

Rao S. Bezwada, Ph.D.

President

Bezwada Biomedical, LLC

P.O. Box 6357

Hillsborough, NJ 08844

Tel: 908-334-1575

Fax: 908-534-5789

E-mail: rao@bezwadabiomedical.com

EXECUTIVE SUMMARY

- ❑ Invented and championed a new ultra-limp synthetic absorbable suture (for Ethicon, a J & J company) known as MONOCRYL that is being sold commercially all over the world. Total worldwide sales of MONOCRYL suture since its 1993 introduction are over \$250 million, and current annual sales are over \$60 million.
- ❑ Received J&J most prestigious R&D award, the JOHNSON MEDAL, in 1996 for the research, development and commercialization of MONOCRYL suture.
- ❑ 71 issued U.S. patents and sixteen published articles and eight presentations on polyurethane chemistry and absorbable polymers.
- ❑ Received J&J's Philip B. Hofmann Research Scientist Award in 1987 for research in the area of radiation sterilizable absorbable polymers, a new absorbable coating (polyglactaprone 90), and a new VICRYL-Like, monofilament.
- ❑ Invented a class of absorbable coatings for biomedical applications, absorbable liquid polymers, absorbable elastomers, absorbable polyoxaesters, absorbable adhesion prevention barriers, radiation sterilizable absorbable polymers and various absorbable resins for suture applications.
- ❑ Made major contributions to Johnson & Johnson's business, and contributed to the advancement of the science of synthetic absorbable polymers.

EXPERIENCE

President (2003-Present), Bezwada Biomedical, LLC

Research Fellow (1996-2003), Ethicon, Inc., Somerville, NJ

Principal Scientist (1985-1995), Ethicon, Inc., Somerville, NJ

Senior Scientist (1982-1985), Ethicon Inc., Somerville, NJ

Research Scientist (1981-1982), American Cyanamid, Bound Brook, NJ

Scientist (1977-1979), American Cyanamid, Bound Brook, NJ

Supervisor (1974-1976), American Cyanamid, Bound Brook, NJ

Chemist (1969-1973), A.J. & J.O. Pilar, Inc., Newark, NJ

EDUCATION

Stevens Institute of Technology, Ph.D., Polymer Chemistry

Stevens Institute of Technology, M.S., Chemistry

University of Madras, India, 1968, B. Tech. (Bachelor of Technology)

AWARDS:

- ❑ The **Johnson Medal** for the research, development and commercialization of MONOCRYL Suture, 1996
- ❑ **Philip B. Hofmann Research Award** for outstanding contributions to the development of new proprietary absorbable sutures, and coatings, 1987
- ❑ American Cyanamid Junior Education Award, 1979-1981
- ❑ Kannamal Krishnaswamy Memorial Prize, 1968
- ❑ State Government Scholarship, 1964-1968
- ❑ Madras Leather Club Endowment Medal, 1968
- ❑ Gold Medal for University First Rank, University of Madras, 1968

RESEARCH INTERESTS

Invent and develop new biomedical devices targeted towards coatings, new sutures, drug delivery and other novel concepts. Provide contract research in the areas of drug/device research and drug delivery research, and tissue engineering. Conduct basic and product-focused research on new absorbable polymers for biomedical devices. Conduct natural products research in identifying new chemical entities (NCE) for drug research. Invent and develop new polyurethane polymers for biomedical applications.

SKILLS/TECHNIQUES

Organic synthesis, small and medium scale polymer synthesis (ring-opening and polycondensation). Synthesis of radiolabelled polymers. Synthesis and characterization of polyurethanes as well as their structure/property relationships.

SIGNIFICANT ACCOMPLISHMENTS

Experience includes elastomers and rubber technology, leather technology, and polyurethane science. Expertise has been directed toward polymer science and organic chemistry over the past 20 years to biomaterials, especially the synthesis of new absorbable monomers and polymers for absorbable sutures and coatings.

Invented and developed a family of new, low cost, single component adhesion promoters for bonding steel cords to rubber. Five U. S. patents were awarded. Returned to school to pursue a doctorate, dissertation entitled, "Synthesis and Characterization of Model Comb-Branched Polyurethanes" (Stevens Institute of Technology), resulted in four papers and one presentation.

Reentered industry and developed a new polyurethane system for American Cyanamid (U.S. patent, "Storage Stable, One Package, Heat Curable Polyurea/Urethane Coating Compositions and Method of Preparation").

Joined Johnson and Johnson (Ethicon), and invented and developed a new class of "Radiation Sterilizable Absorbable Polymers" for biomedical applications. Discovered and developed a new class of absorbable liquid polymers and controlled delivery for drugs and wound healing agents, and a new class of absorbable elastomers.

Invented and championed a new Ultra limp Absorbable Sutures known as MONOCRYL, a new coating (New Vicryl Coating (NVC)), a new class of absorbable polymers, known as Polyoxaesters. Sixty-nine U.S. Patents have been issued and several U.S. patents are pending on absorbable polymers. Published sixteen articles and presented eight times on polyurethane chemistry and absorbable polymers.

MONOCRYL

Invented and championed MONOCRYL suture by making major contributions in a number of areas:

(a) Made several key discoveries in the research and development of MONOCRYL Monofilament Suture. The copolymer of glycolide/ ϵ -caprolactone had to be prepared in a two-stage process, with the prepolymer molecular weight being very high, at least 1.2 dl/g, and the conversion essentially complete. The composition of the prepolymer was also selected in such a way that it is easily soluble in glycolide in the second stage polymerization. Finally, the selection of the prepolymer composition and the overall composition were critical in order to get the best overall properties. These key inventive contributions led to the development of MONOCRYL suture and resulted in an important U.S. patent issued to ETHICON in the area of glycolide/ ϵ -caprolactone copolymers (i.e., "the MONOCRYL" patent).

(b) In addition to developing an excellent synthetic method for preparing MONOCRYL, led the project in the concept stage and was responsible for the management of all phases of the MONOCRYL developmental work which included small scale fiber spinning, biological testing, and initial polymer scale-up. Presented the project to the ETHICON board and got approval soon after the presentation.

(c) Led the team that produced the radiolabelled suture needed for the ADME (Absorption Distribution, Metabolism, and Elimination) studies working with more than 14 associates of various disciplines.

New VICRYL Coating (NVC)

Responsible for the development of New Vicryl Coating (Polyglecaprone 90). This, like MONOCRYL, has been approved by the FDA, and can be used as a coating material for VICRYL. A U.S. patent was issued on the use of the ϵ -caprolactone/glycolide 90/10 composition as a coating for sutures.

VICRYL Like Monofilament (VLM)

Invented and championed a unique monofilament derived from p-dioxanone and glycolide. The monofilament exhibits a breaking strength retention (BSR) profile equivalent to VICRYL with tensile and handling properties better than PDS-II. A U.S. Patent was issued to Ethicon.

PDS-Melt/Lactide Copolymer

Invented and developed a pliable monofilament derived from p-dioxanone and lactide that has the following property profile: BSR profile between VICRYL and PDS-II, tensile properties equivalent to PDS-II, and handling properties equivalent to MONOCRYL. A U.S. Patent was issued to Ethicon on compositions of PDO/lactide.

Absorbable Elastomers

Discovered certain compositions of ϵ -caprolactone and glycolide that exhibit unique elastomeric properties. Many biomedical device prototypes have been developed from these fast-absorbing elastomers. Two U.S. Patents were issued.

Liquid Absorbable Polymers

The first to discover that absorbable liquid copolymers can be prepared from certain monomers and at certain compositions. Many applications such as drug delivery, coatings, lubricants, and injectables are being examined. Several U.S. Patents were issued on compositions and applications.

Absorbable Polyoxaesters

The first to discover a new class of absorbable polymers, "polyoxaesters", which exhibit unique properties, such as liquids, low melts, high melts, microdispersions, and elastomers. Many biomedical devices are being developed from this new class of polymers. Over sixteen U.S. Patents have issued on composition of matter and applications of these polymers.

Research Interests/Technical Skills:

One of the few individuals throughout the world who has in-depth knowledge of synthetic absorbable sutures and absorbable coatings. Through his creative capabilities, significant contributions in absorbable materials for biomedical applications have been achieved.

Research interests include the synthesis and characterization of bioabsorbable polymers as well as their structure/property relationships, and polyurethane chemistry. Technical skills include general problem solving, small-scale organic synthesis, small and medium scale polymer synthesis (ring opening and polycondensation), and radiotracer studies.

Professional Societies:

American Chemical Society

Society for Biomaterials

The New York Academy of Science

Technical Presentations / Publications:

Presented five times at national technical meetings and as an invited speaker at two section meetings. Published thirteen technical articles, and co-authored chapters in two ACS books. The attached Appendix contains information on patents, presentations and technical papers.

Appendix - Patents, Presentations and Papers Granted US Patents:

4,228,045	10/14/80	METHOD OF ADHESION OF RUBBER TO REINFORCING MATERIALS
4,292,111	9/29/81	METHOD OF ADHESION OF RUBBER TO REINFORCING MATERIALS
4,284,536	8/18/81	COMPOSITION FOR ADHESION OF RUBBER TO REINFORCING MATERIALS
4,300,973	11/17/81	METHOD OF ADHESION OF RUBBER TO REINFORCING MATERIALS
4,339,359	7/13/82	COMPOSITION FOR THE ADHESIONS OF RUBBER TO REINFORCING MATERIALS
4,523,003	6/11/85	STORAGE STABLE, ONE PACKAGE, HEAT CURABLE POLYUREA/URETHANE COATING COMPOSITIONS AND METHOD OF PREPARATION
4,510,295	4/9/85	ABSORBABLE POLYMERS OF SUBSTITUTED BENZOIC ACID
4,532,928	8/6/85	SURGICAL SUTURES MADE FROM ABSORBABLE POLYMERS OF SUBSTITUTED BENZOIC ACID
4,546,152	10/8/85	POLY(P-DIOXANONE) POLYMERS HAVING IMPROVED RADIATION RESISTANCE
4,643,191	2/17/87	CRYSTALLINE COPOLYMERS OF P-DIOXANONE AND LACTIDE AND SURGICAL DEVICES MADE THEREFROM
4,649,921	3/17/87	POLY(P-DIOXANONE) POLYMERS HAVING IMPROVED RADIATION RESISTANCE
4,653,497	3/31/87	CRYSTALLINE P-DIOXANONE/GLYCOLIDE COPOLYMERS AND SURGICAL DEVICES MADE THEREFROM
4,838,267	6/13/89	GLYCOLIDE/P-DIOXANONE BLOCK COPOLYMERS
4,994,074	2/19/91	COPOLYMERS OF ϵ -CAPROLACTONE ,GLYCOLIDE AND GLYCOLIC ACID FOR SUTURE COATINGS
5,007,923	4/16/91	CRYSTALLINE COPOLYMERS OF AMORPHOUS (LACTIDE/GLYCOLIDE)AND P-DIOXANONE
5,019,094	5/28/91	CRYSTALLINE COPOLYMERS OF P-DIOXANONE AND POLY(ALKYLENE OXIDES)
5,037,950	8/6/91	BIOABSORBABLE COPOLYMERS OF POLYALKYLENE CARBONATE/P-DIOXANONE FOR SUTURES AND COATINGS

5,047,048	9/10/91	CRYSTALLINE COPOLYMERS OF P-DIOXANONE AND CAPROLACTONE
5,076,807	12/31/91	RANDOM COPOLYMERS OF P-DIOXANONE, LACTIDE AND/OR GLYCOLIDE AS COATING COPOLYMERS FOR SURGICAL FILAMENTS
5,089,013	2/18/92	SUTURE COATED WITH POLYVINYL ESTER
5,100,433	3/31/92	SUTURE COATED WITH A COPOLYMER COATING COMPOSITION
5,133,739	7/28/92	SEGMENTED COPOLYMERS OF CAPROLACTONE AND GLYCOLIDE
5,147,383	9/15/92	SUTURE COATED WITH POLYVINYL ESTER
5,371,176	12/6/94	CASTOR OIL POLYMERS
5,411,554	5/2/95	LIQUID FILLED ENVELOPES FOR USE AS SURGICAL IMPLANTS
5,427,778	6/27/95	GEL FORMULATIONS CONTAINING GROWTH FACTORS AND ACRYLAMID POLYMER
5,442,032	8/15/95	COPOLYMERS OF 1,4-DIOXEPANE-2-ONE and 1,5,8,12-TETRAOXACYCLOTETRADECANE-7,14-DIONE
5,442,033	8/15/95	LIQUID COPOLYMERS OF CAPROLACTONE/LACTIDE
5,464,929	11/7/95	ABSORBABLE POLYOXAESTERS
5,468,253	11/21/95	ELASTOMERIC MEDICAL DEVICES
5,470,340	11/28/95	COPOLYMERS OF(p-DIOXANONE/GLYCOLIDE and/or LACTIDE)
5,595,751	01/21/97	ABSORBABLE POLYOXAESTERS CONTAINING AMINES and/or AMIDO GROUPS
5,597,579	01/28/97	BLENDS OF ABSORBABLE POLYOXAAMIDES
5,599,852	02/04/97	INJECTABLE MICRODISPERSIONS FOR SOFT TISSUE REPAIR AND AUGMENTATION
5,607,687	03/04/97	POLYMER BLENDS CONTAINING ABSORBABLE POLYOXAESTERS
5,618,552	04/08/97	ABSORBABLE POLYOXAESTERS
5,620,698	04/15/97	BLENDS OF ABSORBABLE POLYOXAESTERS CONTAINING AMINES AND/OR AMIDO GROUPS
5,631,015	05/20/97	LIQUID ABSORBABLE COPOLYMERS FOR PARENTERAL APPLICATIONS

5,633,343	05/27/97	HIGH STRENGTH, FAST ABSORBING, MELT PROCESSABLE, GLYCOLIDE RICH, POLY(GLYCOLIDE-CO-p-DIOXANONE) COPOLYMERS
5,639,851	06/17/97	HIGH STRENGTH, MELT PROCESSABLE, LACTIDE-RICH, POLY(LACTIDE-CO-p-DIOXANONE) COPOLYMERS
5,645,850	07/08/97	BLENDS CONTAINING ABSORBABLE POLYOXAAMIDES
5,648,088	07/15/97	BLENDS OF ABSORBABLE POLYOXAESTERS CONTAINING AMINES AND/OR AMIDE GROUPS
5,653,992	08/05/97	LIQUID ABSORBABLE COPOLYMERS FOR PARENTERAL APPLICATIONS
5,674,921	10/07/97	RADIATION-CURABLE, URETHANE-ACRYLATE PREPOLYMERS AND CROSSLINKED POLYMERS
5,698,213	12/16/97	HYDROGELS OF ABSORBABLE POLYOXAESTERS
5,700,583	12/23/97	HYDROGELS OF ABSORBABLE POLYOXESTERS CONTAINING AMINES OR AMIDO GROUPS
5,703,200	12/30/97	ABSORBABLE COPOLYMERS AND BLENDS OF 6,6-DIALKYL-1,4-DIOXEPAN-2-ONE AND ITS CYCLIC DIMER
5,713,920	02/03/98	ELASTOMERIC MEDICAL DEVICE
5,714,551	02/03/98	HIGH STRENGTH, MELT PROCESSABLE, LACTIDE-RICH, POLY(LACTIDE-CO-p-DIOXANONE) COPOLYMERS
5,728,752	02/17/98	INJECTABLE MICRODISPERSIONS FOR SOFT TISSUE REPAIR AND AUGMENTATION
5,824,333	10/20/98	INJECTABLE LIQUID COPOLYMERS FOR SOFT TISSUE REPAIR AND AGGMENTATION
5,844,017	12/01/98	PREPOLYMERS OF ABSORBABLE POLYOXAESTERS CONTAINING AMINES AND/OR AMIDO GROUPS
5,859,150	01/12/99	PREPOLYMERS OF ABSORBABLE POLYOXAESTERS
5,868,788	02/09/99	HIGH STRENGTH, MELT PROCESSABLE, LACTIDE-RICH, POLY(LACTIDE-CO-p-DIOXANONE) COPOLYMERS
5,951,997	09/14/99	ALIPHATIC POLYESTERS OF ϵ -CAPROLACTONE, p-DIOXANONE AND GLYCOLIDE
5,962,023	10/05/99	HYDROGELS CONTAINING ABSORBABLE POLYOXAAMIDES

6,031,018	02/29/2000	SOLVENTLESS TIPPING OF BRAIDED SURGICAL LIGATURE
6,074,660	06/13/2000	ABSORBABLE POLYOXAESTERS CONTAINING AMINES AND/OR AMIDO GROUPS
6,100,346	08/08/2000	COPOLYMERS OF POLYOXAAMIDES
6,113,624	09/05/2000	ABSORBABLE ELASTOMERIC POLYMER
6,147,168	11/14/2001	COPOLYMERS OF ABSORBABLE POLYOXAESTERS
6,224,894	05/01/2001	COPOLYMERS OF ABSORBABLE POLYOXAESTERS
6,251,435	06/26/2001	HYDROGELS CONTAINING ABSORBABLE POLYOXAAMIDES
6,325,810	12/04/2001	FOAM BUTTRESS FOR STAPLING APPARATUS
6,335,383	01/01/2002	MICRODISPERSIONS FOR COATING SURGICAL DEVICES
6,372,256	04/16/2002	HYDROGELS CONTAINING ABSORBABLE POLYOXAMIDES
6,403,655	06/11/2002	METHOD OF PREVENTING ADHESIONS WITH ABSORBABLE POLYOXAESTERS
6,458,385	10/01/2002	HYDROGELS CONTAINING ABSORBABLE POLYOXAMIDES
6,712,838	03/30/2004	BRAIDED SUTURE WITH IMPROVED KNOT STRENGTH AND PROCESS TO PRODUCE THE SAME

Chapters in Books:

1. Rao S. Bezwada, Dennis D. Jamiolkowski and Kevin Cooper "Poly(p-Dioxanone) and its Copolymers" in Handbook of Biodegradable Polymer, Harwood Academic Publishers, Australia, 1997, Abraham J. Domb, Joseph Kost, David M. Wiseman, eds., Chapter 2, pages 29-61.
2. Dennis D. Jamiolkowski, Rao S. Bezwada, and Shalaby W. Shalaby "Copolymerization of Glycolide with Polymeric Radiostabilizers for the Preparation of Radiation Sterilizable Braided Sutures", in Irradiation of Polymeric Materials; Process, Mechanisms, and Applications, ACS Symposium Series No. 527; American Chemical Society, Washington DC, 1993; Chapter 21.

Presentations:

Las Vegas, 1982 National ACS Meeting

Dallas, Texas, 1989 National ACS Meeting

Charleston, SC, May 1990 Annual Meeting of the Society for Biomaterials

Scottsdale, Arizona, May 1991 Annual Meeting of the Society for Biomaterials

Alabama, GA, May 1993 Annual Meeting of the Society for Biomaterials

Invited Speaker at the fall 1991 Lecture Series, "Advances in Biotechnology and Bioengineering" sponsored by the North Jersey section of American Institute of Chemical Engineers. Delivered a talk entitled, "Synthetic Absorbable Polymers for Biomedical Applications".

Invited Speaker at the US-Australia Bilateral Workshop on "Radiation Effects on Polymeric Materials", August 18-22, 1991, sponsored by the Australia Department of Science and the US National Science Foundation at Stanford University. Delivered a talk entitled, "Copolymerization of Glycolide with Polymeric Radiostabilizers for the Preparation of Radiation Sterilizable Absorbable Braided Sutures".

Visiting professor at Stevens Institute of Technology and taught graduate courses in polyurethane chemistry during 1981-1982 and 1983-84 fall semesters.

Technical Publications:

R.S. Bezwada and S.S. Stivala, "Selective reaction of Isocyanates with the Amino groups of 2-Amino-2-Methyl-1,3-Propane diol", J. Chem. Eng. Data, **25**, 292 (1980).

R.S. Bezwada and S.S. Stivala, "Synthesis and Characterization of Model Comb-Branched Polyurethanes", ACS National Spring Meeting, 278-279, 23, (1982).

R.S. Bezwada and S.S. Stivala, "Synthesis and Characterization of Model Comb-Branched Polyurethanes: 1. Synthesis of Model Comb-Branched Polyurethanes", Polymer Communications, **84**, **26**, (1985).

R.S. Bezwada and S.S. Stivala, "Synthesis and Characterization of Model Comb-Branched Polyurethanes: 2. Dilute Solution and Viscoelastic Properties", Polymer Communications, **91**, **26**, (1985).

R.S. Bezwada, S.W. Shalaby, and H.D. Newman Jr., "Bioabsorbable Fibers of p-Dioxanone Copolymers", Agric. Synth. Polym.-ACS Symp. Ser., ~~433~~, 167-173 (1990).

R.S. Bezwada, S.W. Shalaby, H.D. Newman Jr., and A. Kafrawy, "Bioabsorbable copolymers of p-Dioxanone and Lactide for surgical Devices", Transactions of the 16th Annual Meeting of the Society for Biomaterials, 1990, XV, 194.

R.S. Bezwada, S.W. Shalaby, and H.D. Newman Jr., "Bioabsorbable copolymers of p-Dioxanone: Effect of Composition and Microstructure of physical and biological properties of Copolymeric p-Dioxanone/Glycolide Fibers", 197th ACS National Meeting, 197, 39 BTEC (1989).

D.F. Koelmel, D.D. Jamiolkowski, S.W. Shalaby, and R.S. Bezwada, "Low Modulus Radiation Sterilizable Monofilament Sutures", Polym. Prepr. 1991, 32 (2) 235.

D.D. Jamiolkowski, S.W. Shalaby, R.S. Bezwada, and H.D. Newman Jr., "Bioabsorbable Block Copolymers of p-Dioxanone and Glycolide For Surgical Devices", Transactions of the 16th Annual Meeting of the Society for Biomaterials, 1990, XV, 193.

R.S. Bezwada, and D.D. Jamiolkowski, "Radiation Sterilizable Bioabsorbable Sutures" Transactions of the 17th Annual Meeting of the Society for Biomaterials, 1991, *XIV*, 186.

R.S. Bezwada, and D.D. Jamiolkowski, "Segmented Copolymers of ϵ -Caprolactone and Glycolide For New Absorbable Monofilament Sutures", Transactions of the 19th Annual Meeting of the Society for Biomaterials, 1993, *XVI*, 40.

Rao S. Bezwada, Dennis D. Jamiolkowski, and In-Young Lee, "Preparation, Absorption, Distribution, Metabolism, and Elimination (ADME) of ¹⁴C Labeled MONOCRYL Suture", Transactions of the 21st Annual Meeting of the Society for Biomaterials, 1995, *XVIII*, 209.

Rao S. Bezwada, Dennis D. Jamiolkowski, In-Young Lee, Vishvaroop Agarwal, Joseph Persivale, Susan Trenka-Benthin, Modesto Ermeta, Jogendra Suryadevara, Alan Yang, and Sylvia Liu, "MONOCRYL™ Suture, a New Ultra-Pliable Absorbable Monofilament Suture", BIOMATERIALS 16, 1141-1148 (1995)

Rao S. Bezwada and Dennis D. Jamiolkowski, "Hydrophilic Synthetic Absorbable Polyoxa-esters", Transactions of the Sixth World Biomaterials Congress (2000) Vol. 2, page 430.