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EXPERIMENTAL TESTING OF THE BONDED JOINT USED FOR SPINAL ARTIFICIAL REPLACEMENT

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Abstract: The Laboratory of Human Biomechanics, CTU in Prague is engaged in development of an artificial disc on the basis of silicone. The designed artificial disc comprise elastic core made of silicone (MED 4565 Nusil Technology) and two outer plates made of rigid material (PEEK or Titanium). The use of silicone as the main part of the artificial disc comes from the material properties that are similar to the intervertebral disc and from the biocompatibility of this material. Between the elastic silicone core and the two outer plates is designed the adhesive bonded joint among others by the reason of the space limitation. The material for the outer plates must be than also selecting regarding to the strenght of the adhesive bonded joint.

Keywords: Material parameter, bonded joint, measurement, spinal replacement

1. Introduction

Joining is a key enabling technology for many manufacturing industries and the medical industry is no exception. Medical components, whether external to the body in the form of external instrumentation and control systems or surgical tools, or internal in the form of pacemakers, sensors or prostheses, generally require a mix of materials, which are connected in some way. Mechanical fixing is one option but is often limited in the joint design, mechanical and environmental performance it offers. Adhesive bonded joining process provides technical and economic advantages especially for the design of spinal implant where an extensive space limitation is.

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Fig. 1. The designed artificial disc

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joint among others by the reason of the space limitation. The material for the outer plates must be than also selecting regarding to the strenght of the adhesive bonded joint.

2. Materials and methods

2.1. Adhesion

Adhesion may be defined as the physical and chemical bonding of two substrates. Substrates that have reactive groups available for bonding such as hydroxyl groups (OH) or carbonyl groups (C=O) groups on glass, plastics and aluminium make this chemical attraction greater through van der Waals forces or weak hydrogen attraction. Some plastics are difficult to adhere to because of their low surface energy. Most plastics are less than 50 dynes/cm. Surface energy is a thermodynamic effect of how a liquid will “wet out” on a surface. Low surface energy materials do not allow a liquid adhesive to easily wet out on its surface. Adhesion chemistry reveals that the better an adhesive can wet out on a substrate, the more surface area it can cover, which allows more reactive groups to interact and a stronger bond. Better wet out also provides a means for greater penetration into the substrate to fill in those peaks and valleys found on the surface of a metal or plastic, and allows better adhesion as a result of a mechanical interlock. To improve adhesion to a specific substrate, silane adhesion promoters can be used to hydrolyse the surface of the plastic so that it readily accepts a silicone adhesive. The mechanism reacts in a similar way, whether the adhesion promoter is applied through a primer or contained within the adhesive as a self-priming adhesive.

2.2. Materials

Primers have become a necessary evil for adhering to difficult substrates. Silane primers are used to promote adhesion between two non-bonding surfaces. The primers usually consist of one or more reactive silane, a condensation catalyst and some type of solvent carrier. The reactive silane typically have two different reactive groups; one that is compatible with the substrate and the other with the adhesive. These different groups form a compatible interface between the incompatible substrates and promote adhesion. The one-part silicone adhesive MED-1511 and primer MED-160 were selected from the Nusil Technology offer.

2.3. Methods

The tensile strenght of two “PEEK-silicone” and “Titanium- silicone” adhesive double bonded joints were tested. Between two PEEK and Titanium cylinders (diametr 15 mm and hight 90 mm) was bonded silicone cylinder (diametr 15 mm and hight 6mm) see Figure 2. The primer was applied in a thin, uniform film, allowing the solvent to evaporate and the reactive groups to hydrolyze and condense into a film. After 30 minute the specimen was bonded with MED 1511 silicone adhesive and sufficient pressure was applied to ensure full contact.

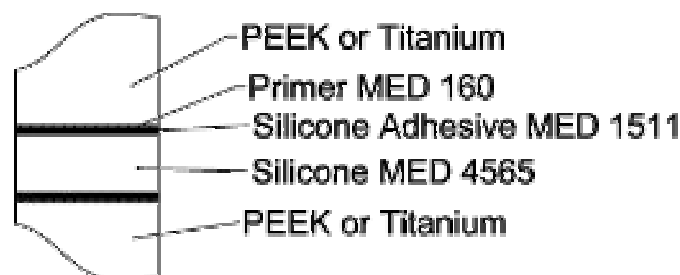


Fig. 2. Adhesive bonded joint

3. Results

Twelve PEEK-silicone and twelve Titanium-silicone specimens were tested on tensile strength. The average force-deformation results are shown on the Figure 3. The tensile strengths were calculated from the maximal forces see Table 1

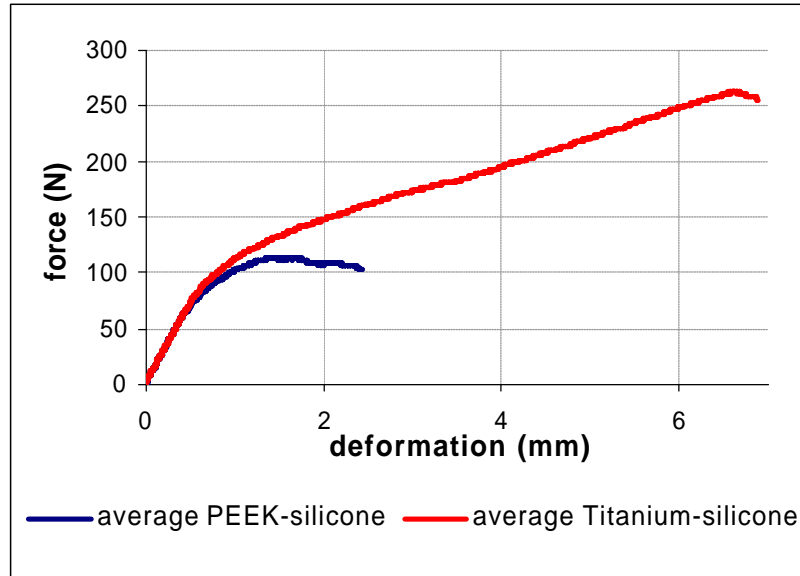


Fig. 3: The result - force deformation average curve

PEEK	spec. number	F_{max} (N)	p (MPa)	Titanium	spec.number	F_{max} (N)	p (MPa)
	1	132.81	0.75		21	265.51	1.50
	2	113.70	0.64		22	250.00	1.41
	3	115.25	0.65		23	332.99	1.88
	4	155.29	0.88		24	281.48	1.59
	5	119.36	0.68		25	246.62	1.40
	6	127.54	0.72		26	262.82	1.49
	7	114.27	0.65		27	160.42	0.91
	8	122.30	0.69		28	266.25	1.51
	9	87.73	0.50		29	161.73	0.92
	10	132.44	0.75		30	171.54	0.97
	11	134.32	0.76		31	221.19	1.25
	12	151.94	0.86		32	167.39	0.95
average		125.58	0.71	average		232.33	1.31

Tab. 1: Maximal forces and tensile strength of bonded joints of the measured specimens

4. Conclusion

When an implant is placed inside a bone, there are local changes in stress levels at any point in the bone. The loads on the bone remain the same, but mechanical stresses in the bone

adjacent to the implant will be altered. From that reason it's preferable to use material PEEK for the implant because its mechanical properties are getting more close to the properties of the bone. But the tensile strenght of "Titanium-silicone" bonded joint is nearly twice higher than the tensile strenght of "PEEK – silicone". The spinal implant is mainly loaded by tension it seems that for our aplication for the spinal implant the tensile strenghts from the tests will be suficient for both adhesive bonded joints (PEEK –silicone, Titanium-silicone).

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References

- [1] BERGMANN G. et al: Load Measurements at Spinal Fixators, Free University of Berlin, Benjamin Franklin School of Medicine, Biomechanics Laboratory, Berlin, Germany, <http://www.medizin.fuberlin.de/biomechanik/Homefrme.htm>.
- [2] CALLAGHAN, J.P., et al.: Low back three-dimensional joint forces, kinematics and kinetics during walking. Clin Biomech, 14, 1999, pp 203-216.
- [3] CSN EN 26922 . Lepidla - Stanovení pevnosti v tahu lepených spoj. ČNI.
- [4] MORLOCK M. M., BONIN V. et al, "Determination of the in vivo loading of the lumbar spine with a new approach directly at the workplace – first results for nurses", Clinical Biomechanics, Elsevier, 15, 2000, pp. 549-558.
- [5] RHODES, K.: Silicone adhesives and primers on low surface energy plastics and high strength metals for medical devices. NuSil Technology-Carpinteria, 2004 <http://www.nusil.com/whitepapers/index.aspx>.
- [6] SALERNI C. : Selecting Engineeering Adhesives for Medical Device Assembly, Medical device & Diagnostic Industry 22, no.6, 2000: 90.