed into the borehole and the pinhead fused with the biodegradable plate. In both situations, the boreholes were irrigated with saline before insertion of the screws/pins to simulate the in situ lubrication.

The 2 PMMA blocks, linked by the osteofixation device (1 plate and 4 screws/pins) were stored in a water tank containing water (37.2°C) for 24 hours to simulate the relaxation of biodegradable screws/pins at body temperature.¹⁵ The tests were carried out in another tank containing water at the same temperature to simulate physiologic conditions. The use of saline was omitted because of the associated corrosion problems of the test set-up. Omitting the use of saline was not expected to influence the test results.

The plates and screws/pins were subjected to tensile, side bending, and torsion tests. The tensile test was carried out as a standard loading test (Fig 1). Side bending tests were carried out to simulate an in vivo bilateral sagittal split osteotomy (BSSO) situation (Fig 2). Torsion tests were carried out to subject the osteofixation devices to high torque to simulate the most unfavorable situation (Fig 3). The 2 PMMA blocks, linked by the osteofixation device, were mounted in a test machine (Zwick/Roell TC-FR2, 5TS.D09, 2.5 kN test machine, force accuracy 0.2%, positioning accuracy 0.0001 mm; Zwick/Roell Neder-

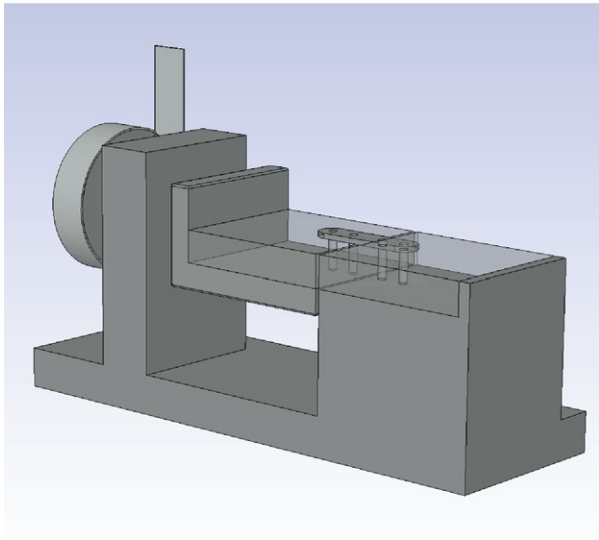


FIGURE 1. Tensile test set-up.

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land, Venlo, The Netherlands). Regarding the tensile tests, the 2 PMMA blocks, and thus the osteofixation plate, were subjected to a tensile force with a constant speed of 5 mm/min until fracture occurred (according to the standard ASTM D638M). For the side bending test, the 2 PMMA blocks were supported at their ends whereas the plates were loaded in the center of the construction with a constant speed of 30 mm/min (with this speed the outer fibers were loaded as fast as the fibers of the osteofixation system in the tensile test) until the plate achieved a 30° bend. For the torsion test, the 2 PMMA blocks were rotated along the long axis of the

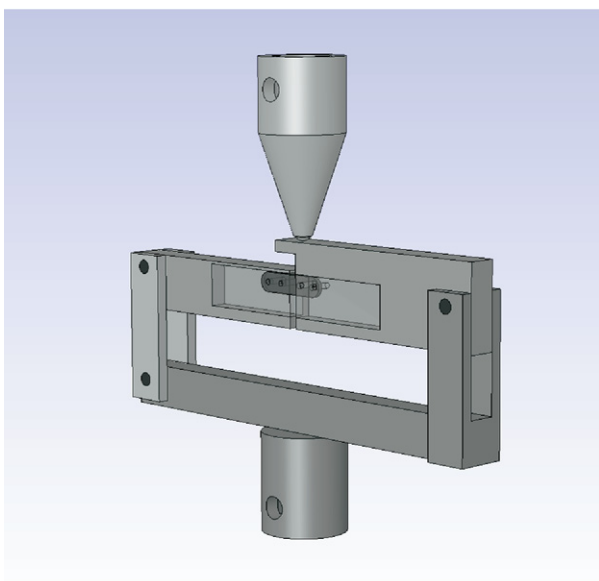


FIGURE 2. Side bending test set-up.

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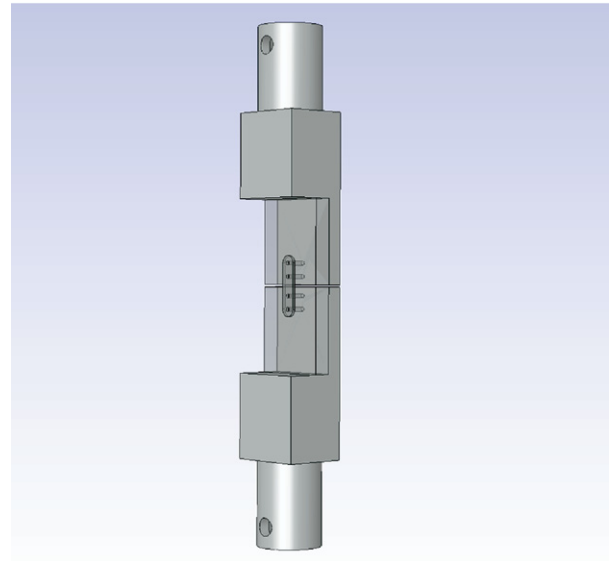


FIGURE 3. Torsion test set-up.

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osteofixation system with a constant speed of 90°/min (with this speed the outer fibers were loaded as fast as the fibers of the osteofixation system in the tensile test) until the plate was turned 160°.

During testing the applied force was monitored by the load cell of the test machine. Both force and displacement were recorded with a sample frequency of 500 hertz and graphically presented in force-displacement diagrams. During tensile tests, the strength of the osteofixation system was measured. The stiffness was calculated for the tensile, side bending, and torsion tests by determining the slope of the curve between 25% and 75% of F_{max} on the force-displacement curves.

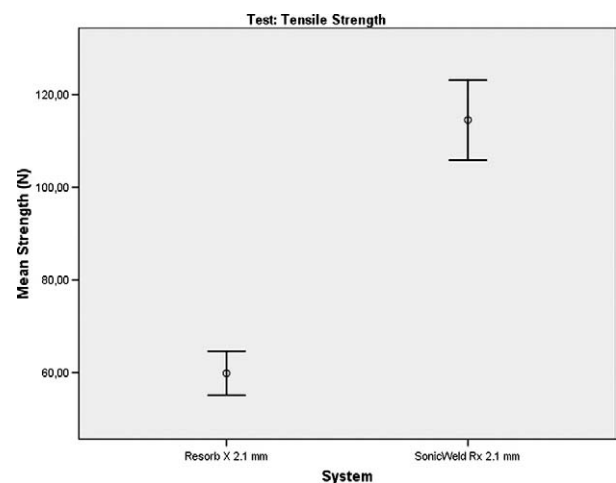


FIGURE 4. Mean tensile strength organized by system. Legend: bars, SD of the mean strength; points in figure, mean strength; x-axis, brand names of the investigated osteofixation systems; y-axis, mean strength in Newtons.

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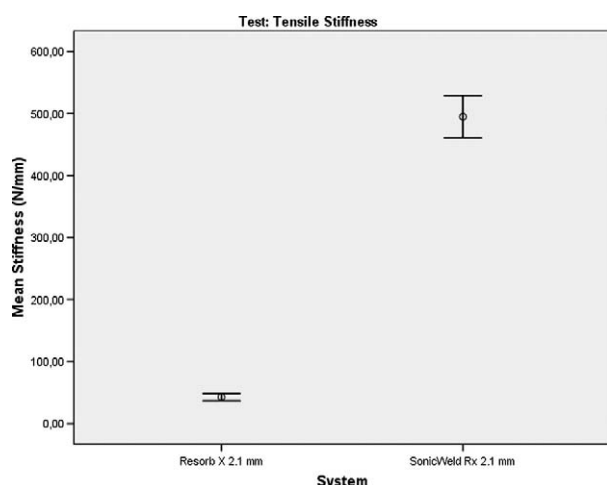


FIGURE 5. Mean tensile stiffness organized by system. Legend: bars, SD of the mean stiffness; points in figure, mean stiffness; x-axis, brand names of the investigated osteofixation systems; y-axis, mean stiffness in Newton/mm.

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STATISTICAL ANALYSIS

Statistical Package of Social Sciences (version 14.0; SPSS, Chicago, IL) was used to analyze the data. Means and standard deviations (SD) were calculated to describe the data. To determine whether there were significant differences between the 2 biodegradable osteofixation systems in tensile strength and stiffness, side bending stiffness, and torsion stiffness, the maximum values were subjected to independent samples *t* tests. Differences were considered to be statistically significant when *P* was less than .05 for all tests.

Results

The mean tensile strength and stiffness of the Resorb X as well as the SonicWeld Rx biodegradable osteofixation systems are graphically presented in Figures 4 and 5, respectively. Tensile strength and stiffness of the SonicWeld Rx system were significantly higher than those of the Resorb X system. The tensile strength of the SonicWeld Rx system was approximately

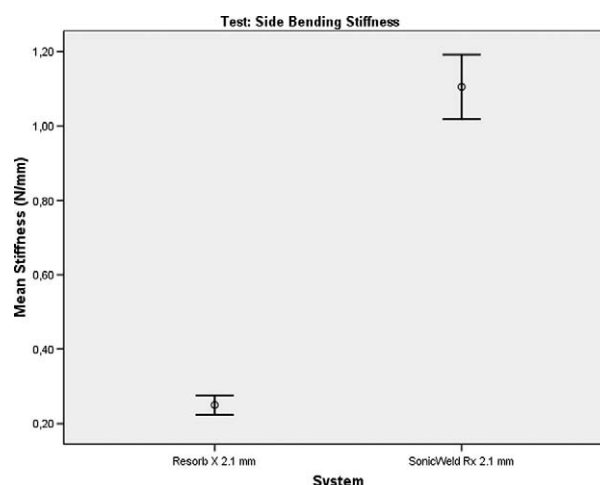


FIGURE 6. Mean side bending stiffness organized by system. Legend: bars, SD of the mean stiffness; points in figure, mean stiffness; x-axis, brand names of the investigated osteofixation systems; y-axis, mean stiffness in Newton/mm (deducted unit).

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2 times the tensile strength of the Resorb X system, whereas the tensile stiffness of the SonicWeld Rx system was about 11.5 times that of the Resorb X system. The significant differences between the 2 systems are outlined in Table 2. The SD for the systems regarding the tensile strength and stiffness were small.

The mean side bending stiffness of the 2 biodegradable osteofixation systems is plotted in Figure 6. The SonicWeld Rx system showed significantly higher side bending stiffness than with the Resorb X system. The SDs of the 2 systems were small (Table 3). The significant results were additionally illustrated by the 95% confidence interval of the difference, which did not include zero.

There was no significant difference between the mean torsion stiffness of the SonicWeld Rx and the Resorb X osteofixation system (Table 2), as is graphically displayed in Figure 7. Table 3 shows a summary of the descriptive statistics of the tensile strength and stiffness, side bending stiffness as well as torsion stiffness.

Regarding the side bending test, no fracture at all of either the plate or the screws/pins has been observed

Table 2. COMPARISON BETWEEN OSTEOFIXATION SYSTEMS

Systems	Test	Property	95% CI	
			Lower Bound	Upper Bound
Resorb X 2.1 mm vs SonicWeld Rx 2.1 mm*	Tensile	Strength	45.31	64.05
Resorb X 2.1 mm vs SonicWeld Rx 2.1 mm*	Tensile	Stiffness	420.54	483.20
Resorb X 2.1 mm vs SonicWeld Rx 2.1 mm*	Side bending	Stiffness	0.76	0.95
Resorb X 2.1 mm vs SonicWeld Rx 2.1 mm	Torsion	Stiffness	-0.06	0.05

Abbreviation: CI, confidence interval.

*Significant.

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Table 3. SUMMARY OF DESCRIPTIVE STATISTICS TESTS

Test Type	System	Mean (N/mm)	SD (N/mm)
Tensile strength	Resorb X 2.1 mm	59.87	4.73
	SonicWeld Rx	114.55	8.69
Tensile stiffness	Resorb X 2.1 mm	42.86	5.82
	SonicWeld Rx	496.74	33.95
Side bending stiffness	Resorb X 2.1 mm	0.25	0.03
	SonicWeld Rx	1.11	0.09
Torsion stiffness	Resorb X 2.1 mm	0.32	0.04
	SonicWeld Rx	0.32	0.4

Abbreviation: SD, standard deviation.

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for both systems. For the tensile as well as the torsion test, shear of the screw-heads was observed regarding the Resorb X system whereas fracture of the plates was observed regarding the SonicWeld Rx system.

Discussion

The differences in strength and stiffness between the SonicWeld Rx and the Resorb X biodegradable osteofixation systems can be explained partly by the difference in geometry of the screws and pins, but predominantly by the 2 different methods of application. Using a sonotrode to bring the plate and pin in a thermoplastic state fusing the plate and pin, results in a firm and stable fixation. The tensile strength and stiffness as well as the side bending stiffness of the SonicWeld Rx system presented significantly higher mean values compared with the conventional Resorb X system (Table 2). In contrast, the torsion stiffness of both systems presents remarkably similar means and standard deviations. The torsion test was used to simulate the torsion forces that exist in the area between the 2 canine teeth when a median fracture of the mandible is present. In various clinical cases, however, these torsion forces are neutralized by the interdigitation of the fracture segments.¹⁶ The torsion forces exerted on the fixation devices are transferred subsequently to tensile forces in these cases.

The biodegradable polymers used to manufacture the SonicWeld Rx plates and pins are melted through an ultrasound-activated sonotrode resulting in a fusion of the plate and screwhead/pinhead. As mentioned before, fusion results in a firm and stable device especially where shear strength and stiffness of the device are concerned. This is supported by the authors' experience that in all test samples of the SonicWeld Rx system for both the tensile and side bending test, fracture of the plate occurred away from the pin, and not near the pin or of the pin or pinhead itself. Regarding the conventionally screwed Resorb X

system, the authors experienced shear of the screw-heads in all test samples. These in vitro observations support the hypothesis that the principle of fusion of the plate and the pinheads results in better mechanical biodegradable device strength and stiffness. For orthopedic and maxillofacial metallic plates and screws, this principle is well-known as locking plates. These locking plates present increased in vitro strength and stiffness of the device characteristics¹⁷⁻¹⁹ as well as good clinical performance.¹⁷

As described in Materials and Methods, the Resorb X screws were applied with a specific torque defined in a previous study,¹⁴ resulting in a pressure of the plates to the PMMA blocks. For the SonicWeld RX pins this pressure was not specified; the pins were applied as the surgeon would do in clinical practice. This difference could theoretically confound the test results of especially the SonicWeld RX system. When looking to the test results, however, the authors conclude that the lack of pressure of the plates to the PMMA blocks for the SonicWeld RX system could not confound the test results because fracture of the plates (instead of shear of the screws) occurred in all specimens.

The use of PMMA instead of real bone was a conscious decision of the authors. Real bone could have different calcification levels that could result in different fracture patterns of the plates and screws. Subsequently, this could influence the results. PMMA blocks have the same mechanical characteristics as real bone and each block does have the same "quality" level. Moreover, the difference between cancellous/cortical bone and PMMA was not a major concern. Theoretically, the flow of polymers of the ultrasound-activated SonicWeld Rx pin into the cavi-

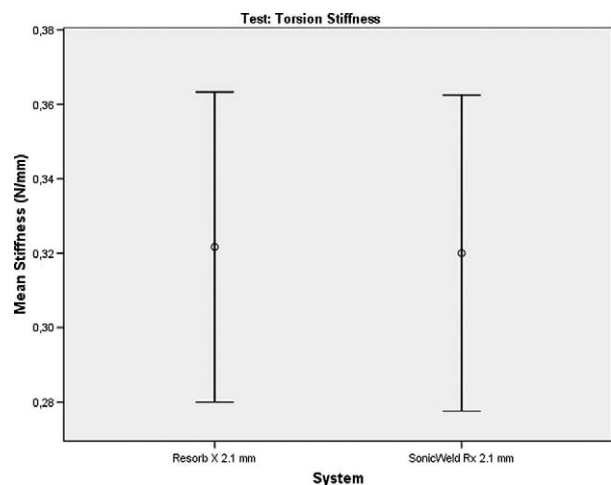


FIGURE 7. Mean torsion stiffness organized by system. Legend: bars, SD of the mean stiffness; points in figure, mean stiffness; x-axis, brand names of the investigated osteofixation systems; y-axis, mean stiffness in Newton/mm (deducted unit).

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ties of the cancellous bone would enhance the pull out strength of the screws. However, none of the screws were pulled out during testing.

Regarding the thermoplastic state of the biodegradable pin, we were concerned about the fusion or sticking of the biodegradable pin to the PMMA blocks. This could theoretically affect the test results. To prevent this, the boreholes were irrigated with saline before insertion of the pins. To check whether fusion or sticking had occurred, we checked whether the pin could be pulled out of the PMMA blocks after the test. Despite not actually measuring the pull out strength of the pins, the authors noted that high forces were not required to do so.

The SonicWeld Rx system is obviously an improvement in the search for a mechanically strong and stiff as well as a biodegradable osteofixation system. Moreover, usage of the device is relatively easy and comfortable. The application of SonicWeld Rx plates and pins is fast and easy. Nevertheless, the plates and screws are still bulky compared with the conventional titanium plates and screws. The question is whether the promising in vitro results can be transferred to the in situ clinical situation. Future research about biodegradable osteofixation devices should include the SonicWeld Rx system in randomized clinical trials in which a conventional titanium fixation device serves as the "gold standard" fixation device.

Acknowledgments

The authors thank Gebrüder Martin GmbH & Co for supplying the biodegradable plates and screws/pins. The authors also thank Dr H. Groen for his statistical assistance. Mr J. de Jonge is acknowledged for the fabrication of the test set-ups.

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